4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, and 110

[Docket No.]

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food (CGMPs) to modernize it and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. FDA is taking this action as part of its announced initiative to revisit the CGMPs since they were last revised in 1986 and to implement new statutory provisions in the FD&C Act. The proposed rule is intended to build a food safety system for the future that makes modern, science-, and risk-based preventive controls the norm across all sectors of the food system.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE Federal Register]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE Federal Register], (see the “Paperwork Reduction Act of 1995” section of this document).

ADDRESSES: You may submit comments, identified by Docket No. , by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. INTRODUCTION

Each year, about 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from food-borne diseases, according to recent estimates from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing

food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides us with new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law gives us important new tools to better ensure the safety of imported foods and directs us to build an integrated national food safety system in partnership with State, local, tribal, and territorial authorities.

This new law continues efforts by the food industry and government to protect and improve the safety of the nation's food supply. At the Federal level, these efforts go back to the Pure Food and Drug Act of 1906, the United States' first national food safety law. FSMA carries forward the basic principle embodied in the 1906 law that food establishments have the primary responsibility and capacity to make food safe and that government's role is to set standards for food safety and provide oversight to help ensure standards are met.

Since passage of the 1906 Act, and the most recent revision of its basic food safety provisions in the Federal Food, Drug, and Cosmetic Act of 1938, the combined efforts of the food industry and government have produced a set of standards and practices that make the U.S. food supply among the safest in the world. These efforts include the development and adoption by the Food and Drug Administration (FDA) of current good manufacturing practice (CGMP) standards that have long provided the regulatory foundation for food safety. They also include, in more recent years, the adoption for some elements of the food supply of more targeted, risk-based approaches, such as the Hazard Analysis and Critical Control Points (HACCP) approach to food safety.

HACCP was pioneered by the food industry and reflects the understanding that food safety is best assured if each producer and processor understands the hazards that are reasonably

likely to occur in their particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate the hazard. FDA has by regulation required seafood and juice processors to implement the HACCP approach to preventive controls. The U.S. Department of Agriculture has also mandated HACCP for meat and poultry processors, and many food companies have implemented such modern preventive control systems for other commodities.

While these efforts have contributed to progress on food safety, significant food safety challenges persist in today's complex, dynamic, and global food system. Today's food supply is highly diverse and increasingly complex, with many new foods in the marketplace that pose new food safety challenges. New pathogens are emerging, and we are seeing commonly known pathogens appear in foods where they have not been traditionally seen. The population of individuals at greater risk for foodborne illness, such as those who are immune-compromised, is increasing. When illness outbreaks occur, they can have devastating impacts on public health and impose substantial economic disruption and cost on the food industry. The food safety challenge is only compounded by globalization, which has resulted in approximately 15 percent of the U.S. food supply being imported, including 80 percent of our seafood, 50 percent of our fresh fruit, and 20% of our vegetables.

Congress responded to today's food safety challenges by enacting FSMA. FSMA builds on past experience and the strong foundation provided by the current food safety system, but it also marks an historic turning point for food safety. FSMA directs FDA to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system; meets the food safety challenges of the global food system; and establishes stronger partnerships for food safety across all levels of government and with the

private sector to ensure optimal use of public and private resources. FDA has embarked on a comprehensive effort to build the food safety system mandated by Congress, as described on its FSMA implementation web page at www.fda.gov/fsma.

A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and FDA's ability to oversee their implementation for both domestic and imported food. These include, among others, regulations establishing preventive control standards for human food and animal food facilities, fresh produce safety standards, standards that define the accountability of importers to verify the safety of food produced overseas, and a new program for accrediting public and private bodies to provide credible certifications that regulated entities are meeting U.S. safety standards.

In this volume of the Federal Register, FDA is publishing three documents that propose rules to establish preventive control standards for human food and animal feed facilities and require importers to implement foreign supplier verification programs, as required by FSMA. These closely interconnected rules establish the central core of the regulatory framework envisioned by FSMA. In the coming months, we intend to propose produce safety standards, as well as rules to implement the accredited third-party certification program. These also are critical elements of the new food safety system.

Since enactment of FSMA, FDA has been reaching out to stakeholders in industry, the consumer community, other government agencies, and the international community to gain input and perspective on how best to implement FSMA and meet today's food safety challenges. That input and perspective has helped shape our proposed regulations in a way that will help to ensure they are practical and flexible as well as effective proposals and will be critical to the adoption of final rules that successfully carry out the vision embodied in FSMA. We encourage stakeholders

to carefully consider and comment on the proposed rules announced in the Federal Register today and how they interact to create a coherent system of preventive controls and achieve consistency between the levels of food safety assurance provided for domestic and imported food.

In this document, we propose standards to implement the requirement in section 103 of FSMA for the adoption of preventive controls in human food facilities. The preamble that follows provides critical background on FDA's previous efforts in establishing and implementing CGMPs and preventive controls, because these past efforts are the critical starting point and foundation for FSMA implementation. The preamble then explains and provides background on the rationale for our proposed updating of current CGMP requirements and for the new rules implementing FSMA's preventive controls requirement. We are seeking comments on all aspects of this proposal.

II. BACKGROUND

A. Regulatory Framework for Human Food

1. Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food

In the Federal Register of April 26, 1969, FDA issued a final rule to establish in 21 CFR part 128 current good manufacturing practice (CGMP) requirements for the manufacturing, processing, packing, or holding of human food (34 FR 6977). The CGMP regulation established criteria for effective sanitation control in the manufacture, processing, packing, or holding of human foods to effect compliance with section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)), under which food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (33 FR 19023; December 20, 1968). In 1973, we

amended the CGMP regulation by adding a new section regarding natural or unavoidable defect levels in foods. (38 FR 854; January 5, 1973). In 1977, we redesignated the CGMP regulation as part 110 (21 CFR part 110) (42 FR 14301 at 14338; March 5, 1977).

In the Federal Register of June 19, 1986, FDA issued a final rule to revise the CGMP regulation in part 110 (hereinafter current part 110) (51 FR 22458). That final rule established new, updated, and more detailed CGMP requirements for food industry personnel; plants and grounds; sanitary facilities, controls, and operations; equipment and utensils; processes and controls; warehousing and distribution; and natural or avoidable defect levels (51 FR 22458). During the rulemaking to establish current part 110, we clarified that the CGMP regulations also identify the applicable criteria for implementing the requirements of section 402(a)(3) of the FD&C Act (21 U.S.C. 342(a)(3)), such that compliance with the CGMP requirements is also required to ensure that food does not consist in whole or in part of any filthy, putrid, or decomposed substance, or are otherwise unfit for food (51 FR 22458 at 22462). In addition, we noted that the CGMP requirements in part 110 serve two purposes: (1) to provide guidance on how to reduce insanitary manufacturing practices and on how to protect against food becoming contaminated; and (2) to state explicit, objective requirements that enable industry to know what FDA expects when an investigator visits one of its plants (51 FR 22458 at 22459).

In the rulemaking to establish current part 110, we also invoked section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), which authorizes FDA to issue regulations for any requirements that, in the Commissioner's judgment, are necessary to prevent the introduction, transmission, or spread of food-borne communicable diseases from one State to another (44 FR 33238 at 33239; June 8, 1979). As we noted in that rulemaking, "[b]ecause this authority is designed to eliminate the introduction of diseases . . . from one State to another, this

authority must of necessity be exercised upon the disease-causing substance within the State where the food is manufactured, processed, or held," and that "[d]ue to the nationwide, interrelated structure of the food industry, communicable diseases may, without proper intrastate food controls, easily spread interstate" (44 FR 33238 at 33239).

Current part 110 serves as an "umbrella" regulation applicable to the manufacturing, processing, packing, or holding of all human food, with the exception that it does not apply to establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities (RACs) which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to consumers (§ 110.19(a)).

In 2002, FDA convened a CGMP Modernization Working Group (the CGMP Working Group) to determine whether part 110 is in need of further revision. The CGMP Working Group initiated research programs, presented preliminary findings, and solicited public comments, data, and scientific information through three public meetings (69 FR 40312; July 2, 2004). In 2005, the CGMP Working Group issued a report (hereinafter the CGMP Working Group Report) summarizing the oral and written comments we received in response to the Federal Register notice announcing the public meetings, as well as our key findings (Ref. CGMP report).

The CGMP Working Group Report presented seven "opportunities" for CGMP modernization. The report called for:

- Requiring appropriate training for food production supervisors and workers, including the maintenance of personnel training records;
- Requiring the creation and implementation of a written food allergen control plan for food processing establishments that handle major food allergens;

- Requiring a written environmental pathogen control program, including the maintenance of appropriate implementation records, for food processors that produce ready-to-eat foods that support the growth of the pathogenic microorganism Listeria monocytogenes;
- Requiring food processors to develop and maintain written cleaning and sanitation procedures, at a minimum for all food contact equipment and food contact surfaces, that define the scope, cleaning or sanitation objective, management responsibility, monitoring, corrective action, and recordkeeping associated with the cleaning or sanitation procedure;
- Considering whether to remove the current exemption for facilities solely engaged in the harvesting, packing, storage, and distribution of RACs by requesting further public comment on this issue;
- Requiring food processors to maintain certain critical records that document that controls and systems that ensure food safety are being properly implemented and requiring that FDA be given access to such documents to verify compliance with the CGMP requirements; and
- Requesting further public comments and suggestions regarding how the use of time-temperature relationships can be incorporated into CGMP regulations or guidances for proper refrigerated storage or hot holding (Ref. CGMP Report).

2. Other Food Safety Regulations Established by FDA

Although the umbrella CGMP requirements of current part 110 apply to the full range of human food, FDA concluded over time that they do not directly address unique safety issues associated with the manufacturing, processing, packing, or holding of certain specific types of food products. We therefore promulgated additional food safety regulations to provide for specific process controls for the manufacturing, processing, packing, or holding of certain

specific foods that are not captured by the more general part 110 CGMP requirements. Currently, such specific food safety regulations include those for:

- Thermally processed low-acid foods packaged in hermetically sealed containers (i.e., "low-acid canned foods," hereinafter referred to as LACF) (part 113 (21 CFR 113)) (Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as "cans," the term "low-acid canned foods" has been used for decades as a shorthand description for "thermally processed low-acid foods packaged in hermetically sealed containers," and we continue to use that term and its abbreviation, LACF, for the purposes of this document);
- Acidified food (part 114 (21 CFR part 114));
- Bottled drinking water (part 129 (21 CFR part 129));
- Infant formula (parts 106 and 107 (21 CFR parts 106 and 107));
- Fish and fishery products (part 123 (21 CFR part 123));
- Juice (part 120 (21 CFR part 120));
- Dietary supplements (part 111 (21 CFR part 111));
- Refrigeration of shell eggs held for retail distribution (§ 115.50 (21 CFR 115.50); and
- Production, storage, and transportation of shell eggs (part 118) (21 CFR part 118)).

We discuss these food safety regulations immediately below.

a. Acidified food and LACF. In the Federal Register of January 24, 1973, FDA issued a final rule (the canned food CGMP regulation) to establish specific CGMP requirements to address safety issues unique to the manufacturing, processing, packing, and holding of thermally

processed foods packaged in hermetically sealed containers (38 FR 2398). In the Federal Register of May 14, 1973, we issued a final rule to establish an emergency permit control regulation, in accordance with section 404 of the FD&C Act (21 U.S.C. 344), to serve as an enforcement mechanism for the canned food regulation (38 FR 12716). In the Federal Register of January 29, 1974, we issued a final rule to establish procedures to implement the emergency permit control enforcement mechanism (39 FR 3748). The emergency permit control regulation is currently codified in 21 CFR part 108.

In 1979, we issued a final rule to revise the canned food CGMP regulation and separate it into two distinct regulations. One of these regulations, established in part 113, is directed to the safe manufacturing, processing, packing, and holding of LACF (44 FR 16209, March 16, 1979). The second regulation, established in part 114, is directed to the safe manufacturing, processing, packing, and holding of acidified foods (44 FR 16230, March 16, 1979). Acidified foods are low-acid foods to which acid(s) or acid food(s) are added; they have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below; and certain foods are excluded from the coverage of part 114 (21 CFR 114.3(b)). In the Federal Register of March 16, 1979, we also issued an emergency permit control regulation to serve as an enforcement mechanism for the new acidified foods regulation (44 FR 16204).

In establishing the regulations for LACF and acidified foods, FDA determined that CGMP regulations specific to LACFs and acidified foods are necessary to control the presence of Clostridium botulinum (C. botulinum), a bacterium commonly found in soil that can form spores that are capable of prolonged survival under adverse conditions and produce a botulinum toxin under anaerobic conditions, such as those in canned foods (41 FR 30442, July 23, 1976). Botulinum toxin can cause botulism, a rare but serious paralytic illness that can be fatal and is

considered a medical emergency (Ref. Shapiro, et al. 1998. Botulism in the US). The primary factors that determine the formation and growth of C. botulinum in food are pH, water activity, and storage conditions, and LACFs and acidified foods can pose a risk of botulism if these critical factors are not carefully controlled (44 FR 16209).

Part 113 establishes requirements for equipment; control of components, food product containers, closures, and in-process material; production and process controls; and records and reports for LACF. Part 114 establishes requirements for production and process controls and records and reports for acidified foods. In light of the severity of the hazard presented by botulinum toxin, parts 113 and 114 require that supervisory personnel be trained at schools approved by FDA (§§ 113.10 and 114.10, respectively).

The enforcement regulations in §§ 108.25 and 108.35 require manufacturers, processors, and packers of acidified foods and LACF, respectively, to file food canning establishment registration information with FDA. The registration information must include, among other things: the name, principal place of business, and the location of the establishment engaged in the manufacturing, processing, or packing of acidified foods or LACF; processing methods; and a list of the foods prepared at the establishment (§§ 108.25(c) and 108.35(c), respectively). Under the procedural enforcement regulations of subpart A of part 108, if after an investigation we determine that a manufacturer, processor, or packer of acidified foods or LACF is not in compliance with the requirements of §§ 108.25 or 108.35, respectively, we may issue an order requiring that the entity apply for and obtain a temporary emergency permit from us, which we might or might not issue, before introducing any acidified food or LACF into interstate commerce. Subpart A of part 108 also establishes the criteria and procedures related to a determination of the need for an emergency permit, revocation of the determination of need for

an emergency permit, issuance or denial of an emergency permit, and suspension and reinstatement of an emergency permit.

b. Bottled drinking water. In the Federal Register of November 26, 1973, FDA issued a final rule to establish quality standard regulations establishing allowable levels for microbiological, physical, chemical, and radiological contaminants in bottled drinking water (38 FR 32558). The quality standard regulation is codified at 21 CFR § 165.110(b). In the Federal Register of March 12, 1975, we issued a final rule to establish CGMP requirements for the processing and bottling of bottled drinking water (40 FR 11566). The bottled water CGMP regulation is codified in part 129 (21 CFR part 129).

FDA promulgated part 129 in light of surveys and analyses of field investigations that we and the U.S. Environmental Protection Agency (EPA) conducted in 1971 and 1972. The surveys and analyses revealed, among other things, that some bottled water failed to meet some of the prevailing regulatory criteria for non-bottled, public drinking water (38 FR 1019 at 1019; January 8, 1973), some of the bottling plants surveyed did not conduct adequate bacteriological and chemical analyses of their products, and in other cases, bottling was not performed under sanitary conditions (38 FR 32563).

Part 129 requires that bottled water be safe and that it be processed, bottled, held, and transported under sanitary conditions. Processing practices addressed in part 129 include the protection of the water source from contamination, sanitation at the bottling facility, and quality control to ensure the safety of the water. Part 129 also establishes certain analytical testing requirements for chemical, physical, radiological, and microbiological contaminants.

c. Infant formula. The Infant Formula Act of 1980 (the 1980 infant formula act) (Pub. L. 96-359) amended the FD&C Act to include section 412 (21 U.S.C. 350a) and was intended to

improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula. Enactment of the law resulted largely from the emergence of a substantial number of cases involving a serious medical disorder known as hypochloremic metabolic alkalosis, which is most frequently characterized by an infant's inability to thrive. The illnesses were found to be associated with prolonged exclusive use of soy protein-based infant formulas that lacked adequate amounts of the essential nutrient, chloride (45 FR 86362 at 86362; December 30, 1980).

In response to the 1980 act, FDA issued final rules to establish the following regulations regarding infant formula:

- Subpart B of part 106 (21 CFR part 106, subpart B) regarding infant formula quality control procedures (47 FR 17016; April 20, 1982);
- Subpart D of part 107 (21 CFR part 107, subpart D) regarding infant formula recalls (47 FR 18832; April 30, 1982);
- Subpart B of part 107 (21 CFR part 107, subpart B) regarding the labeling of infant formula (50 FR 1833; January 4, 1985);
- Subpart C of part 107 (21 CFR part 107, subpart C) regarding exempt infant formula (50 FR 48183; November 22, 1985);
- Subpart D of part 107 (21 CFR part 107, subpart D) regarding nutrient requirements for infant formulas (50 FR 45106; October 30, 1985).

In 1986, Congress amended section 412 of the FD&C Act as part of the Anti-Drug Abuse Act of 1986 (Pub. L. 99-570) (the 1986 infant formula amendments) to address concerns regarding the sufficiency of quality control testing, CGMP, recordkeeping, and recall requirements. In 1989, FDA issued revised recall regulations in subpart E of part 107 (54 FR

4006; January 27, 1989), and in 1991, FDA issued regulations in § 106.100 to implement the provisions of the 1986 infant formula amendments for records and record retention (56 FR 66566; December 24, 1991).

In the Federal Register of July 9, 1996, FDA issued a proposed rule to implement the remaining provisions of the 1986 infant formula amendments (61 FR 36154). Specifically, we proposed to amend the existing infant formula regulations in parts 106 and 107 to: (1) establish CGMPs, including microbiological testing; (2) revise the quality control procedures in part 106 to ensure that an infant formula contains the level of nutrients necessary to support infant growth and development; (3) specify audit procedures to ensure compliance with CGMP and quality control procedure regulations; (4) establish requirements for quality factors to ensure that required nutrients will be in a bioavailable form; (5) establish batch and CGMP recordkeeping requirements; (6) specify submission requirements for registration and notification to FDA before the introduction of an infant formula into interstate commerce; and (7) update 21 CFR part 107 to reflect the 1986 amendments. In 2002 and 2003, FDA held three Food Advisory Committee meetings (67 FR 12571; March 19, 2002; 67 FR 63933; October 16, 2002; 68 FR 8299; February 20, 2003). FDA reopened the comment period for the proposed rule twice (68 FR 22341; April 28, 2003; 71 FR 43393; August 1, 2006). FDA is developing a final rule.

d. Fish and fishery products. In the Federal Register of December 18, 1995, FDA issued a final rule to establish in part 123 procedures for the safe and sanitary processing and importing of fish and fishery products (60 FR 65096). Part 123 requires seafood processors to develop, implement, and document sanitation control procedures and mandates the application of hazard analysis and critical control point (HACCP) procedures. In the remainder of this document, the phrases “seafood HACCP regulation” and “HACCP regulation for seafood” refer to part 123.

We discuss the HACCP concept in more detail in section II.C of this document. We describe the seafood HACCP regulation in more detail in section II.C.5.a of this document.

e. Juice. In the Federal Register of January 19, 2001, FDA issued a final rule to establish in part 120 (21 CFR part 120) requirements to ensure the safe and sanitary processing and importation of fruit and vegetable juices and juice products by mandating the application of HACCP principles to the processing of these foods (66 FR 6138). In the remainder of this document, the phrases "juice HACCP regulation" and "HACCP regulation for juice" refer to part 120. We describe the juice HACCP regulation in more detail in section II.C.5.c of this document.

f. Dietary supplements. The Dietary Supplement Health and Education Act of 1994 (DSHEA) (Pub. L. 103-417) among other things added section 402(g) to the FD&C Act (21 U.S.C. 342(g)). Section 402(g)(2) in part authorizes the Secretary of HHS to promulgate regulations to prescribe CGMPs for dietary supplements. Section 402(g)(2) also stipulates that such regulations must be modeled after existing CGMP regulations for food.

In the Federal Register of June 25, 2007, FDA issued a final rule to establish in part 111 (21 CFR part 111) CGMP requirements for the manufacturing, packaging, labeling, and holding of dietary supplements to ensure their quality (72 FR 34752). FDA established part 111 because the umbrella food CGMP provisions of part 110 alone do not adequately address the unique characteristics of dietary supplements (72 FR 34752 at 34761). For example, unlike most foods, the majority of dietary supplements are packaged into tablets, gel caps, and capsules; some dietary supplements may contain bioactive ingredients for which specific, controlled amounts are intended to be in each tablet or capsule; vitamins can present a concentrated source of biologically active components that have adverse health consequences at high doses; and herbal

and botanical dietary supplements are often complex mixtures that can vary in composition and be contaminated with substances having adverse health consequences depending on factors such as the part of the plant used, the location of harvesting and growing conditions that can vary from year-to-year (72 FR 34752 at 34761).

Part 111 includes those requirements of part 110 that are common to the manufacturing, packaging, labeling and holding of dietary supplements, such as requirements for personnel, physical plant and grounds, and equipment and utensils. Part 111 also establishes requirements such as for the use of written procedures for certain operations; a production and process control system that includes the establishment of specifications for incoming ingredients and finished product; certain requirements for testing of incoming ingredients and finished product; the establishment and implementation of quality control operations; the preparation and use of a written master manufacturing record for each unique formulation and for each batch size of a given dietary supplement; the preparation of an individual batch production record every time a dietary supplement batch is produced; the establishment and use of certain laboratory control processes; the investigation of any product complaint that involves the possibility of a failure to meet any CGMP requirement; and the establishment and retention of records associated with the manufacture, packaging, labeling, or holding of a dietary supplement for specified periods of time.

g. Refrigeration of shell eggs held for retail distribution. In the Federal Register of December 5, 2000, FDA issued a final rule that established in § 115.50 (21 CFR § 115.50) refrigeration requirements for shell eggs held for retail distribution (the shell egg refrigeration regulation) (65 FR 76092). FDA promulgated the shell egg refrigeration regulation to prevent foodborne illnesses and deaths resulting from the contamination of shell eggs with the

Salmonella Enteritidis (SE), a specific Salmonella serotype. As discussed in the proposed rule to establish the shell egg refrigeration regulation (64 FR 36492, July 6, 1999), the disease salmonellosis results from an intestinal infection with Salmonella microorganisms and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Most healthy people recover, but the infection can spread to the bloodstream, and then to other areas of the body, leading to severe and fatal illness, which is more likely to occur in children, the elderly, and persons with weakened immune systems. Salmonella is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are the predominant source of SE related cases of salmonellosis in the United States where a food vehicle is identified for the illness (64 FR 36492 at 36493).

The shell egg refrigeration regulation requires that shell eggs held at retail establishments be stored and displayed under refrigeration at a temperature of 7.2 °C (45 °F) or less to help prevent the growth of Salmonella, except for shell eggs that have been specifically processed to destroy all viable Salmonella that might be present. The shell egg refrigeration regulation includes administrative procedures with which refrigeration requirements may be enforced, including providing for the diversion or destruction of shell eggs that have been held in violation of the refrigeration requirements.

h. Production, storage, and transportation of shell eggs. In the Federal Register of July 9, 2009 (74 FR 33030), FDA issued a final rule to establish in part 118 (21 CFR part 118) requirements for shell egg producers to register with FDA, implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and maintain records related to their compliance with the requirements of the regulation. As

with the shell egg refrigeration rule, FDA promulgated part 118 to reduce SE-associated illnesses and deaths by reducing the risk that shell eggs are contaminated with SE (74 FR 33030).

3. Food Safety Guidance to Industry

FDA has issued numerous guidance documents (hereinafter, "guidance" or "guidances") to assist the food industry in implementing food safety regulatory requirements under FDA's jurisdiction. We issue guidances, in accordance with our regulations in § 10.115 (21 CFR 10.115) for "good guidance practices," to describe our interpretation of or policy on a regulatory issue. Guidances do not establish legally enforceable rights or responsibilities and do not legally bind the public or FDA (§ 10.115(d)(1)). Accordingly, regulated industry is not required to employ the approaches contained in a guidance and instead may choose to use an alternative approach, provided that the alternative approach complies with the relevant statutes and regulations (§ 10.115(d)(2)). Although guidances do not legally bind FDA, they represent our current thinking on a particular interpretation of or policy regarding a given regulatory issue (§ 10.115(d)(3)). Under §§ 10.115(c)(1) and (g), we publish a guidance in draft form for public comment before issuing the guidance in final form, except where prior public participation is not feasible or appropriate, if the guidance (1) sets forth initial interpretations of statutory or regulatory requirements, (2) sets forth changes in interpretation or policy that are of more than a minor nature; (3) includes complex scientific issues, or (4) covers highly controversial issues.

FDA generally issues guidance to industry for the purpose of communicating our policy decisions and interpretations of our regulatory requirements so that regulated industry better understands how to comply with those requirements. In some cases, we issue guidance specifically targeted to assisting industry in complying with a particular food safety regulation. For example, we have issued guidances to assist industry in complying with the seafood HACCP

regulation (Ref. Fish Hazards and Controls Guidance; Fourth Edition) and the juice HACCP regulation (Ref. Juice Hazards and Control Guidance, First Edition). In other cases, we issue guidance that is more narrowly focused in scope or is not directly targeted to assisting industry in complying with a particular food safety regulation. For example, we have issued guidance that addresses the chemical contamination of candy with lead (Ref. 2006 Lead in Candy) and guidance on measures to address the risk for contamination by Salmonella spp. in food containing a peanut-derived product as an ingredient (Ref. peanut guidance).

4. Food Safety Compliance Policy Guides

FDA issues guidance to its staff in the form of compliance policy guides (CPGs). The primary purpose of a CPG is to explain FDA's policy on regulatory issues related to the statutes and regulations that we are responsible for implementing. CPGs advise FDA field inspection and compliance personnel as to FDA's standards and procedures to be applied when determining industry compliance with our regulatory requirements. FDA issues CPGs in accordance with our regulation for good guidance practices in § 10.115 and makes the CPGs available to the public, thereby providing regulated industry with additional insight into how we interpret the statutes and regulations we are responsible for implementing for purposes of assessing compliance with our regulatory requirements. In general, our food safety CPGs are relatively focused in scope. For example, we have issued a CPG regarding microbial contaminants in dairy products (Ref. FDA, CPG Section 527.300, Dairy Products), and a CPG that sets forth the criteria that are to be used by FDA personnel to determine whether foods other than dairy products will be considered adulterated because of the presence of Salmonella (Ref. CPG Section 555.300, Foods Except Dairy Products).

5. Current Inspection System

Section 704 of the FD&C Act authorizes FDA to enter and inspect establishments in which food is manufactured, processed, packed, or held and to inspect all pertinent equipment, finished and unfinished materials, containers, and labeling located in such establishments (21 U.S.C. 374). We inspect food establishments both for cause, for example as part of foodborne illness outbreak investigations, and as a matter of routine practice. Section 421 of the FD&C Act (21 U.S.C. 350j), which was added to the FD&C Act by section 201 of FSMA, directs FDA to "identify high risk-facilities and . . . allocate resources to inspect facilities according to the known safety risks of the facilities" as determined by several factors, including among other things "[t]he known safety risks of the food manufactured, processed, packed, or held at the facility" and "[t]he compliance history of a facility" (Section 421(a)(1)). In addition, Section 421 requires FDA to: immediately "increase the frequency of inspection of all facilities," and includes schedules for the increased frequency with which "domestic high-risk facilities," "domestic non-high risk facilities," and "foreign facilities" must be inspected over time (Section 421(a)(2)). Section 421 also directs FDA to "allocate resources to inspect any article of food imported into the United States according to the known safety risks of the article of food" as determined by a number of factors, including among other things "[t]he known safety risks of the countries or regions" from which the food originates or through which it is transported, and "[t]he compliance history of the importer" (Section 421(b)).

FDA inspectors, or inspectors from other Federal agencies or the States authorized to conduct inspections on our behalf, inspect food establishments to determine whether the establishments are in compliance with the requirements of the FD&C Act and other applicable laws and regulations, and document their findings in Establishment Inspection Reports.

Following an inspection, FDA may decide that: (1) no further action is required because no objectionable conditions or practices were found during the inspection; (2) voluntary action on the part of the food establishment is appropriate to correct violations that are serious enough to document but not serious enough to warrant a regulatory action, or (3) the practices and conditions discovered during the inspection are significant enough to require regulatory action by FDA (Ref. FDA, ORA Field Management Directive No 86).

If we decide to initiate a regulatory action against a food establishment, we may elect to take an advisory action, such as issuing a Warning Letter, an Untitled Letter, or scheduling a regulatory meeting. (Ref. FDA, RPM, Chapter 4). If we determine that the conditions and practices found at a food establishment constitute serious violations of the law that cannot be, or have not been, resolved by voluntary compliance, we may decide to initiate an administrative or judicial action, such as an administrative detention, an order to cease distribution and give notice under section 423(b) of the FD&C Act (21 U.S.C. 3501), a seizure of violative products, an injunction, or a criminal prosecution (Ref. FDA, Regulatory Procedures Manual, Chapters 5 and 6).

6. Systems for Identifying Food Safety Problems

a. Contamination of food and foodborne illness. Food can become contaminated (e.g., with biological, chemical, physical, or radiological hazards) at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. As discussed more fully in section II.D of this document, consumption of contaminated food can lead to acute or long term illness or injury. Early detection of contamination enables food establishments to prevent contaminated food from entering commerce. When contamination is not detected in

time to prevent contaminated food from entering commerce, the contamination may be detected while the food is in storage or in transit; at retail establishments; in restaurants; or in the home. This often necessitates a recall to retrieve the contaminated product from commerce.

We learn about contaminated food through a variety of mechanisms, including required reporting by industry; investigations of outbreaks of foodborne illness; recalls; and state surveillance and reporting programs. We discuss these mechanisms immediately below.

b. Required reporting by industry. In some cases, a firm that manufactures, processes, packs, or holds food, or a regulatory official, detects contamination of a food in the market. This may occur even when there is no known or suspected association between the food and reports of foodborne illness. The Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085) established, among other things, section 417 of the FD&C Act (21 U.S.C. 350f), which requires FDA to establish a Reportable Food Registry (RFR). A "reportable food" is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals (Section 417(a)(2) of the FD&C Act). Under section 417(d)(1) of the FD&C Act, food firms that are "responsible parties" as defined in the statute are required to notify FDA electronically with certain information within 24 hours of determining that a food they manufactured, processed, packed, or held is a reportable food. On September 8, 2009, FDA launched the electronic portal for submission of these required reports. Information about reportable foods becomes part of the RFR.

Infant formula and dietary supplements are excluded from the requirements of the RFR. Infant formula manufacturers must comply with notification requirements for violative infant formula as established in 21 CFR § 107.240. Manufacturers, packers and/or distributors whose

names appear on the label of a dietary supplement marketed in the United States must submit to FDA any report received of a serious adverse event associated with that dietary supplement when used in the United States, accompanied by a copy of the dietary supplement's label, under section 761 of the FD&C Act (21 U.S.C. 379aa-1).

When contamination of food could cause illness or injury, quick action is necessary to remove the food from the market. FDA evaluates the information submitted to the RFR and that submitted by infant formula and dietary supplement firms and takes regulatory action when appropriate. Often this information can be used to determine the distribution of contaminated (and potentially contaminated) food, including raw agricultural commodities, food ingredients, and single- or multi-ingredient processed foods.

c. Outbreaks of foodborne illness. In some cases, contaminated food goes undetected until it is associated with an outbreak of foodborne illness. (An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) When an outbreak of foodborne illness occurs, quick action is critical to prevent additional illness. The Centers for Disease Control and Prevention (CDC) of HHS, and State, local, territorial and/or tribal health departments conduct epidemiologic investigations to identify the food(s) that may be involved in an outbreak. Many outbreaks are reported to the National Outbreak Reporting System (NORS) by the State, local, territorial, or tribal health department that conducted the outbreak investigation. Outbreak reporting is voluntary. Multi-state outbreaks are generally reported to NORS by CDC (Ref. cdc outbreaknet). The Foodborne Outbreak Online Database (FOOD) allows the public direct access to information on foodborne outbreaks reported to CDC (Ref. FAQs CDC's Foodborne Outbreak Online Database).

In July 1995, the Foodborne Diseases Active Surveillance Network (FoodNet) was established as a collaborative program among CDC, 10 state health departments, the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS), and FDA. FoodNet conducts surveillance for infections caused by specific pathogenic microorganisms as diagnosed by laboratory testing of samples from patients. The surveillance area includes approximately 15 percent of the United States population (approximately 46 million persons). The objectives of FoodNet are to determine the burden of foodborne illness in the United States; monitor trends in the burden of specific foodborne illness over time; attribute the burden of foodborne illness to specific foods and settings; and disseminate information that can lead to improvements in public health practice and the development of interventions to reduce the burden of foodborne illness (Ref. foodnet). Information from FoodNet is used to assess the impact of food safety initiatives on the burden of foodborne illness (Ref. Qs and As Vital Signs: FoodNet).

FDA works closely with CDC to monitor those outbreaks in which there is some indication or early information to suggest that an FDA regulated product may be implicated in an outbreak of foodborne illness. In some cases (e.g., when it appears unlikely that an implicated food was contaminated at the point of sale, such as at a restaurant), FDA works closely with multidisciplinary Federal, State, local, territorial, and tribal investigators during the investigation of the outbreak. Depending on the circumstances, such multidisciplinary investigations may involve a traceback investigation (i.e., an investigation to determine and document the production chain and the source(s) of contaminated or potentially contaminated food); a traceforward operation (i.e., an operation to determine the distribution of contaminated or potentially contaminated food); regulatory inspections; and, in some cases, root cause

investigations (to try and determine the specific causes of contamination and contributing factors).

PulseNet is another collaborative program for the surveillance and detection of foodborne illness that is coordinated by the CDC, with laboratory participants from state health departments, local health departments, and Federal agencies, including the FDA and USDA/FSIS. Using pulsed-field gel electrophoresis (PFGE), PulseNet participants perform standardized molecular subtyping (or fingerprinting) of foodborne disease causing bacteria. The patterns are then submitted electronically to PulseNet, which is a dynamic database that allows for the rapid comparison of patterns and facilitates identification of common source outbreaks. PulseNet is considered to be a powerful intelligence network that allows for the collection and analysis of state and local epidemiological surveillance data for the identification of outbreaks that may otherwise go unnoticed. In addition, PulseNet helps food regulatory agencies identify areas where the implementation of new measures and enhanced surveillance are likely to increase the safety of our food supply.

The Food Emergency Response Network (FERN) is a network coordinated by the FDA and USDA to integrate the nation's food testing laboratory. The FERN supports all four phases of incident management – prevention, preparedness, response, and recovery – and coordinates the testing activities of Federal, state, and local laboratories. As of April 2011, FERN has 172 laboratory members (39 Federal, 116 State, and 17 local), located in all 50 States and Puerto Rico. FERN member laboratories represent the large majority of food testing laboratories in the U.S., including public health, agriculture, veterinary diagnostic and environmental laboratories. At this point, it is estimated that the FERN membership represents about 85% of all eligible food regulatory laboratories in the U.S.

FERN members use eLEXNET as their primary, real-time data exchange and communication system. Many participating laboratories conduct food surveillance testing programs for microbial pathogens (e.g., E. coli O157:H7, Salmonella, Listeria monocytogenes,), aflatoxin, antibiotics, undeclared allergens, heavy metals, and other threats to the food supply. Laboratory results can be uploaded into eLEXNET for the early identification of threats to the food supply. For example, overlaying laboratory results with distribution and epidemiological data can assist in identifying the source of the outbreak. The system also allows officials to analyze risks and identify trends for future surveillance efforts. In addition, the eLEXNET serves as a method repository for laboratories to rapidly search, access, review, and print methods.

d. Recalls. In 1978, we established a program regarding recalls, including guidance on policy, procedures, and industry responsibilities (43 FR 26202, June 16, 1978). Our regulations in part 7, subpart C (21 CFR part 7, subpart C) address recall policy; health hazard evaluation and recall classification; recall strategy; FDA-requested recall; firm-initiated recall; recall communications; public notification of recall; recall status reports; termination of a recall; and general industry guidance. In addition, under authority in section 412(f) of the FD&C Act (21 U.S.C. 350a(f)), we have issued regulations establishing specific requirements for infant formula recalls (21 CFR part 107, subpart E). More recently, FSMA amended the FD&C Act by establishing section 423 of the FD&C Act (21 U.S.C. 350l), which provides FDA with mandatory recall authority for food (other than infant formula, which remains subject to section 412(f) of the FD&C Act).

Section 7.41 (Health hazard evaluation and recall classification) describes how we evaluate the health hazard presented by a product being recalled by considering whether any

disease or injuries have already occurred from the use of the product; whether any existing conditions could contribute to a clinical situation that could expose consumers to a health hazard; how the hazard could impact various segments of the population (e.g., children, surgical patients), with particular attention paid to the hazard to those individuals who may be at greatest risk; the degree of seriousness of the health hazard to which the populations at risk would be exposed; the likelihood of occurrence of the hazard; and the potential consequences (immediate or long-range) of occurrence of the hazard. On the basis of this evaluation, we classify the recall (i.e., Class I, Class II, or Class III) to indicate the relative degree of health hazard of the product being recalled or considered for recall. A Class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (§ 7.3(m)(1)). A Class II recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote (§ 7.3(m)(2)). A Class III recall is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences (§ 7.3(m)(3)).

In recent years, recalls of food ingredients have highlighted the potentially large impact that contamination (or potential contamination) of a single food ingredient can have on thousands of food products containing that ingredient (Refs. PCA Peanut Recalls, HVP Recalls, Plainview Milk Recall), with correspondingly significant disruption and cost for industry and consumers.

e. State surveillance and reporting programs. State food safety agencies are involved in indentifying contaminated food by conducting surveillance testing (Ref. CIFOR). Communication of surveillance testing results by state food safety agencies to FDA is essential

for identifying contaminated food. State food safety agencies also conduct thousands of inspections and collect and analyze food samples at food manufacturers/processors every year under contract to FDA. The states perform inspections of food manufacturers, processors, packers and holders to determine compliance with the FD&C Act, state law, or both. Such inspections focus on identifying significant CGMP violations and insanitary conditions which may render the food injurious to health, particularly those involving the introduction of, lack of controls for, and/or growth promotion of pathogenic organisms. State inspections also focus on identifying practices or other conditions that may have caused food to become filthy, putrid, decomposed, or contaminated with foreign objects (Ref. website for state contracts). FDA coordinates the Electronic Laboratory Exchange Network (eLEXNET), which is a web-based information network that allows state food safety officials to share laboratory analysis findings with FDA and other Federal, state and local food safety agencies (Ref. eLEXNET.com). FDA also participates in the Food Emergency Response Network (FERN), which is an FDA/FSIS joint initiative to integrate the nation's food-testing laboratories at the local, state, and Federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food (Ref. http://www.fernlab.org/).

7. Outreach to Consumers and Educators

As part of its efforts to protect the public health, FDA engages in outreach efforts to provide consumers and educators with information regarding the safe handling, preparation, and consumption of food to reduce the incidence of foodborne illness.

We conduct some of our consumer and educator outreach initiatives in cooperation with other Federal departments and agencies. For example, HHS, USDA, and their constituent agencies maintain the Internet site FoodSafety.gov. FoodSafety.gov, which provides consumers

and health educators with the most current information regarding, among other things, food recalls and alerts, health risks posed by particular food safety hazards, instructions for the safe handling and preparation of food, and the most current news and information released by FDA and the other participating Federal departments and agencies regarding food safety issues (Ref. food safety.gov).

We also engage in consumer outreach in partnership with non-governmental entities. Most prominently, HHS, USDA, and the Department of Education work with industry associations, academic institutions, consumer and public health organizations, and professional societies in the food sciences to support the Partnership for Food Safety Education (PFSE). The PFSE, among other things, educates consumers about the importance of safe food handling and health risks posed by specific foodborne illnesses, prepares and disseminates food safety curricula for use by educators, and provides information regarding how consumers can be aware of and respond to food recalls (Ref. http://www.fightbac.org).

FDA also conducts its own independent informational outreach efforts specifically designed for consumers (Ref. Consumers Food Safety & Nutrition Education Campaigns) and for educators (Ref. Health Educators Food Safety & Nutrition Education Campaigns).

B. FDA Food Safety Modernization Act

1. Requirements for Food Facilities

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111–353) was signed into law. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418 with the same name. Many of the provisions in section 103 of FSMA that are relevant to this rulemaking are codified in section 418 of the FD&C Act.

a. General requirements. Section 418 of the FD&C Act contains requirements applicable to food facilities and mandates agency rulemaking. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to "prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act] …."

In addition to those areas specified in section 418(a) of the FD&C Act, sections 418(b)-(i) contain more specific requirements applicable to facilities. These include corrective actions (§ 418(e)), verification (§ 418(f)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit "[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act]." In section XII of this document, we discuss proposed requirements (proposed subpart C) that would implement these provisions of section 418 of the FD&C Act.

b. Qualified facilities. Section 418(l) of the FD&C Act (Modified Requirements for Qualified Facilities) establishes criteria for a facility to be a qualified facility, establishes an exemption for qualified facilities, establishes modified requirements for qualified facilities, and provides that the Secretary may withdraw the exemption otherwise granted to qualified facilities in specified circumstances. Under section 418(l)(1) of the FD&C Act, a facility is a qualified facility if (1) it is a very small business as the term would be defined by this rulemaking or (2) it

falls within specified limitations on the average annual monetary value of its sales and types of customers. Section 418(l)(2)(A) of the FD&C Act exempts a qualified facility from the requirements for hazard analysis and risk-based preventive controls as set forth in sections 418(a)-(i) of the FD&C Act, as well as the requirements issued under section 418(n) of the FD&C Act. Section 418(l)(2)(B) of the FD&C Act requires a qualified facility to submit documentation to the Secretary related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws. Section 418(l)(3) of the FD&C Act authorizes the Secretary to withdraw the exemption from a qualified facility in specified circumstances. In section X.B.1 of this document, we discuss a proposed exemption for qualified facilities (proposed § 110.2(a)). In section XIV of this document, we discuss a proposed process for withdrawing an exemption for a qualified facility (proposed subpart E). In section XIII.A of this document, we discuss proposed modified requirements for qualified facilities (proposed § 110.201).

c. Exemptions and exceptions. In addition to the exemption for qualified facilities in section 418(l)(2)(A) of the FD&C Act, there are several other exemptions and exceptions to the requirements specified in section 418 of the FD&C Act. Section 418(j) of the FD&C Act provides an exemption for facilities that are required to comply and are in compliance with the regulations for seafood HACCP, juice HACCP, or thermally processed low-acid foods packed in hermetically sealed containers. Section 418(k) of the FD&C Act provides an exception for activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety). Section 103(g) of FSMA provides an exemption for certain activities regarding a dietary supplement that is in compliance with sections 402(g)(2) and 761 of the FD&C Act (21 U.S.C.

342(g)(2), 379aa-1). In sections X.B.2 through X.B.4 of this document, we discuss proposed exemptions for activities that are subject to part 123 (proposed § 110.2(b)), part 120 (proposed § 110.2(c)), part 113 (proposed § 110.2(d)), section 419 of the FD&C Act (proposed § 110.2(f)), or the manufacturing, processing, packing, and holding of dietary supplements (proposed § 110.2(e)).

As discussed in section II.B.2.e of this document, section 418(m) of the FD&C Act also authorizes the Secretary to create exemptions or modifications to the requirements with respect to certain facilities.

d. Rule of construction regarding alcohol-related facilities. As discussed in more detail in section X.B.7 of this document, section 116 of FSMA (21 U.S.C. 2206) (Alcohol-Related Facilities) provides a rule of construction for certain facilities engaged in the manufacturing, processing, packing, or holding of alcoholic beverages and other food. In section X.B.7 of this document, we discuss proposed exemptions related to such facilities (proposed § 110.2(h)).

2. Requirements for Agency Rulemaking

Section 103 of FSMA contains two separate rulemaking provisions. Section 103(a) of FSMA requires rulemaking related to the hazard analysis and risk-based preventive controls required by section 418 of the FD&C Act. In addition, section 103(c) of FSMA requires rulemaking in two areas: (1) clarification of certain aspects of the definition of the term "farm" under section 415 of the FD&C Act (21 U.S.C. 350d) (Registration of Food Facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 of the FD&C Act (21 U.S.C. 350j) (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report) for certain facilities as the Secretary deems appropriate and as further specified in section 103(c)(1)(D) of FSMA.

a. General rulemaking requirements. Section 418(n)(1)(A) of the FD&C Act requires that not later than 18 months after the date of FSMA's enactment, the Secretary issue regulations "to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls …."

b. Definition of small and very small business. Section 418(l)(5) of the FD&C Act requires the Secretary, in consultation with the Secretary of Agriculture, to conduct a study of the food processing sector regulated by the Secretary and to make determinations in five areas. These areas include, in part, (1) distribution of food production by type and size of operation, (2) the proportion of food produced by each type and size of operation, (3) the number and types of food facilities co-located on farms, (4) the incidence of foodborne illness originating from each size and type of operation, and (5) the effect on foodborne illness risk associated with certain activities regarding food.

Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms "small business" and "very small business," taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. These terms are significant because section 103 of FSMA contains several provisions specific to such entities.

- Small and very small businesses are subject to modifications or exemptions from requirements under section 418 or 421 of the FD&C Act for facilities engaged only in specific types of on-farm activities and involving foods that the Secretary determines to be low risk (§ 103(c)(1)(D) of FSMA).

- Small and very small businesses are not subject to section 418 of the FD&C Act until 6 months (small businesses) or 18 months (very small businesses) after the effective date of FDA's final rule (§ 103(i) of FSMA).

- A very small business is deemed a "qualified facility" and would, therefore, qualify for the exemptions as discussed in section X.B.1 of this document. (§ 418(l)(1)(B) of the FD&C Act).

Consistent with section 418(l)(5) of the FD&C Act, FDA has consulted with USDA during its study of the food processing sector (Ref. to a memo of consultation). The study is available in the docket established for this proposed rule (Ref. to the study). We request comment on that study. After considering comments and determining whether to revise the study in light of the comments, and consistent with the requirements of the Information Quality Act (Pub. L. 106–554, section 515(a)) and the Final Information Quality Bulletin for Peer Review issued by the Office of Management and Budget (70 FR 2664, January 14, 2005), we will subject the document to peer review. In section X.C.4 of this document, we discuss our proposed definitions for small business and very small business. We will consider comments regarding the study, as well as comments regarding our proposed definitions for small and very small business, in any final rule based on this proposed rule.

c. Clarification of the term "facility". Generally, section 418 of the FD&C Act applies to the owner, operator, or agent in charge of a "facility." Section 418(o)(2) of the FD&C Act defines "facility" as "a domestic facility or a foreign facility that is required to register under section 415." Section 415 of the FD&C Act, in turn, requires any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States to register with the Secretary.

The requirement in section 415 of the FD&C Act that a facility must register does not apply to farms. FDA's implementing regulations for section 415 (see part 1, subpart H) (21 CFR part 1, subpart H) define "farm," in relevant part, as "a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both" (§ 1.227(b)(3)) (21 CFR 1.227(b)(3)). The term "farm" includes a facility that packs or holds food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(i)). Under that same definition, the term "farm" also includes a facility that manufactures/processes food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(ii)).

Section 103(c)(1)(A) of FSMA requires that not later than 9 months after the date of enactment, the Secretary publish a notice of proposed rulemaking in the Federal Register to issue regulations for purposes of section 415 of the FD&C Act with respect to "activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership" and "activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership." The regulation is intended to "enhance the implementation" of section 415 and "clarify the activities that are included within the definition of the term 'facility'" (§ 301(c)(1)(B) of FSMA). In section VIII.E of this document, we discuss our proposal to revise the registration regulation in part 1, subpart H to enhance the implementation of section 415 and to clarify the definition of the term "facility."

d. Science-based risk analysis and requirements under sections 418 and 421 of the FD&C Act. Section 103(c)(1)(C) of FSMA requires that in issuing the proposed rule the Secretary conduct a science-based risk analysis of:

- "Specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and
- Specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership."

As part of the rulemaking, the Secretary is required to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in sections 418 and 421 of the FD&C Act or modify those requirements, as the Secretary determines appropriate, if such facilities are only engaged in specific types of on-farm manufacturing, processing, packing, or holding activities the Secretary determines to be low risk, and involving specific foods that the Secretary determines to be low risk (§ 103(c)(1)(D)(i) of FSMA). Any exemption or modification is limited to small and very small businesses (§ 103(c)(1)(D)(ii) of FSMA).

In sections VIII.G and VIII.H of this document, we discuss our approach to the requirement in FSMA section 103(c) for a science-based risk analysis of the types of on-farm manufacturing, processing, packing, or holding operations that can involve food that is not consumed on that farm or on another farm under common ownership for purposes of section 415 of the FD&C Act (Ref. Risk analysis) and request comment on the risk evaluation we drafted as part of that approach. After considering comments and determining whether to revise that risk evaluation in light of the comments, and consistent with the requirements of the Information

Quality Act (Pub. L. 106–554, section 515(a)) and the Final Information Quality Bulletin for Peer Review issued by the Office of Management and Budget (70 FR 2664, January 14, 2005), we will subject the document to peer review. The final risk evaluation will consider comments received to this proposed rule and the comments received during peer review.

In section VIII.H of this document, we discuss proposed exemptions for small and very small businesses that are solely engaged in certain types of "low risk" activities involving the on-farm manufacturing, processing, packing, and holding of certain "low risk" foods from the requirements of section 418 of the FD&C Act (proposed § 110.2(g) and (h)). We also discuss our tentative conclusion that we should not exempt or modify the frequency requirements under 421 based solely upon whether a facility only engages in such low-risk activity/food combinations and is a small or very small business.

e. Exemption or modification of requirements for certain facilities. Under section 418(m) of the FD&C Act, the Secretary may exempt or modify the requirements for compliance of section 418 of the FD&C Act for hazard analysis and preventive controls for facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. As discussed in section X.B.8 of this document, in accordance with the discretionary language of section 418(m), FDA tentatively concludes that facilities solely engaged in the storage of RACs, other than fruits and vegetables, intended for further distribution or processing should be exempt from the requirements for hazard analysis and preventive controls that we are proposing to establish in subpart C of part 110.

Section 418(m) of the FD&C Act also authorizes the Secretary to exempt or modify the requirements for compliance with section 418 for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment. In section X.D of this document, we

describe our proposal for how the requirements of part 110 would apply to such facilities (proposed § 110.5). In section X.D.4 of this document, we propose modified requirements for such facilities, directed at the storage of packaged foods that are not exposed to the environment and that require time/temperature control to limit the growth of, or toxin formation by, microorganisms of public health significance (proposed § 110.206).

f. Animal food and intentional adulteration. FDA proposes to implement section 103 of FSMA in several regulations, rather than a single regulation that covers all food and hazards subject to preventive controls. This proposal is applicable to certain hazards that may be associated with a food facility that manufactures, processes, packs or holds human food. Section 103 of FSMA applies to "food," which is not limited to human food. Section 201(f) of the FD&C Act defines "food" to include "articles used for food or drink for man or other animals" (21 U.S.C. 321(f)). FDA tentatively concludes that the differences between human and animal food are best addressed through separate regulations. FDA is proposing a separate regulation applicable to certain hazards that may be associated with a food facility that manufactures, processes, packs or holds animal food elsewhere in this issue of the Federal Register. Establishments that manufacture, process, pack, or hold food for both humans and animals should consider this proposed rule as well as the proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" in this issue of the Federal Register, as there may be differences in the requirements that would be applicable to such establishments under the two proposed rules.

In addition, this rulemaking is not intended to address "hazards that may be intentionally introduced, including by acts of terrorism." (§ 418(b)(2) of the FD&C Act). FDA plans to implement section 103 of FSMA regarding such hazards in a separate rulemaking in the future.

FDA tentatively concludes that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, we also recognize that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in foods concerning which there is a widely recognized risk of economically motivated adulteration in certain circumstances. An example of this kind of hazard is the addition of melamine to certain food products apparently to enhance perceived quality and/or protein content. We request comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We also request comment on when an economically motivated adulterant can be considered reasonably likely to occur.

C. Preventive Controls and Hazard Analysis and Critical Control Points (HACCP) Systems

1. HACCP Systems

HACCP is a preventive strategy for food safety that involves a systematic approach to the identification and assessment of the risk (likelihood of occurrence and severity) of hazards from a particular food or food production process or practice and the control of those hazards. HACCP has been endorsed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) as an effective and rational means of ensuring food safety. NACMCF is an advisory committee chartered under USDA. NACMCF includes participants from USDA's FSIS, HHS (FDA and CDC), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry, state employees and consumer groups. NACMCF provides guidance and recommendations to the Secretaries of USDA and HHS, as well as other Federal agencies, regarding the microbiological safety of foods. Although HACCP was first introduced in 1971 at the National Conference for

Food Protection, it was not widely used by the food industry until the concept was more fully developed by NACMCF. In 1989 NACMCF adopted "HACCP Principles for Food Production," which was revised in 1992; in 1997, NACMCF adopted its current version, "Hazard Analysis and Critical Control Point Principles and Application Guidelines" (Ref. NACMCF 1998). Revisions in both the 1992 and 1997 NACMCF HACCP documents were patterned after changes made in HACCP documents issued by the Codex Alimentarius Commission (Codex). (The Codex Alimentarius Commission was formed in 1963 by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts such as codes of practice, and is recognized under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures as the international standards organization for food safety.) (See the discussion of Codex HACCP documents in section II.C.5.e of this document).

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption (Ref. NACMCF 1998). Under HACCP, a food operation develops a plan that identifies food hazards applicable to the food and production process, and the points in the production process where a food hazard could be introduced, controlled or enhanced. A failure at these points would likely result in a food hazard being created or allowed to persist. These points are referred to as critical control points (CCPs). Under HACCP, identified CCPs are systematically monitored to ensure that critical limits are not exceeded, and records are kept of that monitoring. Corrective actions are taken when control of a CCP is lost, including proper disposition of the food produced during that period, and these actions are documented. The effectiveness of HACCP is also systematically verified by the food operation.

2. Section 103 of FSMA and HACCP

FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA. As discussed in section II.B of this document, section 103 of FSMA amended the FD&C Act by adding section 418. Section 418 of the FD&C Act and section 103 of FSMA are both titled "Hazard Analysis and Risk-Based Preventive Controls." This title identifies two critical elements of HACCP – hazard analysis and preventive controls. As discussed in section II.C.4.a of this document, a hazard analysis is the first of the seven principles of HACCP, and is key to an effective food safety system. Further, establishment of a system of preventive controls for these hazards is the central purpose of HACCP. (See 66 FR 6138 and 60 FR 65096 stating that FDA issued the juice and seafood HACCP regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.) In addition, section 418(n)(5) of the FD&C Act requires that in promulgating the regulations to implement preventive controls, "the Secretary shall review regulatory hazard analysis and preventive control programs in existence . . . to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards ...." (See section XVI.B of this document for a discussion of this review.) The hazard analysis and preventive control systems in existence are all based on HACCP principles. Further, section 418 uses HACCP terminology throughout, including hazard analysis, monitoring, corrective actions, and verification. The close relationship of section 418 to HACCP is further illustrated by an exemption created in section 418(j) for "seafood, juice, and low-acid canned food facilities subject to HACCP."

At the same time, FDA notes that not every provision in section 418 of the FD&C Act is identical to HACCP as described in current literature. For example, as discussed in section

II.C.4.b of this document, HACCP systems focus on determining CCPs, whereas section 418(c) requires that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points, if any (emphasis added). Thus, FSMA's approach is broader than the approach in HACCP systems, in that section 418 clearly contemplates that CCPs are only one place to apply a preventive control, and that there may in fact not be any CCPs.

As another example, as discussed in section II.C.4.c of this document, HACCP systems focus on establishing critical limits for CCPs, whereas section 418(c) of the FD&C Act requires that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at CCPs, if any, without specifying that the preventive controls establish critical limits. In fact, section 418 of the FD&C Act does not use the term "critical limit." Again, the approach of section 418 is broader than the approach in HACCP systems, in that section 418 is less prescriptive than HACCP systems in terms of mechanisms to control hazards.

As another example, as discussed in section II.C.4.a of this document, HACCP systems refer to hazards as "biological, chemical and physical agents" whereas section 418(b)(1)(A) of the FD&C Act requires that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including "biological, chemical, physical, and radiological hazards" (emphasis added). Although radiological hazards are not common, the consequences to consumers of exposure to radiological hazards may be severe (e.g., cancer). As discussed in section II.C.4.a of this document, under HACCP systems the hazard analysis includes a written assessment of the likelihood that the hazard will occur and its severity if it does occur (emphasis added). Thus, section 418(b)(1)(A)

of the FD&C Act is consistent with the framework for HACCP even though it lists an additional type of hazard that must be considered and controlled as necessary.

Throughout this document, we identify the sections of FSMA applicable to specific proposed provisions and describe how the proposed provisions relate to HACCP principles as established by NACMCF in the NACMCF HACCP guidelines, by Federal agencies in HACCP regulations, and by Codex in the HACCP Annex in the Codex General Principles of Food Hygiene (Ref. Codex Annex).

3. Five Preliminary Tasks of HACCP/Preventive Controls

The NACMCF HACCP guidelines recommend a process for developing a HACCP system, or the implementation of a HACCP plan (Ref. NACMCF 1998). The "five preliminary tasks" of HACCP include: (1) Assembling a HACCP team; (2) describing the food and its distribution; (3) identifying the intended use and consumers of the food; (4) developing a flow diagram; and (5) verifying the flow diagram. The NACMCF HACCP guidelines advise that these preliminary tasks be accomplished before the application of HACCP principles to developing a HACCP plan for a specific food and process. Although FDA is not proposing to mandate that the owner, operator, or agent in charge of a facility conduct these preliminary tasks, facilities will greatly benefit from completing these preliminary tasks in developing their hazard analysis and risk-based preventive control systems.

4. The Seven Principles of HACCP

NACMCF has developed and adopted seven principles that describe the HACCP concept: (1) Conduct a hazard analysis; (2) Determine the CCPs; (3) Establish the critical limits; (4) Establish monitoring procedures; (5) Establish corrective actions; (6) Establish verification

procedures; and (7) Establish recordkeeping and documentation procedures (Ref. NACMCF 1998). We discuss these immediately below.

a. Principle 1: Conduct a hazard analysis. The first HACCP principle is the identification of the hazards associated with the product and process. The NACMCF HACCP guidelines define a hazard as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (Ref. NACMCF, 1998). The hazard analysis includes an identification of the hazard, an assessment of the likelihood that the hazard will occur and its severity if it does occur, and identification of control measures for each identified hazard, all of which should be documented.

b. Principle 2: Determine the CCPs. The second HACCP principle is identification of CCPs. The NACMCF HACCP guidelines define a CCP as a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Ref. NACMCF, 1998). Steps in the manufacturing process that may be CCPs include heat treatment, chilling, product formulation, and metal detection.

c. Principle 3: Establish the critical limits. The third HACCP principle is establishing the critical limits, which involves establishing values for parameters that must be met for each control measure associated with a CCP. The NACMCF HACCP guidelines define a critical limit as a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard (Ref. NACMCF, 1998). Critical limits can be thought of as boundaries of safety for each CCP (Codex defines a critical limit as a criterion which separates acceptability from unacceptability (Ref. Codex 2003)) and may be set for control measures such as temperature, time, physical dimensions, moisture level, water activity, pH, and available

chlorine. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. For example, the minimum temperature and the minimum time at that temperature in a heat treatment step that will kill specific pathogens identified as hazards for a food are the critical limits for that CCP.

d. Principle 4: Establish monitoring procedures. The fourth HACCP principle is establishing monitoring procedures. The NACMCF HACCP guidelines define monitoring to mean conducting a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record of the monitoring for use in future verification procedures (Ref. NACMCF, 1998). For example, monitoring can assess whether a CCP is operating within its critical limit. An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a deviation from a critical limit, monitoring procedures must be effective. Depending on the circumstances, monitoring may be on a continuous or a non-continuous basis. Continuous monitoring of a critical limit is possible with many types of physical and chemical methods. When it is not possible to monitor a critical limit on a continuous basis, monitoring intervals must be established that are frequent enough to determine whether the measure designed to control the hazard is consistently being met.

e. Principle 5: Establish corrective actions. The fifth HACCP principle is establishing corrective actions. The NACMCF HACCP guidelines define corrective actions as procedures followed when a deviation occurs (Ref. NACMCF, 1998). While the HACCP system is intended to prevent deviations in a planned process from occurring, total prevention can rarely, if ever, be achieved. Therefore, procedures need to be in place to fix or correct the cause of the deviation to ensure that the CCP is brought under control, there is appropriate disposition of any food

produced during a deviation, and records are made of the corrective actions taken. Out-of-control situations should be used to identify opportunities for improvement of the process to prevent future occurrences.

f. Principle 6: Establish verification procedures. The sixth HACCP principle is establishing verification procedures. The NACMCF HACCP guidelines define verification as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan (Ref. NACMCF, 1998). These activities may involve the application of methods, procedures, tests, and evaluations, other than monitoring. Verification activities, particularly those directed to validation, may be very scientific and technical in nature. For additional information about verification activities, see the discussion in section XII.G of this document. For additional information about the specific verification activity of "validation," see the discussion in section XII.G.2 of this document.

g. Principle 7: Establish recordkeeping and documentation procedures. The seventh HACCP principle is establishing recordkeeping and documentation procedures. Written HACCP records list the hazards, CCPs, and critical limits identified by the facility, as well as the procedures that the facility intends to use to implement the system. Written HACCP records also include those generated during the operation of the HACCP system.

5. History of the Use of HACCP

a. HACCP regulation for fish and fishery products. In 1995, FDA issued a final rule to establish in part 123 procedures for the safe and sanitary processing and importing of fish and fishery products (60 FR 65096). Part 123 requires, among other things, that seafood processors apply HACCP principles to the processing of seafood. In the proposed rule to establish part 123, FDA identified several food safety hazards specific to the processing of fish and fishery products

that warranted the promulgation of the seafood HACCP regulation, including microbiological hazards, naturally occurring toxins, chemical contaminants that might be present in the aquatic environment, and decomposition of fish and fishery products that might result from improper product handling and produce the toxin, histamine (59 FR 4142 at 4143 – 4144, January 28, 1994).

The HACCP regulation for seafood incorporated the seven HACCP principles as established in the 1992 revision of NACMCF's HACCP Principles for Food Production ("Hazard Analysis and Critical Control Point System") (Ref. 1992 HACCP principles). The HACCP regulation for seafood also requires that individuals assigned the tasks of developing, reassessing, or modifying a HACCP plan, and conducting required records review must be adequately trained in the application of HACCP principles to fish and fishery products, evidenced either by the successful completion of the equivalent of a standardized curriculum recognized as adequate by FDA or by sufficiently adequate work experience (§ 123.10). The HACCP regulation for seafood does not require the use of NACMCF's five preliminary tasks as prerequisites to conducting a hazard analysis or developing a HACCP plan. We believe, however, that processors greatly benefit from using these preliminary steps in developing their HACCP systems (60 FR 65096 at 65117).

The HACCP regulation for seafood also requires that processors of seafood products monitor the conditions and practices of a sanitation standard operating procedure (SSOP); correct, in a timely manner, those conditions and practices that are not met; and document the monitoring and corrections (§ 123.11). In addition, the HACCP regulation for seafood is explicit that the general, umbrella CGMP requirements for human food of part 110 apply to processors of fish and fishery products in determining whether the facilities, methods, practices, and controls

used are safe, and whether the products have been processed under sanitary conditions (§ 123.5(a)).

In section XII of this document, we describe provisions of the HACCP regulation for seafood in more detail when we compare the proposed requirements for hazard analysis and risk-based preventive controls that are the subject of this document to provisions of current HACCP systems, including the HACCP regulation for seafood.

b. HACCP regulation for meat and poultry. In 1996, FSIS issued a final rule to establish in 9 CFR part 417 a regulation that, among other things, requires each meat and poultry establishment to develop and implement a system of HACCP controls designed to improve the safety of their products (61 FR 38806, July 25, 1996). In the remainder of this document, the phrase "FSIS HACCP regulation for meat and poultry" refers to 9 CFR part 417. FSIS issued its HACCP regulation for meat and poultry in light of outbreaks of foodborne illness and studies (conducted by the National Academy of Sciences, the U.S. General Accounting Office, and FSIS) that established the need for fundamental change in the FSIS meat and poultry inspection program to improve food safety, reduce the risk of foodborne illness in the United States, and make better use of FSIS' resources (61 FR 38806 at 38807).

The FSIS HACCP regulation for meat and poultry incorporates the seven HACCP principles as established in the 1992 revision of NACMCF's HACCP Principles for Food Production (Ref. 1992 HACCP principles). Unlike our HACCP regulations for seafood and for juice, the FSIS HACCP regulation for meat and poultry requires two of the NACMCF preliminary tasks – i.e., that a flow chart describing the steps of each process and product flow in the establishment be prepared and that the intended use and consumers of the finished product be identified (9 CFR 417.2(a)(2)).

The FSIS HACCP regulation for meat and poultry requires the establishment to develop, implement and maintain written SSOPs that describe the procedures an establishment will conduct daily, before and during operations, to prevent direct contamination or adulteration of products (9 CFR 416.11 and 416.12(a)). Establishments must monitor the implementation of the SSOPs (9 CFR 416.13(c)), take appropriate corrective actions (9 CFR 416.15), and maintain records that document the implementation and monitoring of the SSOPs (9 CFR 416.16).

In section XII of this document, we describe provisions of the FSIS HACCP regulation for meat and poultry in more detail when we compare the proposed requirements for hazard analysis and risk-based preventive controls that are the subject of this document to provisions of current HACCP systems, including the FSIS HACCP regulation for meat and poultry.

c. HACCP regulation for juice. In 2001, FDA issued a final rule to establish in part 120 requirements to ensure the safe and sanitary processing and importation of fruit and vegetable juices for beverages (66 FR 6138). Part 120 requires, among other things, that processors of juice products apply HACCP principles to the processing of juice. We issued the juice HACCP regulation in light of a number of food safety hazards associated with juice products, including microbiological hazards that led to outbreaks of foodborne illness associated with juice products (63 FR 20449, at 20450-20451, April 24, 1998).

The HACCP regulation for juice incorporated the seven HACCP principles as established in the NACMCF HACCP guidelines adopted in 1997 and published in 1998 (Ref. NACMCF 1998). As with the HACCP regulation for seafood, the HACCP regulation for juice requires that individuals assigned the tasks of developing the hazard analysis, developing a HACCP plan, and verifying and modifying the HACCP plan must be adequately trained in the application of HACCP principles to juice products, evidenced either by the successful completion of the

equivalent of a standardized curriculum recognized as adequate by FDA or by sufficiently adequate work experience (§ 120.13). As with the HACCP regulation for seafood, the HACCP regulation for juice does not require the use of NACMCF's five preliminary tasks as prerequisites to conducting a hazard analysis or developing a HACCP plan.

As with the HACCP regulation for seafood, the HACCP regulation for juice requires that processors of juice products monitor the conditions and practices of a sanitation standard operating procedure (SSOP); correct, in a timely manner, those conditions and practices that are not met; and document the monitoring and corrections (§ 120.6). In addition, the HACCP regulation for juice is explicit that the umbrella CGMP requirements of part 110 apply in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the juice products have been processed under sanitary conditions (§ 120.5).

Unlike the HACCP regulation for seafood, the HACCP regulation for juice, with certain exceptions, establishes requirements for process controls for pathogen reduction (§ 120.24). The HACCP regulation for juice also establishes requirements for process verification for juice processors, under certain circumstances, to analyze their finished juice products for the presence of E. coli using specified sampling and analytical methodologies (§ 120.25).

In section XII of this document, we describe provisions of the HACCP regulation for juice in more detail when we compare the proposed requirements for hazard analysis and risk-based preventive controls that are the subject of this document to provisions of current HACCP systems, including the HACCP regulation for juice.

d. Dairy HACCP pilot program. The Pasteurized Milk Ordinance (PMO) is a model milk regulation recommended by the U.S. Public Health Service/FDA for voluntary adoption by State and local milk control agencies. This model milk regulation includes provisions governing the

processing, packaging and sale of Grade “A” milk and milk products and provides administrative and technical details on how to obtain satisfactory compliance. It is published to assist States and municipalities in initiating and maintaining effective programs for the prevention of milkborne disease. Currently all fifty states, the District of Columbia, and Puerto Rico have adopted the PMO by reference or have codified the PMO in state requirements. At its biennial conferences, the National Conference on Interstate Milk Shipments (NCIMS) considers changes and modifications to the Grade "A" PMO.

Appendix K of the PMO (the PMO HACCP Appendix) describes a voluntary, NCIMS HACCP Program alternative to the traditional inspection system. No milk plant, receiving station or transfer station may participate in the voluntary NCIMS HACCP Program unless the Regulatory Agency responsible for the oversight of the facility agrees to participate with the dairy plant(s), receiving station(s) and transfer station(s) in the NCIMS HACCP Program (Ref. PMO HACCP Appendix K).

The PMO HACCP Appendix incorporates the seven HACCP principles established in the 1998 NACMCF HACCP guidelines and essentially follows the same requirements as described in the HACCP regulation for juice (part 120). SSOPs are referred to as “required prerequisite programs (PPs).” In contrast to the HACCP regulations for seafood and juice, the PMO HACCP Appendix requires that, in addition to the required PPs, any other PPs that the hazard analysis is relying upon to reduce the likelihood of hazards such that they would not be reasonably likely to occur also be monitored, audited, and documented. In this respect, the PMO HACCP Appendix is broader in scope than HACCP, in that it emphasizes the importance of monitoring, auditing, and documentation for the complete food safety system rather than focusing monitoring, auditing, and documentation solely on critical control points.

e. HACCP in the international food safety community. HACCP is recognized in the international food safety community as the state-of-the-art means to ensure the safety and integrity of food. In particular, the Committee on Food Hygiene of Codex has endorsed the HACCP concept as a worldwide guideline incorporated as an Annex into the GPFH (Ref. Codex 2003). The European Union (EU) and other countries around the world have begun to require that foods be processed using a HACCP system (Refs. EU REG. No 852/2004). A discussion on the comparison of hazard analysis and preventive controls standards in section XVI.B includes those in Regulation (EC) No 852/2004 of the European Parliament and Council of the European Union Regulation (Ref. EU REG. No 852/2004) (the EU Regulation), the Australia-New Zealand Food Standards Code (Ref. FSANZ), and the Canadian Food Inspection Agency's Food Safety Enhancement Program (Ref. CFIA FSEP), all of which are based on the Codex HACCP Annex.

The HACCP reference documents from NACMCF and Codex have changed over the years as experience has been gained from the application of the concept in food production. These reference documents remain consistent with each other. This harmonization is critical, as these documents serve as the basis for hazard analysis and preventive controls standards internationally, thus providing for harmonized food safety standards among countries. Such harmonization facilitates trade by establishing a framework for ensuring safety. In addition to these standards serving as the basis for requirements by governments, there has been widespread international adoption of HACCP/preventive controls by industry at the company level, and as the foundation for food safety in third-party auditing schemes and certification efforts for companies, such as those benchmarked through the Global Food Safety Initiative (GFSI) (Ref. Consumer Goods Forum). (See section II.F for more information on GFSI.)

The proposed rule would require that a food safety system similar to HACCP be implemented in food facilities and would harmonize our requirements with the recommendations and requirements of internationally recognized food safety experts/authorities. These include experts/authorities in NACMCF (Ref. NACMCF), Codex (Ref. Codex), FSANZ (Ref. FSANZ), CFIA (Ref. Canadian FSEP), and the European Union (Ref. EU system). The World Health Organization has recognized the importance of the HACCP system for prevention of foodborne diseases for more than 30 years and has played an important role in its development and promotion (Ref. WHO website on HACCP). FAO likewise emphasizes the importance of HACCP and promotes it through international training and food safety manuals, e.g., for mycotoxin prevention and control (ref. FAO).

The Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), particularly the Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") and the Agreement on Technical Barriers to Trade, had significant implications for Codex standards. Specifically, the SPS Agreement identifies Codex standards, guidelines and other recommendations as the baseline for consumer protection. As a result, the work of Codex (including the Codex HACCP Annex (Ref. Codex)) has become the reference for international food safety requirements. The Codex General Principles of Food Hygiene (GPFH) recommends a HACCP approach wherever possible to enhance food safety (Ref. Codex GPFH 2003). The international recognition of the HACCP approach as essential to ensuring the safety and suitability of food for human consumption enhances the potential for international trade as well as food safety (Ref. FAO).

D. Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding of Food for Human Consumption

1. Contamination of Food

Food can become contaminated (e.g., with biological, chemical, physical, or radiological hazards) at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. Consumption of contaminated food can lead to acute or long term illness or injury. CDC estimates that each year approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths are food related (Refs. Scallan major pathogens and unspecified agents). These numbers include all illnesses that CDC estimates are attributable to food, including those illnesses caused by unspecified agents. These estimates also include a correction factor to account for the fact that foodborne illness is under-reported (Ref. CDC 2011 Estimates). Focusing only on the foodborne illnesses attributable to particular pathogens, a recent CDC report estimated that consumption of food contaminated with pathogenic bacteria (such as Campylobacter spp., Clostridium perfringens, Shiga toxin-producing Escherichia coli (STEC) O157, STEC non-O157, Listeria monocytogenes, Salmonella species, Vibrio species, Yersinia enterocolitica), parasites (such as Cryptosporidium spp. and Giardia intestinalis) and viruses (such as norovirus) cause more than 9 million episodes of foodborne illness, nearly 56,000 hospitalizations, and more than 1,300 deaths in the United States each year (Ref. Scallan major pathogens). (A pathogenic microorganism is a microorganism capable of causing illness or injury.) Other food-related problems are caused by chemicals, allergens, and other harmful substances, such as glass (see sections II.D.2.b through II.D.2.d of this document for a discussion of these problems).

Early detection of contamination enables food establishments to prevent contaminated food from leaving their premises. When contamination is not detected in time to prevent contaminated food from leaving an establishment, the contamination may be detected while the food is in storage or in transit; at retail establishments; in restaurants; or in the home and often results in the need for a recall. Contamination after the food leaves the establishment may be detected during an investigation of an outbreak of foodborne illness or may be detected by end users (e.g., restaurants and consumers may identify physical hazards such as metal fragments or pieces of glass).

In recent years, we have taken a number of actions to prevent contamination of food at each step in the farm-to-table continuum. We have worked with other Federal, State, local, territorial, tribal, and foreign counterpart food safety agencies to strengthen the Nation's food safety systems across the entire distribution chain. This cooperative work has resulted in a greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new or better surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. (An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) However, changes in consumer preferences, changes in industry practices, and the rising volume of imports continue to pose significant challenges for FDA (72 FR 8750, February 27, 2007; 73 FR 55115, September 24, 2008). There are also many foodborne illnesses associated with unknown agents, which presents challenges in outbreak investigations (Ref. Scallan unspecified agents). In addition, microorganisms can change their characteristics by acquiring genes, including those for virulence, from other microorganisms (Refs. Scheutz Characteristics of the enteroaggregative).

2. Microbiological, Chemical, Physical, and Radiological Hazards

In the following sections, we highlight problems associated with foods in four categories: microbial, chemical (including allergens), physical, and radiological. Of the four types of hazards, there is far more information and data on microbiological problems associated with foods than with the others.

a. Microbiological hazards. Foodborne illness can have very serious consequences, including death. Below, we discuss several microorganisms commonly associated with foodborne illness.

Salmonella spp.

Salmonella contamination has been associated with eggs, milk and dairy products, fish, shrimp, frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, cocoa, and chocolate (Ref. Bad Bug Book). In a recent report tracking trends in foodborne illness, CDC reported that in 2010 Salmonella spp. was the most common foodborne pathogen and the most common cause of hospitalization and death (Ref. CDC, Trends in Foodborne Illness). The incidence of foodborne illness due to Salmonella spp. has not declined significantly in the last 15 years (Ref. CDC, Trends in Foodborne Illness). Salmonella spp. can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems (Ref. CDC.gov/Salmonella; FDA BBB). Healthy persons infected with Salmonella spp. often experience fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. In rare circumstances, infection with Salmonella spp. can result in the organism getting into the blood stream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis, and arthritis (Ref. CDC.gov/Salmonella; FDA BBB).

Listeria monocytogenes

Listeria monocytogenes is another pathogen often implicated in foodborne illness. In 2011, CDC reported that of all the foodborne pathogens tracked by CDC through FoodNet, L. monocytogenes had the highest case fatality rate (12.8 percent) and the highest hospitalization rate (89.6 percent) (Ref. CDC MMWR 60(22): 749-755). Listeria monocytogenes is a bacterium that occurs widely in both agricultural (soil, plants and water) and food processing environments. L. monocytogenes can multiply slowly at refrigeration temperatures, thereby challenging an important defense against foodborne pathogens – i.e., refrigeration (Refs. CAC Lm 2007, FDA/FSIS 2003 Lm RA). Ingestion of L. monocytogenes can cause listeriosis, which can be a life-threatening human illness. Serious illness almost always occurs in people considered to be at higher risk, such as the elderly and those who have a preexisting illness that reduces the effectiveness of their immune system (Ref. FAO/WHO Lm risk assessment). In addition, perinatal listeriosis results from foodborne exposure of the pregnant mother leading to in utero exposure of the fetus, resulting in fetal infection that leads to fetal death, premature birth, or neonatal illness and death. L. monocytogenes also causes listerial gastroenteritis, a syndrome typically associated with mild gastrointestinal symptoms in healthy individuals (Ref. Exec. Summary 2003 FDA/FSIS Listeria RA; FAO/WHO Lm RA).

The risk of illness from L. monocytogenes associated with a particular food is dependent on five key factors (Ref. FDA/FSIS 2003 RA; CAC 2007 Lm):

- Amount and frequency of consumption of a food;
- Frequency and extent of contamination of a food with L. monocytogenes;
- Ability of the food to support the growth of L. monocytogenes;
- Temperature of refrigerated/chilled food storage; and

- Duration of refrigerated/chilled storage.

In 2003, FDA and USDA/FSIS, in consultation with CDC, released a quantitative assessment (the FDA/FSIS Lm RA) of relative risk associated with consumption of 23 categories of ready-to-eat (RTE) foods that had a history of contamination with L. monocytogenes, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis (Ref. 2003 FDA/FSIS Listeria RA). The FDA/FSIS Lm RA shows that the risk of illness from L. monocytogenes increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of L. monocytogenes than from those that do not (Ref. Interpretation and Conclusions from the Lm RA). FAO/WHO released a risk assessment on L. monocytogenes in RTE foods in 2004. A key finding of that risk assessment was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (Ref. FAO/WHO risk assessment). Refrigerated foods present a greater risk from L. monocytogenes because some refrigerated foods that support growth may be held for an extended period of time, thus increasing the risk if L. monocytogenes is present in a food. Growth of L. monocytogenes does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with L. monocytogenes is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from L. monocytogenes in that food increases.

Escherichia coli O157:H7

One of the most serious foodborne pathogens in terms of symptoms is Escherichia coli O157:H7, one of the enterohemorrhagic strains of E. coli. While the incidence of E. coli O157:H7 infection has been declining in recent years, it is still among the top five pathogens causing hospitalization as a result of foodborne illness (Ref. Scallan major pathogens).

E. coli is a normal inhabitant of the intestines of all animals, including humans. However, E. coli O157:H7 is a rare variety of E. coli that, among other virulence factors, produces one or more related, potent toxins that cause severe damage to the lining of the intestine. Hemorrhagic colitis is the name of the acute disease caused by E. coli O157:H7. The illness is characterized by severe cramping (abdominal pain) and diarrhea, which often becomes bloody. Occasionally vomiting occurs. The illness is usually self-limited and lasts for an average of 8 days. Some victims, particularly the very young, develop hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia. From 0 to 15 percent of hemorrhagic colitis victims may develop HUS. The disease can lead to permanent loss of kidney function and death. (Ref. for whole paragraph = FDA Bad Bug Book)

Noroviruses

Noroviruses are a group of related, single-stranded RNA, non-enveloped viruses that cause acute gastroenteritis in humans. Norovirus is the official genus name for the group of viruses previously described as "Norwalk-like viruses" (NLV) or small round structured viruses (SRSVs) because of their morphologic features. Norovirus infection usually presents as acute-onset vomiting, watery non-bloody diarrhea with abdominal cramps, and nausea. Low-grade fever also occasionally occurs, and diarrhea is more common than vomiting in children. Dehydration is the most common complication, especially among the young and elderly, and may require medical attention. Symptoms usually last 24 to 72 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae (i.e., chronic conditions resulting from the illness) (Ref. cdc.gov - norovirus-factsheet). Noroviruses are transmitted primarily through the fecal-oral route, either by consumption of fecally contaminated food or water or by direct person-to-person spread. Noroviruses are highly contagious and as few as 10

viral particles may be sufficient to infect an individual. During outbreaks of norovirus gastroenteritis, more than one mode of transmission has been documented – e.g., initial foodborne transmission in a restaurant by a contaminated food, followed by secondary person-to-person transmission to household contacts. CDC recently estimated that there are 5.4 million cases of domestically-acquired foodborne illness each year due to norovirus infection, and more than 58 percent of all foodborne illnesses can be attributed to norovirus (Ref. Scallan major pathogens).

As part of the work of the CGMP Working Group, FDA reviewed its food recall records for recall actions that were classified I or II for fiscal years 1999 through 2003 to identify those recalls that took place because of problems that could have been prevented by CGMP-type preventive measures such as proper equipment sanitation, adequate training of employees, review of product labels for accuracy and agreement with the product formulation, and adequate preventive maintenance of equipment (Ref. summary of recall data 1999-2003). The review did not include Class III recalls because these recalled products are not likely to have caused adverse health consequences. FDA repeated this type of review 5 years later, for the period 2008-2009 (Ref. summary of recall data 2008-2009). In these two reports, the second most common reason for such recalls was microbiological contamination (Ref. FDA Recalls Rpts). Approximately 17 percent of such recalls during 1999-2003 and 24 percent of such recalls during 2008-2009 were linked to microbiological hazards. During 2008-2009, the two most commonly implicated pathogens in such recalls were L. monocytogenes (9.9 percent) and Salmonella (7.6 percent). In the 2010 annual report on the Reportable Food Registry, the three main pathogens associated with the reports received by the RFR were Salmonella (31.6 percent), L. monocytogenes (17.6 percent), and E. coli O157:H7 (3.2 percent).

There are many other pathogens associated with foodborne illness; however the four described above have been implicated in many recent outbreaks of foodborne illness as demonstrated by the examples below.

- In 2006-2007, a commercial brand peanut butter contaminated with Salmonella enterica serotype Tennessee (usually shortened to Salmonella Tennessee) caused 715 confirmed cases of illness, including 129 hospitalizations (Ref. cdc.gov - foodborneoutbreaks). (Salmonella species are grouped into serotypes (also called serovars) based on cell surface antigens, which are determined by serologic testing. The serotype is often named after the location where it was isolated.) This was the first outbreak associated with peanut butter in the United States (CDC, 2007) (Ref. CDC, 2007. MMWR). Investigators detected Salmonella in environmental samples collected at the manufacturer's facility as well as in finished product (Refs. Conagra EIRs in 02/14/2007 and 08/20/2007). Two years later, in 2008-2009, another large Salmonella outbreak was linked to peanut butter and peanut paste (Ref. CDC, 2009. MMWR; Cavallaro 2011 NEJM). Implicated products included contaminated peanut butter consumed at institutional settings and peanut crackers made with the contaminated peanut butter as an ingredient (CDC, 2009). This single outbreak resulted in 714 confirmed cases of illnesses, including 166 hospitalizations, and 9 deaths (Ref. Cavallero 2011 NEJM). Inspections conducted by FDA at the manufacturing facilities revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Refs. FDA EIRs for GA and for TX).

- In 2007, a puffed snack food was implicated in a Salmonella Wandsworth and Salmonella Typhimurium outbreak. There were 87 confirmed reports of illnesses, including 8 hospitalizations. The likely source of contamination was a contaminated ingredient – i.e.,

imported dried vegetable powder that was applied to the puffed snack food after the cooking step (Refs. cdc.gov/foodborneoutbreaks and cdc.gov/Salmonella).

- From October 2008 to March 2009, a multistate L. monocytogenes outbreak was linked to Mexican-style cheese that was contaminated post-pasteurization. There were 8 confirmed cases of illness in 5 states (Ref. cdc.gov/foodborneoutbreaks). An investigation at the plant revealed the potential for product contamination due to deficiencies in cleaning and plant and equipment maintenance (Jackson et al., 2011 J. Food Protection. 74(6):949-953).

- In 2008-2009, white pepper was implicated in a Salmonella Rissen outbreak that resulted in a 87 confirmed cases of illness, including 8 hospitalizations and 1 death (Ref. www.cdph.ca.gov and white pepper 010611.pdf). During the investigation, FDA isolated the outbreak strain from raw whole white pepper, in-process samples, finished products, and environmental samples taken at various locations throughout the processing areas. (Ref. fda.gov/ICECI/Warning Letters).

- In 2009, a prepackaged, refrigerated cookie dough was implicated in an E. coli O157:H7 outbreak that caused 76 confirmed cases of illness, including 35 hospitalizations (Ref. cdc.gov/ecoli; FDA fda.gov - PublicHealthFocus). E. coli O157:H7 was found in unopened packages of cookie dough in the production facility, although it was not the outbreak strain (Ref. Nestle press release; fda.gov – PublicHealthFocus).

b. Chemical hazards other than food allergens. There are a variety of "chemical" hazards that may be associated with food, including pesticide and drug residues, natural toxins, decomposition resulting in the production of toxins such as histamine, food or color additives, and food allergens. (We discuss food allergens in more detail in the next section of this document). Under the FD&C Act, certain products, such as food additives, color additives, new

animal drugs, and pesticides require premarket approval before they may be legally used. (In the case of pesticides, EPA "registers" (i.e., approves) the use of pesticides and establishes tolerances (the maximum amounts of residues that are permitted in or on a food) if the use of a particular pesticide may result in residues in or on food. FDA enforces those tolerances, except for meat, poultry, and certain egg products, which are the responsibility of FSIS (Ref. FDA 2008 Pesticide Monitoring Report). Moreover, this approval can be limited so that the product may only be used legally on or with specific foods, or for specific purposes, for which approval has been obtained. This limitation reflects a longstanding recognition that the safety of these types of products is variable and must be established on a use-by-use basis. Whether an additive, drug, or pesticide is safe for a particular use, in a particular food, at a particular level, depends on factors such as the amount of the food that is consumed and, if the additive, drug, or pesticide is ingested in a living animal before capture, and how the product is metabolized in that animal.

Therefore, an additive, drug, or pesticide that has been approved for use in some foods, but not other foods, is deemed by the FD&C Act to be unsafe for use with those other foods. By specifically identifying pesticides, drug residues, and unapproved food and color additives as potential known or reasonably foreseeable hazards that a facility must consider and evaluate in its hazard analysis, section 418(b) of the FD&C Act emphasizes the current provisions of the FD&C Act regarding substances that require premarket review.

Natural toxins such as aflatoxin in foods such as peanuts and tree nuts and patulin in apple juice products are well recognized as hazards (Refs. CPG 570.375 for peanuts, CPG 570.200 for Brazil nuts, CPG 570.500 for pistachios and 510.150 for patulin in apple juice). Decomposition products such as histamine, produced from the amino acid histidine when certain bacteria grow, can pose a risk to health. Biogenic amines other than histamine have been

associated with illnesses, and these may also be formed when bacteria grow in some foods. Although certain fish species are the most common source of illness from histamine and other biogenic amines, illness from histamine has been reported from consumption of other foods, in particular cheese (Ref. Taylor, S. 1985. Histamine; Stratton, et al. 1991). Heavy metals (such as lead) can lead to adverse health consequences (such as impaired cognitive development in children) (Ref. to supporting document for lead in candy guidance).

Depending on the particular chemical hazard and its level in the food, contamination of food with a chemical hazard may lead to immediate or near-term onset of illness (e.g., gastrointestinal illness), or may more commonly be associated with chronic exposure, long-term effects. Industrial chemicals (such as caustic cleaning compounds) can cause an acute reaction. Examples of long-term effects include impaired cognitive development in children exposed over time to relatively low levels of lead in contaminated candy (Ref. Supporting document for the guidance in lead in candy) and liver cancer in persons exposed over time to the mycotoxin aflatoxin (Ref. Gordon S. Shephard , 2008 RA of aflatoxins in food in Africa).

c. Chemical hazards – food allergens. Food allergies are immune-mediated adverse reactions to proteins. It has been estimated that food allergies affect four to six percent of children and two to three percent of adults (Ref. Sampson, 2004; Sampson, 2005; Sicherer and Sampson, 2010). A recent study by CDC estimates that approximately 3 million children in the United States (3.9 percent) have food allergies (Ref. Branum and Lukacs, 2009). This study also reported that the prevalence of food allergies increased by 18 percent in this age group between 1997 and 2007 (Ref. Branum and Lukacs, 2009).

The severity of a food allergic reaction varies depending on factors such as the amount of allergen ingested, the type of allergen, and the presence of other underlying medical conditions.

Sensitive individuals may experience reactions to allergen doses as low as a few micrograms of food protein (Refs. Bindslev-Jensen, Briggs, and Osterballe, 2002; Taylor and others, 2009; Taylor and others, 2010). As high as one-third of sensitive individuals can experience severe reactions at the minimal eliciting dose of an allergen.

Allergic reactions from food result in an estimated 125,000 emergency room visits in the United States each year (Ref. Ross, et al Analysis of food-allergic and anaphylactic events in the National Electronic Injury Surveillance System), and as many as 100-150 deaths in the United States each year (Refs. Simon, M. R., and Mulla, Z. D. (2008) and Yocum et al (1999)). For children under 18 years of age, CDC estimates that there are approximately 9,500 food allergy-related hospitalizations per year (Ref. Branum, A.M., and Lukacs, S.L. (2008)). The signs and symptoms associated with allergic reactions can range from oral irritation and swelling to cardiovascular collapse (Ref. Jackson, W. F. (2003)).

Although more than 170 different foods have been reported to cause allergic reactions, most severe reactions are caused by the major food allergens defined in the Food Allergen Labeling and Consumer Protection Act (FALCPA) (21 U.S.C. 321(qq)): milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. These eight allergens account for 90 percent of allergic reactions in affected individuals (Ref. Branum, A.M., and Lukacs, S.L. (2008)). FALCPA amended the FD&C Act to prescribe the manner in which food labels must disclose that a food is, or contains an ingredient that bears or contains, a major food allergen (one of the eight listed above).

The most common CGMP related problem we have identified that resulted in a recall, both before and after FALCPA was passed, is labeling problems (i.e., undeclared allergen). In conjunction with the work of the CGMP Working Group, FDA reviewed CGMP-related food

recalls during the period 1999-2003 (Ref. summary of recall data 1999-2003). Labeling problems accounted for 68 percent of food recalls, including 34 percent of recalls due to undeclared major food allergens. FDA followed up with a similar review of CGMP-related food recalls during the period 2008-2009, with a focus on primary recalls. (A primary recall is a recall initiated by a firm where the food safety problem first occurred. A subsequent recall is triggered by a primary recall. In a subsequent recall, the recalling firm is a recipient of an ingredient that is implicated in a primary recall.) In that follow-up review, labeling problems accounted for 62 percent of primary food recalls, including 43 percent of recalls due to undeclared major food allergens (Ref. summary of recall data 2008-2009). Thus, although FALCPA was passed in 2004, we continue to see problems with undeclared allergens in foods, as evidenced by recalls.

Some of the problems with undeclared allergens come to light only after consumers experience allergic reactions. For example, in August 2010, a prepared food with undeclared milk was recalled after a consumer complaint of an allergic reaction. It was discovered that the "natural flavors" used might have contained a milk product, but milk was not listed as an allergen on the product label (Ref. http://www.fda.gov/Safety/Recalls/ucm222663.htm). In December 2010, a snack product with undeclared egg was recalled after a consumer complaint of an allergic reaction. The egg-containing product was mistakenly packaged in packaging designed for a similar product that did not contain egg (Ref. fda.gov/Safety/Recalls).

d. Physical hazards. Physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. Physical hazards may be associated with raw materials, especially raw agricultural commodities. The facility and equipment can also be a source of

physical hazards, e.g., container glass and metal fragments such as nuts and bolts from equipment used in manufacturing/processing.

The RFR Annual Report issued in January 2011 identified only three primary RFR entries for "foreign objects" (which were physical hazards that could have resulted in serious adverse health consequences or death), and all of these were in animal feed or pet food (Ref. RFR Jan 2011 report). However, there have been recalls of human foods due to contamination or potential contamination with physical hazards. In October 2010, several types of frozen vegetables were recalled after shards of broken glass were found in some packages (Ref. Picksweet recall) and in May 2011 several types of English muffins and bread products were recalled due to possible contamination with small pieces of metal (Ref. Flowers Foods recall).

e. Radiological hazards. Radiological contamination of foods is a rare event. Examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium, strontium-90 and iodine-131. The most common way these radionuclides are incorporated into foods is through use of water that contains a radionuclide to manufacture a food. For example, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium have been detected in private wells (Refs. two refs from USGS). Radiological hazards also may result from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. In 2011, following the damage to a nuclear power plant during an earthquake and tsunami in Japan, radioactivity was subsequently detected in foods, particularly milk, vegetables, and seafood produced in areas neighboring the plant (Ref. WHO FAQs Japan Nuclear Concerns).

Consuming food contaminated with radioactive material will increase the amount of radioactivity a person is exposed to, which could have adverse health effects. The health effect

depends upon the radionuclide and the amount a person is exposed to. For instance, exposure to certain levels of radioactive iodine is associated with increased risk of thyroid cancer (Ref. WHO FAQs Japan Nuclear Concerns).

f. Summary. As discussed above, food safety problems associated with microbiological, chemical, physical, and radiological hazards continue to cause illnesses and deaths and result in significant recalls. In its reviews of CGMP-related food recalls, FDA summarized key factors that contributed to the food safety problems that initiated the recalls. For recalls during 1999-2003, FDA concluded that the contributing factors (there could be more than one for a single recall) included incorrect packaging/labeling (68 percent), ineffective employee training (32 percent), failure to follow processing standard operation procedures (26 percent), excess/mistaken addition of chemicals/ingredients (9 percent), contamination of raw materials (8 percent), ineffective use of sanitation principles (8 percent), and unknown (4 percent). For recalls during 2008-2009, FDA used a slightly different methodology to categorize the contributing factors; the contributing factors included lack of label controls (57 percent), lack of supplier controls (37 percent), deficiencies in employee training (24 percent), lack of sanitation controls (17 percent), poor processing controls (13 percent), lack of environmental monitoring (9 percent), and unknown (1 percent). The findings from the two recall analyses demonstrate that over the past decade, similar types of food safety problems caused by similar types of contributing factors continue to challenge the food industry (Refs. FDA's Two Food Recall Summaries).

3. Preventing Food Safety Problems

As discussed in section II.C of this document, HACCP is a preventive food safety strategy that is a systematic approach to the identification and assessment of the risk of hazards

from a particular food or food production process or practice and the control of those hazards that are reasonably likely to occur. The HACCP system aims to identify the points in the manufacturing process at which hazards might occur and to continuously monitor and control those points in an attempt to ensure that products meet pre-specified performance criteria (Ref. NACMCF, 1998). The HACCP system is universally endorsed by international bodies such as Codex, the Food and Agriculture Organization, and the World Health Organization. During the last few years, HACCP systems have been mandated by U.S. Federal regulations established by FDA for seafood and juice, and established by FSIS for meat and poultry. (In the remainder of this document, we use the term "Federal HACCP regulations" to refer to these HACCP regulations for seafood, juice, and meat and poultry.) Codex has issued guidelines for HACCP systems (Ref. Codex 2003), and several industrialized nations or unions have mandated HACCP for part or all of their food industries (Refs. Canadian, Australian, and European HACCP programs).

As discussed in sections II.C.1 through II.C.4 of this document, HACCP is a preventive system made up of interdependent activities including hazard analysis, preventive controls, monitoring, corrective actions, verification, and record keeping associated with these activities. These activities work together to prevent food safety problems; the individual activities, by themselves, are not as effective as the combination of these activities in the complete HACCP system. For example, a facility may determine that certain pathogens are reasonably likely to occur in a food product and establish and implement a heat treatment, for a specified combination of time and temperature, as a control to prevent the pathogens from contaminating finished food products. Unless the facility monitors the temperature and time during the heat treatment, the facility will not be able to determine whether its preventive control was, in fact,

implemented. Moreover, the monitoring, by itself, would provide less value if the temperature was not documented during the monitoring and the documentation was not reviewed so that the facility can verify that the proper temperature was achieved for sufficient time. If the proper temperature or time is not achieved, corrective actions would be necessary to ensure that the food is reprocessed, diverted to a use that does not raise a food safety concern, or disposed. For the heat treatment to be effective, the level of any pathogens contaminating ingredients or other raw materials used to make the food must not exceed the level of pathogens that the heat treatment is validated to eliminate.

As discussed in section III of this document, FDA tentatively concludes that a modern food safety system based on HACCP principles can address the food safety problems discussed in sections II.D.1 through II.D.2 of this document.

E. The Role of Testing as a Verification Measure in a Food Safety System

1. Verification of Preventive Controls

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. CAC MC 1997; NACMCF 1998). Prevention of hazards in food is much more effective than trying to differentiate safe from unsafe food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Ref. ICMSF Book 7, Chapters 1 and 4). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified

limits for parameters established in the food safety plan. Although testing may be conducted for biological, chemical, physical or radiological hazards, the most common testing is for microbiological hazards. Thus, much of the testing described below focuses on microbial testing, but many of the issues discussed apply to testing for other hazards as well. We focus more of our discussion below on verification testing of the environment because of the increasing recognition of the benefits of such testing in identifying conditions that could result in environmental pathogens contaminating food; thus such verification testing is important in preventing contamination in food, whereas verification testing of raw materials, ingredients, and finished products is used to detect contamination that has already occurred.

As discussed in sections II.E.3, II.E.5, and II.E.6, microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;
- Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate RTE food; and
- Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the food.

Each type of testing provides information applicable to managing hazards in foods, depending on the food and process. For example, a dry blending operation, e.g., spices and seasonings, often verifies its supplier controls by testing incoming ingredients before use (as discussed in section II.E.3) and periodically sampling and testing finished products. If all the ingredients being blended had been treated to adequately reduce hazards such as Salmonella, a dry blending operation generally does less testing to verify supplier controls than if this were not the case. We use the term “adequately reduce” (which is a term used in some of our guidance

documents) (Refs. peanut guidance and pistachio guidance) to mean the same as "significantly minimize or prevent" as described in section 418 of the FD&C Act or "prevent, eliminate or reduce to an acceptable level" as used in our seafood and juice HACCP regulations. All these terms mean to reduce a hazard to an extent that it is not reasonably likely to cause illness or injury.) A dry blending operation generally does not test incoming ingredients if the facility treats the blended materials to ensure adequate reduction of pathogens but sometimes tests finished product to verify preventive controls have been effective. The facility also sometimes uses environmental monitoring to verify that sanitation controls to significantly minimize or prevent the potential for environmental pathogens to contaminate the blended materials have been effective.

For acidified canned vegetables in which a lethal process is delivered in the final package, microbial testing of incoming ingredients and of finished product provides little benefit as a verification activity (although it would be used in process validation); however, facilities producing such products sometimes conduct periodic testing of incoming ingredients for pesticides as an appropriate supplier verification activity.

2. Scientifically Valid Sampling and Testing

Consistent with our previous discussion of the term "scientifically valid" in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements (68 FR 12157 at 12198), we use the term "scientifically valid" with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12157

at 12198). Sampling and testing used for verification in a food safety system must be scientifically valid if they are to provide assurance that preventive controls are effective.

3. Verification Testing of Raw Materials and Ingredients

Raw materials and ingredients are often tested as part of a supplier approval and verification program, as one of the verification activities when a preventive control that is adequate to significantly minimize or prevent the hazard is not applied at the receiving facility. The utility and frequency of raw material and ingredient testing for verification of supplier controls depend on many factors, including:

- The hazard and its association with the raw material or ingredient;
- The likelihood that the consumer would become ill if the hazard were present in the raw material or ingredient;
- How that raw material or ingredient will be used by the receiving facility (e.g., the effect of processing on the hazard); and
- The potential for contamination of the environment with the hazard in the raw material or ingredient.

Testing a raw material or ingredient occurs more frequently when there is a history of the hazard in the raw material or ingredient, e.g., from a specific supplier or from the country of origin. Once a facility has developed a relationship with a supplier and there is a history of tests negative for the hazard, the frequency if often reduced.

Testing a raw material or ingredient is more useful, and a facility generally tests a raw material or ingredient more frequently, when the raw material or ingredient contains a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. However, when a hazard that the receiving

facility has identified as reasonably likely to occur in a raw material or ingredient is one for which the receiving facility has preventive controls that significantly minimize or prevent the hazard, testing generally is less frequent. An exception to this general paradigm is when the process control depends on the amount of the hazard present in the raw material or ingredient (e.g., when the process control is effective at eliminating 100 microorganisms per gram of ingredient, but not 1000 microorganisms per gram of ingredient) and there is a need to verify that the hazard is not present in amounts that would render the process control ineffective. A receiving facility often finds that testing of raw materials or ingredients is most useful, and generally tests more frequently, when the receiving facility does not have a process that would significantly minimize the hazard and is relying on preventive controls earlier in the supply chain to significantly minimize or prevent the hazard in the raw material or ingredient, as in a bagged salad facility or a dry-mix operation producing, for example, spice blends or trail mix. In such situations, the testing is conducted to verify the preventive controls used to ensure that hazards in the raw material or ingredient have been significantly minimized or prevented.

The frequency of the testing conducted by a facility generally depends in part on the likelihood and severity of illness to the consumer if the hazard were present, the ability of supplier controls to significantly minimize or prevent the hazard in the raw material or ingredient, the practicality of testing to detect the hazard, and other factors. For example, a facility generally tests a raw material or ingredient more frequently from a supplier that does not have a kill step for Salmonella in shelled nutmeats compared to a supplier that steam treats the nuts to kill Salmonella. As another example, if a facility tests a raw material or ingredient as part of its food safety program for salad greens, the facility is more likely to test more frequently for E. coli O157:H7 than for other Shiga-toxin producing E. coli (pathogenic E. coli that produce

the same toxin as E. coli O157:H7 but are less likely to cause severe illness (Ref. CDC shiga site)), based on both the severity of the illness to the consumer and practical problems with testing fresh produce for pathogenic strains of Shiga-toxin producing E. coli. Where a raw material or ingredient could introduce an environmental pathogen such as Salmonella or L. monocytogenes to the facility (e.g., raw nuts or soy powder for Salmonella, and chopped celery to be used in a salad for L. monocytogenes), a facility generally tests the raw material or ingredient more frequently to verify that supplier controls for the raw material or ingredient minimize to the extent possible the potential for the contaminated raw material or ingredient to introduce the environmental pathogen to the facility's environment.

As discussed in section II.E.6 of this document, there are limitations to testing food. Thus, as with other testing, raw material or ingredient testing is rarely the sole basis for making a determination on the safety of a raw material or ingredient.

4. Verification of Sanitation Controls to Significantly Minimize or Prevent the Potential for an Environmental Pathogen to Contaminate Food

a. Environmental pathogens in food. As discussed in section II.D of this document, food can become contaminated with pathogenic microorganisms at many different steps in the farm-to-table continuum. Any time a food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated with pathogenic microorganisms. As discussed in section X.C of this document, proposed § 110.3 would define the term "environmental pathogen" to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. The environmental pathogens most frequently

involved in the contamination of foods leading to foodborne illness are Salmonella spp. and L. monocytogenes.

b. Salmonella spp. as an environmental pathogen. We discuss Salmonella spp. in section II.D.2.a of this document. Salmonella has been isolated from a variety of foods and it can get into food by a variety of mechanisms (see section II.D). Our focus here is on Salmonella contamination from the environment (discussed further in section II.E.4.b), particularly as a hazard associated with low-moisture foods (Ref. Scott et al., 2009). Low-moisture foods include cereal, peanuts, nuts, nut butters (including peanut butter), spices, dried herbs, milk powder, chocolate and many other foods. Although Salmonella outbreaks from low-moisture foods are less common than from foods such as eggs and produce, several such outbreaks in the last decade have involved hundreds of illnesses (Ref. Scott et al, 2009). The low-moisture foods causing outbreaks included cereal, raw almonds, dried snacks, spices, and peanut butter (Ref. Scott et al., 2009; CA Dept. PH NR2009-23.aspx). Chocolate also has been a source of outbreaks from Salmonella, although none in the U.S. in recent years (Scott et al., 2009). Dried dairy products, such as milk and whey, also present a risk of contamination with Salmonella from the environment (Ref. Gabis et al. 1989). A review of FDA recall data from 1970 to 2003 showed there were 21 recalls of spices and herbs contaminated with Salmonella (Ref. Vij et al JFP 69:233-237 2006). Almost half of the 86 primary RFR entries reported in the first RFR Annual Report due to finding Salmonella were from low-moisture foods (Ref. RFR annual report).

c. Listeria monocytogenes as an environmental pathogen. We discuss L. monocytogenes in section II.D.2.a of this document. As discussed in that section, the FDA/FSIS Lm RA shows that the risk of illness from L. monocytogenes increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of L. monocytogenes than

from those that do not (Ref. Interpretation and Conclusions from the Lm RA). A key finding of the risk assessment released by FAO in 2004 was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (Ref. FAO/WHO risk assessment). Refrigerated foods present a greater risk from L. monocytogenes because some refrigerated foods that support growth may be held for an extended period of time, thus increasing the risk if L. monocytogenes is present in a food. Growth of L. monocytogenes does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with L. monocytogenes is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from L. monocytogenes in that food increases. As discussed in section II.D.1 of this document, contamination of RTE food with L. monocytogenes from the environment is common and, thus, targeted preventive controls to significantly minimize or prevent L. monocytogenes contamination of RTE foods are warranted.

d. Environmental pathogens in the plant environment. Environmental pathogens may be introduced into a facility through raw materials or ingredients, people, or objects (Ref. ICMSF 7, Chapter 11). Once in the facility, environmental pathogens can be a source of contamination of food. Environmental pathogens may be transient strains or resident strains (Ref. ICMSF 7, Chapter 11). Transient strains are environmental pathogens that contaminate a site in the facility where they can be eliminated by normal cleaning and sanitizing (Ref. ICMSF 7 Chapter 11). Transient strains tend to vary over time within a facility, e.g., they will be found in different areas and the specific strain will differ. Resident strains are environmental pathogens that contaminate a site in the facility that is difficult to clean and sanitize with normal cleaning and sanitizing procedures and, thus, these strains become established in what is referred to as a

"niche" or harborage site (Ref. ICMSF 7 Chapter 11; Carpentier and Cerf, 2011). The finding of the same specific strain multiple times in a facility often indicates a resident strain.

If a harborage site contains nutrients (i.e., food) and water and is exposed to a temperature that falls within the growth range of the environmental pathogen, the pathogen can multiply, which increases the chance that it will be transferred to other sites (including food-contact surfaces) and to food. Transfer can occur by people (e.g., if a person touches the contaminated site and then touches other objects, or tracks the pathogen from the contamination site to other sites on shoes), by equipment (e.g., if the pathogen is picked up by the wheels of a cart or forklift and is transferred to other locations), by water (e.g., water that contacts the harborage site is splashed onto other areas, including equipment, or aerosols containing the pathogen transfer it to other areas) or by air (dissemination of contaminated dust particles by air handling systems) (Ref. Carpentier and Cerf, 2011, Tompkin et al., 1999). Such transfer mechanisms from harborage sites can result in intermittent contamination of food-contact surfaces and food over long periods of time often with the same strain of the pathogen (Ref. ICMSF 7, Ch. 11; Breuer, 1999, Carpentier and Cerf, 2011).

e. Contamination of food with Salmonella spp. from the plant environment. As discussed immediately below, the available data and information associate insanitary conditions in food facilities with contamination of a number of foods with the environmental pathogen Salmonella spp. Such contamination has led to recalls and to outbreaks of foodborne illness.

In 1998, a breakfast cereal product was implicated in an outbreak, due to Salmonella Agona, that caused 409 illnesses and one death in 23 states (Ref. Breuer, 1999; CDC Epi-Aid 1999). During the outbreak investigation, Salmonella was isolated from various locations in the plant, including the floor, processing equipment, and the exhaust system of the implicated

processing line (Ref. Breuer, 1999). In 2008, the same Salmonella Agona strain was again implicated in an outbreak linked to a similar cereal product from the same manufacturing facility (Ref. CDC. salmonella/agona/). In the 2008 outbreak, the same strain was isolated from patients, cereal and the plant environment (Ref. CDC. salmonella/agona/).

In 2006-2007, a commercial brand peanut butter contaminated with Salmonella Tennessee caused 715 illnesses and 129 hospitalizations (Ref. CDC Outbreak website). FDA isolated Salmonella Tennessee from 13 unopened jars of peanut butter with production dates ranging from August 2006 to January 2007 and from two plant environmental samples (Ref. CDC, 2007 MMWR 56:521-524).

During the years 2008 through 2010, there were three large recalls of foods containing ingredients contaminated with Salmonella spp. where FDA's investigation identified insanitary conditions at the facility that manufactured the ingredient and detected Salmonella in the plant environment. (Refs. /peanutbutterrecall/index.cfm; Plainview recall; and HVP recall). In 2008-2009, an outbreak was linked to Salmonella Typhimurium in peanut butter and peanut paste (Ref. CDC, 2009 MMWR 58:85-90; Cavallaro et al. 2011 NEJM). This outbreak resulted in an estimated 714 illnesses, 166 hospitalizations, and 9 deaths (Ref. Cavallaro et al. 2011 NEJM). Implicated foods included contaminated peanut butter consumed at institutional settings and crackers made with the contaminated peanut butter as an ingredient (Ref. CDC, 2009 MMWR 58:85-90; Cavallaro et al. 2011 NEJM). Inspections conducted by FDA at the two implicated ingredient manufacturing facilities (which shared ingredients) revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Refs. 2009 Peanut products recall; FDA 2009 PCA ORA). Several strains of Salmonella were found in multiple

products and in the plant environment (Ref. FDA 483 2/5/09). This outbreak led to the recall of more than 3900 products containing peanut-derived ingredients (Ref. peanutbutterrecall/).

In 2009, USDA detected Salmonella in a powdered dairy shake and FDA began an investigation of the suppliers of ingredients used to manufacture the product. The inspection of the supplier of one of the ingredients uncovered insanitary conditions that resulted in the recall of multiple ingredients manufactured by that supplier, including instant nonfat dried milk and whey proteins, produced over a two-year period (Ref. FDA PressAnnouncements/ucm169471.htm). During its investigation of the supplier's facility, FDA identified several strains of Salmonella on food-contact and non-food-contact surfaces and in other areas of the plant environment, as well as a number of sanitation deficiencies (Ref. FDA 483 UCM173030.pdf).

In 2010, FDA received a report through the RFR of Salmonella contamination of hydrolyzed vegetable proteins that a company purchased as an ingredient. Both the company that submitted the report and FDA found multiple Salmonella-positive samples collected from the plant environment, including food-contact surfaces. FDA found numerous sanitation deficiencies during its inspection of the production facility. There were no reports of illness associated with the contamination, but multiple product recalls resulted (Ref. MajorProductRecalls/HVP/default.htm).

f. Contamination of food with L. monocytogenes from the plant environment. As discussed immediately below, the available data and information associate insanitary conditions in food facilities with contamination of a number of foods with the environmental pathogen L. monocytogenes. Such contamination has led to recalls and to outbreaks of foodborne illness.

Between October 2008 and March 2009, eight cases of listeriosis from five states were linked to Mexican-style cheese that was likely contaminated post-pasteurization (Ref. Jackson et

al, 2011). The outbreak strain was isolated from product and from a vat gasket in a post-pasteurization section of the processing line.

In October 2010, the Texas Department of State Health Services ordered a fresh-cut produce facility to stop processing after laboratory tests of chopped celery indicated the presence of L. monocytogenes (Ref. DSHS press release). The testing was done as part of an investigation of 10 cases of listeriosis, six of which were linked to chopped celery from the facility. Texas Department of State Health Services and FDA inspectors found sanitation deficiencies at the plant (Ref. DSHS press release, FDA UCM232412.pdf) and suggested that the L. monocytogenes in the chopped celery may have contaminated other produce. FDA laboratory testing found L. monocytogenes in multiple locations in the plant environment, including on food-contact surfaces; the DNA fingerprint of the L. monocytogenes in the FDA samples matched the DNA fingerprint of the clinical cases reported by the Texas Department of State Health Services (Ref. FDA /ucm232237.htm).

There have been several outbreaks in which meat or poultry products produced in FSIS-inspected establishments were contaminated with L. monocytogenes from the plant environment (Ref. FDA/FSIS LmRA, Chapter II, Hazard identification), and much of our understanding of sources of L. monocytogenes in the plant environment, as well as appropriate ways to control this organism, has come from the efforts of FSIS and the meat and poultry industry to control this hazard in FSIS-inspected establishments (Ref. Tompkin 2002). For example, harborage sites such as hollow rollers, rubber seals, close-fitting metal-to-metal spaces in equipment such as slicers, and on-off switches of equipment were identified in meat and poultry establishments. The increased risk of contamination resulting from construction, and the importance of control of

traffic and water in the RTE area also became widely know as a result of investigations at meat and poultry establishments (Ref. Tompkin 2002; Tompkin et al.).

Outbreaks of listeriosis resulting from environmental contamination have also occurred in other countries. For example, an outbreak of listeriosis in Finland in 1999 was associated with butter (Ref. Lyytikäinen et al., 2000 JID). The outbreak strain was isolated from the manufacturing facility, including from the packaging machine and the floor (Ref. Lyytikäinen et al., 2000 JID). An outbreak of listeriosis in 2009 in Austria and Germany was associated with acid curd cheese; the outbreak strain was found in the production facility (Ref. Fretz et al. 2010 Euro Surveillance).

Many foods without a known association with illnesses have been recalled due to the presence of L. monocytogenes (Refs. 2011 recall notices for bagged salad, romaine lettuce, queso fresco, and avocado pulp). There is also an extensive body of literature on isolation of L. monocytogenes in the food processing environment. Information on the environment as a source of Listeria has been available for many years. For example, in a 1989 study involving 6 different types of food plants (frozen food, fluid dairy, cheese, ice cream, potato processing, and dry food), drains, floors, standing water, food residues, and food contact surfaces were found to be positive (Cox et al., 1989 FM6:49-61). No finished foods were tested, but the authors concluded that food production environments could be the source of contamination for foods that have received listericidal treatments and that measures should be taken to prevent survival and growth of these organisms in food environments (Cox et al., 1989 FM6:49-61).

Listeria testing in 62 dairy facilities during 1987-1988 (including facilities producing fluid milk, frozen product, butter, processed cheese, natural cheese and dry product plants) found Listeria in a variety of locations, including packaging equipment, conveyors, coolers, drains and

floors (Ref. Nelson, 1990 DFES). Listeria was detected more frequently in wet locations, including drains, conveyors and floors (Ref. Nelson, 1990 DFES). Pritchard and co-workers also examined 21 dairy processing environments for Listeria and found 80 of 378 sites positive for Listeria spp. (Ref. Pritchard et al. 1995). Sites positive for L. monocytogenes included holding tanks, table tops, conveyor/chain systems, a milk filler and a brine pre-filter machine (Ref. Pritchard et al. 1995).

The packaging machine was found to be the main problem with L. monocytogenes that persisted in an ice cream plant in Finland for several years and occasionally contaminated finished product (Ref. Miettinen et al. 1999). A volumetric doser was found to be the source of L. monocytogenes in sauces produced in a fresh sauce production plant in Italy (Ref. Pourshaban et al. 2000), and slicers and conveyor belts were found to contribute to contamination of sandwiches in a Swiss sandwich producing plant (Ref. Blatter et al. 2010). L. monocytogenes also has been found on tables, water hoses, air guns, floors, gloves, drains and a bread-feeding machine (Ref. Blatter et al. 2010).

Some of the available data and information about the potential presence of the environmental pathogen L. monocytogenes comes from studies conducted to detect the presence of Listeria species in lieu of L. monocytogenes. Listeria spp. are "indicators" of the potential presence of L. monocytogenes. (See section II.E.5.b of this document for a discussion of indicator organisms). A study conducted over a four-year time period on the prevalence of L. monocytogenes on produce and in the plant environment in a large produce processing plant in Poland demonstrated that the indicator organism Listeria spp., and the environmental pathogen L. monocytogenes could be isolated from conveyor belts after blanching and from freezing tunnels (Ref. Pappelbaum et al. 2008). Studies in a vegetable processing plant in Spain found the

indicator organism L. innocua (commonly found when the species of Listeria spp. are determined) in frozen RTE vegetables and in the plant environment, e.g., washing tunnels, conveyor belts and floors (Ref. Aguado et al., 2004). L. innocua was more prevalent than L. monocytogenes in the frozen RTE vegetables and in the plant environment. In both of these examples, the presence of an "indicator organism" (either Listeria spp. or L. innocua) demonstrated that insanitary conditions existed that were conducive to the presence and harborage of L. monocytogenes.

5. Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Sanitation Controls in Significantly Minimizing or Preventing the Potential for an Environmental Pathogen to Contaminate Food

a. Purpose of environmental monitoring. Appropriate sanitation controls can minimize the presence of environmental pathogens in the plant and the transfer of environmental pathogens to food-contact surfaces and to food (Ref. ICMSF 7, Ch. 11). The purpose of monitoring for environmental pathogens in facilities where food is manufactured, processed, packed or held is to verify the implementation and effectiveness of sanitation controls intended to significantly minimize or prevent the potential for an environmental pathogen to contaminate food. In so doing, environmental monitoring can find sources of environmental pathogens that remain in the facility after routine cleaning and sanitizing (particularly strains that may have become established in the facility as resident strains) so that the environmental pathogens can be eliminated by appropriate corrective actions (e.g., intensified cleaning and sanitizing, sometimes involving equipment disassembly). Pritchard et al. noted that daily cleaning and sanitizing appeared to be effective in eliminating transient contaminants from equipment and concluded that greater emphasis needs to be placed on cleaning and sanitizing the plant environment (Ref.

Pritchard et al. 1995). A robust environmental monitoring program for environmental pathogens can detect these strains and enables the facility to eliminate them from the environment which can prevent contamination of food with these pathogens and, thus, prevent foodborne illnesses (Refs. CAC 2007 Lm control; Tompkin, et al., 1999; Tompkin, 2002; Scott et al., 2005; and Chen et al. FPT3, 2009). In the situations described in sections II.E.4.e, and II.E.4.f of this document, such a program for the environmental pathogens Salmonella spp. and L. monocytogenes might have allowed the facility to detect a problem before product contamination occurred, thereby preventing an outbreak, recall, or both, or minimizing the amount of product affected by a recall. Studies of environmental pathogens have clearly demonstrated that environmental monitoring can identify the presence of situations that can lead to contamination of food and allow actions to be taken to prevent such contamination (Ref. Pritchard et al., 1995; Jarl and Arnold, 1982).

b. Indicator organisms. The term "indicator organism" can have different meanings, depending on the purpose of using an indicator organism. As discussed in the scientific literature, the term "indicator organism" means a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. Buchanan, 2000). This definition in the scientific literature is consistent with a definition of indicator organism established by NACMCF as one that indicates a state or condition and an index organism as one for which the concentration or frequency correlates with the concentration or frequency of another microorganism of concern (Ref. NACMCF 2002. Ground Beef). FDA considers the NACMCF

definition of an indicator organism to be an appropriate working definition for the purpose of this document.

The use of "indicator organisms" as a verification of hygiene measures in facilities is common practice (Ref. Evancho et al. 2001). For example, it is common practice to use the presence of generic (nonpathogenic) E. coli in a food processing plant as an indication of whether food was prepared, packed, or held under insanitary conditions, without considering whether the insanitary conditions reflect a specific pathogen, such as E. coli O157:H7 or Salmonella. However, such use of an indicator organism is distinct from the use of indicator organisms as discussed in the remainder of this document – i.e., for the specific purpose of monitoring for the presence of environmental pathogens.

Environmental monitoring for environmental pathogens can be conducted by testing for the specific pathogenic microorganism (e.g., Salmonella spp.) or by testing for an "indicator organism." The presence of an indicator organism indicates conditions in which the environmental pathogen may be present. An organism is useful as an indicator organism if there is sufficient association of conditions that could result in the presence of the indicator organism and conditions that could result in the pathogen such that there can be confidence that the pathogen would not be present if the indicator is not present. Attributes that provide scientific support for use of an indicator organism in lieu of a specific pathogen include:

- Similar survival and growth characteristics;
- A shared common source for both organisms; and
- A direct relationship between the state or condition that contributes to the presence of pathogen and the indicator organism (Ref. NACMCF, 2002).

The presence of an indicator organism in the plant environment, including on a food-contact surface, does not necessarily mean that an environmental pathogen is in the plant or in a food produced using that food-contact surface – the indicator may be present but the pathogen may be absent. Pritchard et al., in their study on the presence of Listeria in dairy plant environments, concluded that, because the level of contamination was higher in environmental samples than in equipment samples, environmental contamination with Listeria does not necessarily translate into contamination of equipment in the plant (Ref. Pritchard et al. 1995).

Typically, a facility that finds an indicator organism during environmental monitoring conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the indicator organism is found on retest, the facility generally takes more aggressive corrective actions (e.g., more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts) (Ref. Tompkin et al. 1999). In general, whether a facility takes subsequent steps to determine an indicator organism detected on a food-contact surface is actually the environmental pathogen depends, in part, on the risk of foodborne illness if the food being produced on a food-contact surface that has tested positive for an indicator organism were to be contaminated. For example, the risk of listeriosis is greater if the food supports growth of L. monocytogenes. In some cases, a facility simply assumes that a food produced using a food-contact surface that is contaminated with an indicator organism is contaminated with the environmental pathogen and takes corrective action to either reprocess it or divert it to a use that would not present a food safety concern.

c. Environmental monitoring for L. monocytogenes and the use of an indicator organism. Tests for the indicator organism Listeria spp. detect multiple species of Listeria, including the pathogen L. monocytogenes. There is Federal precedent for the use of Listeria spp. as an appropriate indicator organism for L. monocytogenes. FSIS has established regulations requiring FSIS-regulated establishments that produce RTE meat or poultry products exposed to the processing environment after a lethality procedure (e.g., cooking) to prevent product adulteration by L. monocytogenes.

FSIS has issued guidelines (Compliance Guidelines to Control Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products, or the "FSIS Listeria Guidelines") to help FSIS-regulated establishments that produce RTE meat or poultry products exposed to the processing environment after a lethality procedure comply with the requirements of 9 CFR part 430 (Ref. FSIS 2006 Lm Guidelines). Under the FSIS Listeria Guidelines, FSIS-regulated establishments may establish an environmental monitoring program for Listeria spp. rather than for the pathogen, L. monocytogenes.

In general, under the FSIS Listeria Guidelines, an FSIS-regulated establishment that receives a positive test result for an indicator organism on a food-contact surface:

- Takes corrective action (i.e., intensify the cleaning and sanitizing of the affected food-contact surface);
- Retests the affected food-contact surface; and
- Takes additional corrective action (intensified each time the test is positive for the indicator organism) and conducts additional testing until the affected food-contact surface is negative for the indicator organism.

Some segments of the food industry subject to regulation by FDA have adopted the principles, described in the FSIS Listeria Guidelines, for corrective actions after a finding of Listeria spp. on food-contact surfaces in the plant. For example, in response to a request for comments on a draft guidance document directed to control of L. monocytogenes in refrigerated or frozen ready-to-eat foods, we received letters describing programs similar to the program in the FSIS guidelines, using Listeria spp. as an indicator organism during environmental monitoring for L. monocytogenes (Refs. to comments submitted to Docket 2007-D-0494 by Kraft Foods; by Kraft Foods Appendix; by GMA; by the Alliance for Listeriosis Prevention). In addition, as discussed in section II.A.1 of this document, a key finding of the CGMP Working Group Report was the importance of updating part 110 to require a written environmental pathogen control program for food processors that produce RTE foods that support the growth of L. monocytogenes. Written comments from the food industry supported such a control program, (Ref. Letter dated April 28, 2006 from the CGMP Coalition to Docket No. 2004N-0230). Thus, the importance of controlling L. monocytogenes in the environment of RTE food production facilities and using environmental monitoring to detect the presence of L. monocytogenes or Listeria spp. (as an indicator organism for L. monocytogenes) has been well-established.

FDA's current thinking is that Listeria spp. is an appropriate indicator organism for L. monocytogenes, because tests for Listeria spp. will detect multiple species of Listeria, including L. monocytogenes, and because the available information supports a conclusion that modern sanitation programs, which incorporate environmental monitoring for Listeria spp., have public health benefits.

d. Environmental monitoring for Salmonella spp. and the use of an indicator organism. Salmonella spp. is a member of the family Enterobacteriaceae, and thus there is some

relationship between the presence of Salmonella spp. and the presence of Enterobacteriaceae. There are few studies that have investigated the use of organisms such as Enterobacteriaceae or other members of the family Enterobacteriaceae, such as E. coli, to serve as an indicator organism for Salmonella in the environment. The European Food Safety Agency (EFSA) evaluated whether environmental monitoring for Enterobacteriaceae as an indicator organism for Salmonella spp. (or for Cronobacter spp.) could be useful. Although EFSA's focus was on the utility of Enterobacteriaceae as an indicator organism in the production of a single product – i.e., powdered infant formula – their analysis may be relevant to the utility of Enterobacteriaceae as an indicator organism in other dried foods. EFSA concluded that, although there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and Salmonella spp. in powdered infant formula because Salmonella is so rarely present, monitoring for Enterobacteriaceae in the product environment can be used to confirm the application of GMPs (Ref. EFSA, 2007). ICMSF also considered the utility of environmental monitoring for Enterobacteriaceae as an indicator organism for Salmonella spp. ICMSF indicates that, for powdered infant formula manufacturing, low levels of Enterobacteriaceae do not guarantee the absence of Salmonella (Ref. ICMSF Book 8 2011 Ch 25) and recommends testing directly for the pathogen, as well as for Enterobacteriaceae. FDA agrees with EFSA and ICMSF that there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and Salmonella spp. during the production of powdered infant formula; FDA is not aware of any information supporting the use of an indicator organism for the purpose of environmental monitoring for Salmonella spp. during the production of other foods, particularly dried foods.

ICMSF recommends testing for Salmonella in the environment for a number of other products, e.g., baked dough products (Ref. ICMSF Book 8, p 218-219), dry spices receiving a

kill step (Ref. ICMSF Book 8, p 199), dried cereal products (Ref. ICMSF Book 8, p216), nuts (Ref. ICMSF Book 8, p230), cocoa powder, chocolate and confectionary (Ref. ICMSF Book 8, p243), and dried dairy products (Ref. ICMSF Book 8, p315). For most of these products ICMSF also recommends testing the environment for Enterobacteriaceae as a hygiene indicator, but not in lieu of the environmental pathogen Salmonella. Likewise, food industry guidance for low-moisture foods recommends testing for Salmonella in the environment (Ref. Chen et al. FPT 3. 2009). FDA's current thinking is that there is no currently available indicator organism for Salmonella spp. We request data, information, and other comment bearing on whether there is a currently available indicator organism for Salmonella spp. that could be used for environmental monitoring.

6. Role of Finished Product Testing in Verifying the Implementation and Effectiveness of Preventive Controls

The utility of finished product testing for verification depends on many factors that industry currently considers in determining whether finished product testing is an appropriate approach to reducing the risk that contaminated food would reach the consumer and cause foodborne illness. The first such consideration is the nature of the hazard and whether there is evidence of adverse health consequences from that hazard in the food being produced or in a similar food. If the hazard were to be present in the food, how likely is it that illness will occur and how serious would the consequences be? The more likely and severe the illness, the greater the frequency of conducting verification testing. For example, Salmonella is a hazard that if consumed could cause serious illness, particularly in children and the elderly. In contrast, in situations where unlawful pesticide residues are considered reasonably likely to occur, the presence of a pesticide residue that is not approved for a specific commodity but that is within

the tolerance approved for other commodities, while deemed unsafe as a matter of law, may not actually result in illness. Thus, a firm is more likely to conduct finished product testing to verify Salmonella control than to verify control of pesticides.

Another consideration in determining whether finished product testing is appropriate is the intended consumer of the food. The greater the sensitivity of the intended consumer (as would be the case, for example, for a medical food provided to hospitalized adults), the greater the likelihood that finished product testing would be used as a verification activity.

Another consideration in determining whether finished product testing is appropriate is the impact of the food on the contaminant. For example, depending on the food, pathogens may survive in food, increase in number, or die off. Finished product testing generally is not conducted if pathogens that may be in a food would die off in a relatively short period of time (e.g., before the food reaches the consumer). For example, many salad dressings have antimicrobial properties, including low pH, high acidity, and preservatives, that are lethal for pathogens such as Salmonella or E. coli O157:H7. If a facility has validated the lethality of the formulation of the salad dressing, the facility is unlikely to conduct finished product testing for pathogens such as Salmonella or E. coli O157:H7 would not be an effective use of resources, particularly if proper formulation of the food is verified during production. In contrast, verification testing is more likely in food where pathogens can survive in a food, particularly where pathogens may grow in a food.

Another consideration in determining whether finished product testing is appropriate is the intended use of the food. For example, consumers cook many foods, e.g., dried pasta, cake mixes, and most frozen vegetables, thereby reducing pathogens. A facility should not rely on the consumer to eliminate hazards that can be prevented. However, there is little benefit in testing a

food that is normally consumed following a step that can be relied on to inactivate the hazard. It is important to validate that the instructions provided to the consumer adequately reduce the pathogen of concern. It is also important to understand the customary use of the food, which may include uses that do not include the hazard reduction step. For example, dried soup mixes may be mixed with sour cream to make a dip, without the pathogen inactivation step that occurs when boiling the soup mix with water. If Salmonella may be present in an ingredient for the soup mix, e.g., dried parsley or black pepper, and neither the supplier nor the facility treats the ingredient or the soup mix in a way that significantly reduces Salmonella, then finished product testing for Salmonella would be warranted. Likewise, frozen peas and corn may be added to fresh salads, deli-type salads, or salsas without a pathogen inactivation step; finished product testing for L. monocytogenes would be warranted for these foods where this is a likely use.

Another consideration in determining whether finished product testing is appropriate is the type of controls the supplier has implemented to minimize the potential for the hazard to be present, e.g., whether the supplier uses a kill step for a pathogen or has other programs in place that will adequately reduce the hazard. A facility generally is more likely to conduct finished product testing when the supplier does not have a program that can ensure the hazard has been adequately reduced in the ingredient supplied. Another consideration is the verification procedures that are in place at the supplier and at the receiving facility. If the supplier has a well-executed control program, including a supplier approval and verification program that has been verified through audits to adequately reduce the hazard, the receiving facility performs periodic verification testing of the ingredient provided by the supplier, and the supplier has a good compliance history, the frequency of finished product verification testing by the receiving facility is low, particularly if the receiving facility has a process that further reduces the hazard.

However, if the ingredient is associated with a hazard and the processes used by the supplier and the receiving facility will not significantly minimize it, or if a facility is using a new supplier, the frequency of finished product verification testing increases.

One of the most important considerations in determining whether finished product testing is appropriate is the effect of processing on the hazard. The frequency of finished product testing generally is low when a manufacturing process significantly minimize the hazard (e.g., a 5-log reduction of a pathogen) and procedures are in place to prevent recontamination after that process; the frequency of finished product testing increases when a manufacturing process does not significantly minimize the hazard (e.g., 1- or 2-log reduction of a pathogen). For example, testing is not common for bagged spinach that is irradiated to provide a 5-log reduction of Salmonella and E. coli O157;H7; finished product verification testing would be more common if the only pathogen reduction step is washing the spinach leaves in chlorinated water. Likewise, FDA noted in the preamble to the juice HACCP regulation that it was not requiring end product verification testing for juice treated to achieve a 5-log reduction in a target pathogen because the post-treatment level of microorganisms would be too low to be detected using reasonable sampling and analytical methods (68 FR 6138 at 6174).

Another important consideration in determining whether finished product testing is appropriate is whether a hazard can be reintroduced into a food that has been treated to significantly minimize the hazard, either through exposure to the environment or by the addition of an ingredient after a treatment to significantly minimize a hazard. For example, verification testing is not common if a lethal treatment for a pathogen is given to food in its final package (such as a marinara sauce heated in the jar or hot-filled into the jar) but would be more common if food exposed to the environment, such as a cold gazpacho filled into a container. Likewise,

verification testing generally is more frequent for foods given significant handling before packaging, regardless of whether they have previously received a treatment that would significantly minimize a hazard, if they will be consumed without a treatment lethal for pathogens that can be introduced during handling (e.g., L. monocytogenes or Salmonella from the environment; enteric pathogens such as Staphylococcus aureus or Salmonella from food handlers). Verification testing also would be more frequent if an ingredient that has potential to be contaminated with a pathogen is added to a food that was previously treated to significantly minimize a hazard (e.g., adding seasonings to chips or crackers after frying or baking) than if all ingredients are added before the treatment.

In assessing whether to conduct verification testing and determine the frequency of that testing, a facility generally considers the impact of all the preventive control measures applied in producing the food, because multiple control measures provide greater assurance that a hazard is being controlled. For example, the frequency or finished product verification testing generally would be lower for a food that is subject to supplier controls that include audits and COAs; that contains ingredients that have been subjected to ingredient testing; that is produced under well-implemented sanitation controls that are verified through a robust environmental monitoring program; and that is treated using a validated process that significantly minimizes the hazard than for a food that is not subject to all these controls. Finished product testing generally is more frequent during initial production cycles until there is an accumulation of historical data (e.g., finished product test results that are negative for the hazard) to confirm the adequacy of preventive controls. Once this history has been established, the frequency of testing generally is reduced to that needed to provide ongoing assurance that the preventive controls continue to be effective and to signal a possible loss of control, as discussed further immediately below.

There are well-known shortcomings of product testing, especially microbiological testing, for process control purposes, and it is generally recognized that testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed (Ref. Buchanan, 2000; ICMSF 7 Chapter 5), most likely a book chapter cited elsewhere in this document). Moreover, the number of samples used for routine testing often is statistically inadequate to provide confidence in the safety of an individual lot in the absence of additional information about adherence to validated control measures. This is illustrated below for Salmonella.

FDA's Investigations Operations Manual (IOM) (Ref. IOM on line) and Bacteriological Analytical Manual, BAM, (Ref. BAM on line) provide sampling plans to determine the presence of Salmonella in processed foods intended for human consumption. The stringency of the sampling plan is based on the category of the food. Category III foods are those that would normally be subject to a process lethal to Salmonella between the time of sampling and consumption (e.g., macaroni and noodle products, frozen and dried vegetables, frozen dinners, food chemicals). Category II foods are those that would not normally be subject to a process lethal to Salmonella between the time of sampling and consumption (e.g., fluid milk products, cheeses, nut products, spices, chocolate, prepared salads, ready-to-eat sandwiches). Category I foods are Category II foods intended for consumption by the aged, the infirm, and infants (e.g., foods produced for a hospital). FDA takes 15 samples for Category III foods, 30 for Category II foods, and 60 for Category I foods and tests a 25 g subsample (analytical unit) from each sample. To reduce the analytical workload, the analytical units may be composited (Ref. BAM Chapter 1), with the maximum size of a composite unit being 375 g (15 analytical units). This composite is tested in its entirety for Salmonella. The probability of detecting Salmonella for various

contamination rates under the three IOM Salmonella sampling plans is shown in Table 1. (Probability of Detecting Salmonella.)

Table 1. Probability of detecting Salmonella in lots at various contamination rates under the three different IOM Salmonella sampling plans (left) and the expected number of positive composite samples using weekly testing for one year under the IOM Salmonella sampling plans (right). "N" is the number of subsamples (which are composited in groups of 15 for analysis).

			Probability of Detecting Salmonella in a Lot (Percent)				Expected # of Positive Composites per year (weekly testing)		
Contamination Rate	CFU/X g or kg		N=15	n=30	n=60		n=15	n=30	n=60
1 in 10	250g		79	96	>99		40	81	162
1 in 30	750g		40	64	87		20	41	82
1 in 100	2.5kg		14	26	45		7	15	29
1 in 300	7.5kg		4.9	10	18		2.5	5	10
1 in 1000	25kg		1.5	3	5.8		0.8	1.5	3
1 in 3000	75kg		0.5	1	2		0.3	0.5	1

The probability of detecting Salmonella increases as the defect rate increases. For example, when 15 samples are tested, the probability of detecting Salmonella is 14 percent when the contamination rate is 1 in 100, but 79 percent when the contamination rate is 1 in 10. For a given contamination rate, the probability of detecting Salmonella increases with the number of samples tested. For example, at a contamination rate of 1 in 30, the probability of detecting Salmonella increases from 40 percent if 15 samples are tested to 87 percent if 60 samples are tested.

Table 1 shows that it is clearly not feasible to attempt to identify low levels of contamination in an individual lot based on the IOM Salmonella sampling plan. If the contamination levels are high and 1 in 10 products are contaminated, then Salmonella would be detected in the lot greater than 99 percent, 96 percent, and 79 percent of the time using Category

I, II, and III testing, respectively. If the frequency of contaminated units is reduced to 1 in 300, then the contaminated lot would only be detected 18 percent, 10 percent, and 4.9 percent of the time using Category I, II, and III testing, respectively. At a very low frequency of contamination (e.g., 1 in 1000) even with testing 60 samples the contaminated lot would be detected only about 6 percent of the time.

Periodic testing for trend analysis and statistical process control, however, does provide information to assess whether processes (or the food safety system) are under control over time. Data collected from multiple lots of product produced over days, months or years are used to establish a baseline for the level of control that can be attained under a functioning food safety system and to verify the system is in control or to indicate loss of control. In addition to showing the probability of detecting contamination in a lot of product for a given contamination rate, Table 1 also shows the value of periodic testing when contamination levels are low. Even though a product with 1 in 300 contaminated units is unlikely to be rejected when sampling a single lot at the Category III sampling schedule (i.e., 4.9 percent of the time), testing of finished products with this level of contamination on a weekly basis would be expected to find 2.5 positive composite samples per year. Similarly, if the background contamination rate is thought to be near 1 in 1000 but periodic testing using the Category III schedule has found 3 positives in the last year, then it seems clear that the actual frequency of contaminated units is closer to 1 in 300. Periodic testing according to the Category I Salmonella plan has the potential to detect situations where the contamination rates are as low as 1 in 1000. If 60 samples of a food are collected weekly, then 3,120 samples would be collected over the course of a year. Compositing these 3,120 samples into 375g analytical units would reduce the number of analytical tests to 208 (4 tests per week). If 30 samples are collected weekly, and composited, there would be 104 tests

annually, or two each week. At the 1 in 1000 contamination rate there would be a greater than 95 percent confidence in seeing one or more positive tests during the year for testing composites from either 60 or 30 samples weekly. At higher rates of contamination, more positives would be detected.

There can be significant benefits to a facility testing finished products over time for process control. First, if a lot of product tests positive for a hazard, that lot of product can be disposed of such that the consumer is not exposed to the hazard (i.e., the product can be destroyed, reprocessed, or diverted to another use, as appropriate). If the testing involves enumeration of an indicator organism, it may even be possible to detect a trend toward loss of control before exceeding the criterion that separates acceptable from unacceptable. The process can be adjusted before there is a need to dispose of product. Second, the detection of loss of control, or potential loss of control, e.g., an unusual number of positives in a given period of time, allows a facility to evaluate and modify its processes, procedures, and food safety plan as appropriate to prevent loss of control in the future. In fact, the nature of the trends can provide information useful in determining the root cause of the problem (Ref. Buchanan, 2000). A third benefit to ongoing verification testing is the accumulation of data that can help bracket any problem that occurs. For products in which there are large production runs without intervening sanitation cycles, this may provide data that can be used in conjunction with other information to limit the scope of a recall. A fourth benefit may be in detection of a problem associated with an ingredient supplier that results in changes to a supplier's processes, procedures, or food safety plan. For example, a positive in finished product due to routine verification testing was responsible for determining that hydrolyzed vegetable protein was contaminated with Salmonella, resulting in over 177 products being recalled (Ref. FDA. 2010 HVPCP/) and a

recognition of the need for enhanced preventive controls for the production of this ingredient (Ref. FDA 2010 Major ProductRecalls/HVP/default.htm). Industry commonly uses finished product testing to verify preventive controls used by the facility and by the facility's suppliers. Additionally, it is common for customers to require suppliers to conduct testing of products and ingredients being provided.

7. Metrics for Microbiological Risk Management

Recently there has been much attention paid to microbiological risk management metrics for verifying that food safety systems achieve a specified level of public health control, e.g., the Appropriate Level of Protection (ALOP), for microbial hazards. Microbiological risk management metrics are fully discussed in Annex II of the Codex "Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)" (Ref. Codex MRM 2007). These metrics include traditional metrics such as microbiological criteria, process criteria, and product criteria and emerging metrics such as food safety objectives (FSO), performance objectives and performance criteria. Of particular relevance are performance objectives and performance criteria. A performance objective is the maximum frequency and/or concentration of a microbiological hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable (Ref. Codex 2011 Procedural Manual). A performance criterion is the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective or an FSO (Ref. Codex 2011 Procedural Manual). FDA established a performance criterion (or performance standard) when we required that processors of juice products apply a control measure that will consistently produce, at a minimum, a 5-log reduction for the most resistant microorganism of public health significance (§

120.24). Section 104 of FSMA (Performance Standards) requires the Secretary to determine the most significant foodborne contaminants and issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations for products or product classes. FDA is not proposing to establish criteria or metrics for verifying that preventive controls in food safety plans achieve a specified level of public health control in this proposed rule. However, FDA will give consideration to appropriate microbiological risk management metrics in the future.

F. Role of Supplier Approval and Verification Programs

A food can become contaminated through the use of contaminated raw materials or ingredients. In the past several years, thousands of food products have been recalled as a result of contamination of raw materials or ingredients with pathogens such as Salmonella and E. coli O157:H7. The ingredients included peanut-derived ingredients (Refs. recall refs from peanut guidance), pistachio-derived ingredients (Refs. recall refs from pistachio ingredient guidance), instant nonfat dried milk, whey protein, fruit stabilizers (Ref. 2 Plainview pieces on website and fda.gov press announcement) and hydrolyzed vegetable protein (Ref. "For Consumers; The HVP Recall").

The incident involving Salmonella in hydrolyzed vegetable protein illustrates the impact one supplier can have on the food industry (Ref. FDA RFR First Annual Report). A receiving facility (manufacturer) detected Salmonella in verification testing of finished product. In determining the source of the contamination, the manufacturer detected Salmonella in samples of a hydrolyzed vegetable protein ingredient and reported the finding through FDA's RFR. After FDA determined that the incident was a reportable food, FDA requested that the supplier notify the immediate subsequent recipients of the reported hydrolyzed vegetable protein ingredient.

Over one thousand reportable food reports were submitted to FDA from numerous companies concerning the potentially contaminated hydrolyzed vegetable protein or products made with the hydrolyzed vegetable protein. The hydrolyzed vegetable protein recall involved at least eleven different commodity categories and 177 products, showing the magnitude of this contamination event originating from one supplier (Ref. FDA RFR First Annual Report).

FDA recently reviewed CGMP-related food recall information from 2008-2009 to assess potential root causes for the contamination events. We determined that 36.9 percent of the 960 Class I and Class II recalls were directly linked to lack of supplier controls (Ref. Summary of Food Recalls, 2008 – 2009 July 7, 2011 memo). The recent large recalls of foods containing contaminated or potentially contaminated ingredients have focused attention on supplier approval and verification programs intended to help a manufacturer/processor prevent the introduction of a contaminated raw material or other ingredient into another product (Ref. PCA Peanut recall, HVP recall, Plainview Milk recall). The application of preventive approaches by the entire supply chain (including ingredient vendors, brokers and other suppliers and, ultimately, the manufacturer of a food product) is recognized as essential to effective food safety management (Ref. GMA Supply Chain Handbook 2008).

The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. To ensure safe food and minimize the potential for contaminated food to reach the consumer, each supplier in the chain must implement preventive controls appropriate to the food and operation for hazards reasonably likely to occur in the raw material or other ingredient. A facility receiving raw materials or ingredients from a supplier

must ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program is essential to provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

Supplier approval and verification is widely accepted in the domestic and international food safety community. The NACMCF HACCP guidelines describe Supplier Control as one of the common prerequisite programs for the safe production of food products and recommend that each facility should ensure that its suppliers have in place effective GMP and food safety programs (Ref. NACMCF 1998). The American Spice Trade Association advocates that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. ASTA Spice Guidance 2011). The Grocery Manufacturers Association's (GMA's) Food Supply Chain Handbook, developed for ingredient suppliers to the food industry, recommends that all suppliers in the food chain consider approval programs for their own suppliers; such supplier approval programs consist of a collection of appropriate programs, specifications, policies, and procedures (Ref. GMA Supply Chain Handbook 2008). GMA recommends a number of verification activities that suppliers can take in its Food Supply Chain Handbook,

including self-auditing, third-party auditing and product testing. GMA's handbook also references verification activities that a supplier's customers might take, including second-party audits (done by an employee of the customer) or third-party (independent) audits (conducted by persons who do not work for either the supplier or the customer). Codex specifies that no raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/ or processing (Ref. Codex GPFH CAC/ RCP 1-1969, Rev 4-2003). Codex also specifies that, where appropriate, specifications for raw materials should be identified and applied and that, where necessary, laboratory tests should be made to establish fitness for use (Ref. Codex CAC/ RCP 1-1969, Rev 4-2003).

One of the key supplier verification activities is auditing a supplier to ensure the supplier is complying with applicable food safety requirements, such as the requirements of part 110. Audit activities may include a range of activities, such as on-site examinations of establishments, review of records, review of quality assurance systems, and examination or laboratory testing of product samples (Ref. FDA Guidance Voluntary Third-Party Certification Programs for Foods and Feeds, 2009).

An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requiring, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements (Ref. FDA Guidance for Industry – Voluntary Third-Party

Certification Programs for Foods and Feeds). There are many established third-party certification programs designed for various reasons that are currently being used by industry. Many third party audit schemes used to assess the industry's food safety management systems incorporate requirements for manufacturers and processors to establish supplier approval programs.

The GFSI was established in 2000 to drive continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide. Their objectives include reducing risk by delivering equivalence and convergence between effective food safety management systems and managing cost in the global food system by eliminating redundancy and improving operational efficiency (Ref. GFSI guidance document V 6.1). GFSI has developed a guidance document as a tool that fulfils the GFSI objectives of determining equivalency between food safety management systems (Ref. GFSI guidance document). The document is not a food safety standard, but rather specifies a process by which food safety schemes may gain recognition, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation) in relation to food safety (Ref. GFSI guidance document). This benchmark document has provisions relevant to supplier approval and verification programs. For example, it specifies that a food safety standard must require that the organization control purchasing processes to ensure that all externally sourced materials and services that have an effect on food safety conform to requirements. It also specifies that a food safety standard must require that the organization establish, implement, and maintain procedures for the evaluation, approval and continued monitoring of suppliers that have an effect on food safety. Thus, all current GFSI-recognized schemes require supplier controls to ensure that the raw materials and ingredients that have an

impact on food safety conform to specified requirements. The GFSI guidance document also requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization's facility (Ref. GFSI Guidance Document 6th ed. Aug 2011).

Because GFSI is a document that outlines elements of a food safety management system for benchmarking a variety of standards, it does not have details about how facilities should comply with the elements. This type of information is found in the food safety schemes that are the basis for certification programs. For example, the Safe Quality Food (SQF) 2000 Code, a HACCP-based supplier assurance code for the food industry, specifies that raw materials and services that impact on finished product safety be supplied by an Approved Supplier. SQF 2000 specifies that the responsibility and methods for selecting, evaluating, approving and monitoring an Approved Supplier be documented and implemented, and that a register of Approved Suppliers and records of inspections and audits of Approved Suppliers be maintained. SQF 2000 requires that the Approved Supplier Program contain, among other items, agreed specifications; methods for granting Approved Supplier status; methods and frequency of monitoring Approved Suppliers; and details of certificates of analysis if required.

According to SQF, the monitoring of Approved Suppliers is to be based on the prior good performance of a supplier and the risk level of the raw materials supplied. The monitoring and assessment of Approved Suppliers can include:

- The inspection of raw materials received;
- The provision of certificates of analysis;
- Third party certification of an Approved Supplier; or
- The completion of 2nd party supplier audits.

III. Legal Authority

FDA is proposing changes to the Current Good Manufacturing Regulation under the FD&C Act and the Public Health Service Act. FDA is proposing all other new requirements under the FDA Food Safety Modernization Act, the FD&C Act and the Public Health Service Act.

A. Changes to Current 21 CFR Part 110

FDA is proposing changes to the current CGMP requirements in proposed subparts A, B, and F. These regulations were issued in 1978. Since then there have been significant advancements in the understanding of food safety. Further, as discussed in section II.A.1 of this document, the FDA CGMP Modernization Working Group identified seven opportunities for modernizing the current CGMP requirements.

FDA's legal authority to require Current Good Manufacturing Practices under proposed §§ 110.1, 110.2(k), 110.3, 110.10 - 120, 110.301, 110.305, and 110.315 - 325 derives from sections 402(a)(3), (a)(4) and 701(a) of the FD&C Act (21 U.S.C. 342(a)(3), 342(a)(4), and 371(a)). Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The changes to the current CGMP regulation proposed in this document clarify the existing requirements of the regulation and update existing requirements to reflect changes in the food industry and in scientific understanding of food safety since issuance of the current

regulation. Making requirements clear and relevant to current realities allows for the efficient enforcement of the FD&C Act. The proposed rule also includes new requirements necessary to prevent food from being adulterated (either because it consists in whole or in part of a filthy, putrid, or decomposed substance, because it is otherwise unfit for food, or because it has been held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health). A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. See, e.g., regulations to require HACCP systems for fish and fishery products (21 CFR Part 123) and juice (part 120), regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy Salmonella organisms and to require refrigeration of shell eggs held for retail distribution (parts 101 and 115), and regulations for the production, storage, and transportation of shell eggs (part 118).

In addition to the FD&C Act, FDA's legal authority for the proposed changes to current CGMP requirements derives from the PHS Act to the extent such measures are related to communicable disease. Authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) Many provisions in the proposed rule are

necessary to prevent food from being contaminated with human pathogens such as Salmonella, L. monocytogenes, and E. coli O157, and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. As discussed in section II.D of this document, lack of adequate sanitation in food establishments can lead to the contamination of food with pathogens, increasing the likelihood of foodborne illness. We tentatively conclude that the revisions to the current CGMP regulation proposed in this document are necessary to prevent the spread of communicable disease and to prevent food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

As part of these proposed revisions, we are proposing to use our authority under the FD&C Act and the PHS Act to institute a requirement in proposed § 110.10(c)(3), and related requirements in subpart F, that plant management at food establishments subject to subpart B establish and maintain records that document required training of personnel. As discussed in section XI.C.2 of this document, training of personnel plays a key role in ensuring compliance with the proposed requirements and thereby with prevention of adulteration and the spread of communicable disease. The proposed recordkeeping requirement is necessary for food establishments to ensure their own compliance with the proposed training requirement and for FDA to ensure that food establishments are complying with the proposed requirement. Therefore, this proposed requirement is necessary for the efficient enforcement of the FD&C Act because it will aid both firms and FDA in ensuring that food is not adulterated, and is necessary

to prevent the spread of communicable disease because it will aid both firms and FDA in ensuring that food does not become contaminated with human pathogens.

In addition to having the authority under the FD&C Act and the PHS Act to require this recordkeeping, we also have the authority to require access to the records. Because the training requirement is necessary to minimize the risk of adulteration and the spread of communicable disease, access to records that demonstrate that a firm has followed such requirements is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow up regulatory actions. Therefore, we have tentatively concluded that the ability to access and copy records is necessary to enforce the rule and prevent adulteration and the spread of communicable disease. In other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary and, because they are limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

B. Hazard Analysis and Risk-Based Preventive Controls

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that not later than 18 months after the date of FSMA's enactment, the Secretary issue regulations "to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the

implementation of the preventive controls ….” Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms “small business” and “very small business,” taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Section 103(c)(1)(A) of FSMA requires that not later than 9 months after the date of enactment, the Secretary publish a notice of proposed rulemaking in the Federal Register to issue regulations for purposes of section 415 of the FD&C Act with respect to “activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership” and “activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.” In section VIII.E of this document, we discuss our proposal to revise the registration regulation in part 1, subpart H to enhance the implementation of section 415 and to clarify the definition of the term “facility.” Section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit “[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].”

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to “prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act] or misbranded under section

403(w) [of the FD&C Act] …." In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b)-(i) contain more specific requirements applicable to facilities. These include hazard analysis (§ 418(b)), preventive controls (§ 418(c)), monitoring (§ 418(d)), corrective actions (§ 418(e)), verification (§ 418(f)), recordkeeping (§ 418(g)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). In sections XII and XV of this document, we discuss proposed requirements (proposed subparts C and F) that would implement these provisions of section 418 of the FD&C Act.

We are proposing certain requirements in order to efficiently enforce these requirements of section 418. For example, §§ 418(g) and (h) of the FD&C Act prescribe certain recordkeeping, maintenance, and access requirements for certain kinds of records. As discussed in section XV of this document, we are proposing to establish one set of requirements that would apply to all records that would be required under the proposed rule. This approach will facilitate compliance with the rule on the part of facilities, and will allow for efficient enforcement of the requirements of the FD&C Act.

Sections 418(j)-(m) of the FD&C Act and sections 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to seafood and juice HACCP, and low-acid canned food (§ 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (§ 418(k)); qualified facilities (§ 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (§ 418(m)); facilities engaged only in certain low-risk on-farm activities on certain foods conducted by small or very small businesses

(§ 103(c)(1)(D) of FSMA), and dietary supplements (§ 103(g) of FSMA). In sections X.B, XII, and XIV of this document, we discuss proposed provisions (proposed §110.2(a)-(j), and proposed subparts D and E) that would implement these provisions of section 418 of the FD&C Act and section 103 of FSMA.

FDA tentatively concludes that the provisions in subpart C and related requirements in subparts A, D, and F should be applicable to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b)). The plain language of Section 418 of the FD&C Act applies to facilities that are required to register under section 415 (§ 418(o)(2) of the FD&C Act) and does not exclude a facility because food from such a facility is not in interstate commerce. Section 301(uu) of the FD&C Act provides that "the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418", or the causing thereof, is a prohibited act. Section 301(uu) does not require an interstate commerce nexus. Notably, other subsections in section 301 of the FD&C Act, and section 304 of the FD&C Act (21 U.S.C 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret sections 418 and 301(uu) of the FD&C Act as not limiting the application of subpart C and related requirements only to those facilities with a direct connection to interstate commerce.

FDA is mindful that its interpretation of FSMA and the FD&C Act should not cast doubt on the constitutionality of those statutes. (See Solid Waste Agency of Northern Cook County v. U.S., 531 U.S. 159 (2001)). FDA has considered the relevant provisions of FSMA and the FD&C Act, FDA's responsibilities in implementing those statutes, and the law interpreting the

commerce clause of the Constitution (Article I, section 8). Congress's power to legislate under the commerce clause is very broad. However, such power is not without limits, see United States v. Lopez, 514 U.S. 549, 567 (1995); U.S. v. Morrison, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in Lopez, supra, the Supreme Court acknowledged the continuing vitality of Wickard v. Filburn, 317 U.S. 111 (1942), noting that "although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not `enough to remove him from the scope of Federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.'" (514 U.S. at 556.) See also Gonzales v. Raich, 545 U.S. 1, 17-25 (2005). This principle applies to the application of sections 418 and 301(uu) of the FD&C Act, as added by section 103 of FSMA. Accordingly, given the collective impact on commerce of facilities that manufacture, process, pack, or hold food that is sold in "intrastate" commerce, FDA tentatively concludes that such facilities should be subject to subpart C and related requirements unless an exemption in proposed § 110.2 applies. This outcome is consistent with section 709 of the FD&C Act (21 U.S.C 379a), which states that in any action to enforce the act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with FSMA's risk-based, preventive approach to food safety because the risk presented by unsafe food can be great, whether or not the food moves from one state to another. FDA seeks comment on the number of so-called "intrastate" facilities that would not be exempt from subpart C under one of the exemptions in proposed § 110.2.

FDA also is proposing the provisions in subpart C and related requirements in Subparts A, D, and F, under sections 402(a)(3), 402(a)(4), 403(w), and 701(a) of the FD&C Act to the

extent such requirements are necessary to prevent food from being held under insanitary conditions whereby it may become contaminated with filth or rendered injurious to health, or being unfit for food; and to the extent necessary to prevent food from being misbranded under section 403(w). FDA is also proposing those provisions under sections 311, 361, and 368 of the PHS Act relating to communicable disease to the extent those provisions are necessary to prevent the interstate spread of communicable disease. FDA tentatively concludes that a modern food safety system based on HACCP principles can address the food safety problems discussed in section II.D of this document. The food safety system that we are proposing would require a facility to conduct a hazard analysis to determine those hazards that are reasonably likely to occur and establish and implement preventive controls for those hazards. To ensure that controls are properly implemented and effectively controlling the hazards, the proposed food safety system would establish requirements for monitoring, corrective actions, and verification, including validation that the preventive controls are adequate to control the identified hazards. The proposed food safety system would require a supplier approval and verification program and a recall plan. Certain activities would be required to be conducted by a qualified individual and certain activities would be required to be documented. A written food safety plan would include the hazard analysis, the preventive controls that would be established and implemented to address those hazards determined to be reasonably likely to occur, procedures for monitoring, corrective actions, and verification; the supplier approval and verification program; and a recall plan. FDA tentatively concludes that, taken as a whole, the food safety system described here is necessary to help prevent food safety problems associated with microbiological, chemical, physical, and radiological hazards in foods. Therefore, the proposed system is necessary to prevent food from being adulterated because it is unfit for food or because it has been held under

insanitary conditions whereby it may become contaminated with filth or may be rendered injurious to health; to prevent food from becoming misbranded under section 403(w) of the FD&C Act; and to prevent the spread of communicable disease.

IV. Public Meeting and Preliminary Stakeholder Comments

A. Introduction

On April 20, 2011, FDA held a public meeting entitled "FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities" (Federal Register of April 13, 2011; 71 FR 20588). The purpose of the public meeting was to provide interested persons with an opportunity to discuss implementation of the provisions in section 418 of the FD&C Act. Although the meeting included introductory presentations by the FDA, the primary purpose of the meeting was to listen to our stakeholders. In order to meet that goal, FDA provided multiple opportunities for individuals to express their views, including by providing opportunities for individuals to make presentations at the meeting during an open public and webcast comment session, whereby participants could make presentations in person or via webcast, and during another listening session that was held at the end of the day. Various stakeholders made presentations during these public sessions, including presentations made by representatives from consumer groups, industry trade associations, food companies, and state agencies. The major topics discussed in these comments included food allergens and the importance of allergen controls, verification and the importance of testing, submission of food safety plans to FDA, education and training on preventive controls, the need for flexibility in the regulations, modified requirements for certain packaged food items not exposed to the environment, on-farm manufacturing, processing, packing and holding activities, and states partnering with the FDA to conduct inspections.

Stakeholders were given additional opportunities to express their views during break-out sessions focused on specific topics. Topics for the break-out sessions included preventive controls guidance, on-farm manufacturing and small business, preventive controls and the relationship to CGMPs, product testing and environmental monitoring, and training and technical assistance. A transcript of FDA's remarks at the opening session, the open public and webcast comment session, and the listening session is available on FDA's Web site (Ref. to transcript available at fda.gov). In addition, webcast videos were prepared for the public meeting and subsequently provided on FDA's Web site, including webcast videos of the opening session, open public comment session, listening session, and several breakout sessions (Ref. FDA FSMA Public Meeting webcast).

The notice announcing the public meeting also requested written comments. In response to this request, FDA received 30 written comment letters. The major issues presented in the written comment letters included the following: allergen control, accredited laboratories, environmental monitoring and product testing, flexibility of regulations and guidance, food defense, guidance and outreach, preventive controls, small businesses and exempted facilities, submission of the food safety plans to FDA, and modified requirements for warehouses. In the remainder of this section, we summarize each of the major issues raised in the written comments and identify the key proposed provisions applicable to the comments.

B. Comments on Allergen Control

Comments state that FDA should address the evaluation of allergens as a food hazard and the need for preventive controls for allergens in its implementation of section 418 of the FD&C Act. One comment notes that an effective allergen control plan is critical to protecting the health

and confidence of consumers. Comments recommend that any required allergen control programs should be limited to "major food allergens," as defined in the FD&C Act.

We propose a definition of "food allergen" (proposed § 110.3) in section X.C.4 of this document and discuss proposed requirements for preventive controls directed to food allergens (proposed § 110.135(d)(2)) in section XII.C.6 of this document.

C. Comments on Accredited Laboratories

Several comments urge FDA to require use of accredited laboratories only when there is a known or suspected food safety problem and not in the routine course of business (testing raw/ingredient, in-process, or finished product). Some comments state it would be inconsistent with its statutory authority for FDA to require use of accredited laboratories beyond limited "for cause" circumstances, e.g., testing for "identified or suspected food safety problems" or imports.

Section 202 of FSMA creates a new section 422 in the FD&C Act addressing laboratory accreditation for the analyses of foods, including use of accredited laboratories in certain circumstances. This document does not propose additional requirements for the use of accredited laboratories and does not include a discussion of section 422 of the FD&C Act.

D. Comments on Environmental Monitoring and Product Testing

Many comments assert that the role and need for product testing and environmental monitoring varies depending on the type of products and processing operation and that it should be the facility's responsibility to determine the testing needed to verify that its preventive controls are effective. Others state that environmental and product testing may be appropriate in certain instances as verification activities, but they do not constitute a control step. A number of comments assert that finished product testing is extremely costly and cannot establish safety. As such, they recommend that industry and FDA should focus on ensuring that preventive measures

are properly designated and effective instead of relying on finished product testing. One comment mentions that effective testing programs use aggressive and robust environmental testing and recognize the limited value of finished product testing. A few comments point out that finished product testing is particularly important for ready-to-eat (RTE) products, and others suggest that environmental monitoring should be required only in the part of the facility that handles exposed RTE product. Some comments maintain that FDA should require verification testing when any food has an identified hazard for which a facility has implemented a preventive control, and others state that high-risk plants should be required to do microbial sampling to a standard and frequency set by FDA. A few comments encourage FDA to require plants to conduct both environmental sampling and testing of finished products to provide assurances that product coming off the end of the line has been produced in accordance with the plant's preventive control plan.

Section II.E in the background of this document discusses a number of issues associated with environmental monitoring and product testing. We propose to establish requirements related to the subjects of environmental monitoring and product testing in proposed §§ 110.145(c) and 110.150(d)(3) and (4) (see discussions in sections XII.F.4, XII.G.5.c and XII.G.5.d of this document, respectively).

E. Comments on Flexibility of Regulations and Guidance

The majority of comments addressing this topic state that regulations and guidance should be science and risk-based, non-prescriptive, and flexible because of the wide variety of facilities that will be subject to the regulations. One notes that regulations should not require companies to hire outside consultants either explicitly or in practical terms because of their complexity.

As discussed in section XVI.A of this document, section 418(n)(3) of the FD&C Act requires that the content of the regulations promulgated under § 418(n)(1) of the FD&C Act provide sufficient flexibility to be practicable for all sizes and types of facilities; comply with chapter 35 of title 44, United States code (commonly known as the 'Paperwork Reduction Act'); acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventative controls. Section XVI.A of this document also addresses how this proposed rule complies with the requirements in section 418(n)(3) of the FD&C Act.

F. Comments on Food Defense

Numerous comments reiterate the need for food defense to be treated distinctly from food safety, since they address separate issues and often involve different types of expertise within companies. They recommend that FDA allow manufacturers to develop and maintain two distinct sets of documents on these separate issues. One comment suggests that FDA consider implementing the food and feed defense-related provisions of FSMA through guidance, rather than regulation.

FDA discusses its tentative decision not to address "hazards that may be intentionally introduced, including by acts of terrorism" in section II.B.2.f of this document. As stated there, FDA plans to implement section 103 regarding such hazards in a separate rulemaking in the future.

G. Comments on Guidance and Outreach

Comments urge FDA to focus on education and outreach for farms, facilities, distributors, inspectors, and state departments of agriculture. They support guidance that would

include information on conducting valid hazard analyses and risk assessments, implementing preventive controls, and what constitutes a valid food safety plan. They also support guidance that would provide access to background resources, such as scientific studies, risk analyses and risk-based modeling. They state that guidance should include examples of food safety plans, both acceptable and unacceptable ones. One comment envisions several different types of guidance: how to identify hazards and how to distinguish preventive controls associated with HACCP plans from those falling outside HACCP plans; preventive controls that should be considered for certain categories of food (e.g., high risk food); and what constitutes a hazard and how you determine its likely occurrence.

Section 103(b) of FSMA requires FDA to issue a guidance document related to the "regulations promulgated under subsection (b)(1) with respect to the hazard analysis and preventive controls under section 418" of the FD&C Act. In addition, section 103(d) of FSMA requires, within 180 days after the issuance of the regulations, that FDA issue a small entity compliance policy guide setting forth in plain language the requirements of the regulations established under section 418(n) of the FD&C Act and section 103 of FSMA to assist small entities in complying with the hazard analysis and other activities required under section 418 of the FD&C Act and section 103 of FSMA. On May 23, 2011, FDA published a Federal Register notice announcing the opening of a docket [docket number FDA-2011-N-0238] to obtain information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes (76 FR 29767). FDA established this docket to provide an opportunity for interested parties to provide information and share views that will inform the development of guidance on preventive controls for food facilities that manufacture, process, pack, or hold human food. FDA anticipates issuing

these required guidance documents in a timely manner in coordination with issuing the final regulations to assist our stakeholders in complying with the regulations.

FDA did not conduct HACCP training for persons subject to our HACCP regulations for seafood or juice. However, when implementing those regulations, FDA worked with an alliance of representatives from Federal and State agencies, industry and academia, to create a uniform, core training program that serves as the standardized curriculum against which other course materials can be judged. FDA will be working with an alliance to develop such a standardized curriculum for any final rule establishing requirements for hazard analysis and risk-based preventive controls.

H. Comments on Preventive Controls

A number of comments point out that not all preventive controls need to be constructed as critical control points. Some urge FDA to work with each industry segment to develop a set of general preventive controls for that segment or to use existing preventive controls programs that may already exist for a segment of industry; those general preventive controls would be tailored to each situation, plant design, and product. One comment asserts that preventive controls must consider incoming water as a key risk and states that the risk assessment must be informed by current standards and methodologies and take into account resistance to traditional disinfectants.

FDA is proposing requirements for preventive controls in proposed § 110.135 (discussed in section XII.C of this document).

I. Comments on Small and Very Small Businesses

Several comments urge FDA to define a very small business. Many recommend that these businesses should be significantly smaller than those that gross $500,000 a year. One

comment proposes that FDA define very small business as having fewer than 20 employees, stating that the Small Business Administration has done so. Another suggests that "very small" business be defined by the volume of product that they put into commerce. For facilities that satisfy criteria for the "qualified facility" exemption and therefore have the option of submitting documentation related to preventive controls or compliance with State, local, county, or other applicable non-Federal food safety law, several comments urge FDA to require that such facilities submit documentation of one option or the other. One comment disagrees that small processors should be exempt, since small processors frequently pose a risk to the public precisely because of their lack of sophistication and availability of trained technical staff.

We discuss our proposed definitions for small and very small businesses (proposed § 110.3) in section X.C.4 of this document. We discuss our proposed definition for "qualified facility" (proposed § 110.3) in section X.C.4 of this document; our proposed exemption from subpart C for a "qualified facility" (proposed § 110.2(a)) in section X.B.1 of this document; proposed modified requirements for a "qualified facility" (proposed § 110.201) in section XIII.A of this document; and a proposed process that would govern withdrawal of an exemption from subpart C for a "qualified facility" (proposed Subpart E) in section XIV of this document.

J. Comments on Submission of Food Safety Plan to FDA

Most comments agree that FDA should not require electronic submission of food safety plans, pointing out that not only would it be impractical, but also that food safety plans are most appropriately reviewed by FDA during on-site facility inspections, with the support of people familiar with the system who can answer questions and show an inspector relevant equipment, operations, and procedures. They note that plans are of limited utility outside of the plant context. However, a few comments state that FDA should request all initial food safety plans, as

this would give us an idea of any misunderstandings of the preventive control requirements. These comments also note that submission of plans could help FDA quickly determine if high-risk facilities are developing effective plans and might help FDA prioritize inspections.

FDA is not proposing to require submission of food safety plans. We discuss this topic and request comment on alternate approaches in section XII.A of this document.

K. Comments on Modified Requirements for Warehouses

All comments submitted on the issue of warehouses urge FDA to modify the preventive controls requirements for facilities, such as warehouses, that are solely engaged in the storage of packaged foods that are not exposed to the environment, since no manufacturing or processing takes place at such food warehouses and the product is not exposed to the environment. Most state that the facility should have procedures in place addressing general controls, such as sanitation, pest control, storage, segregation, security, and recordkeeping.

FDA is proposing requirements for warehouses solely engaged in the storage of packaged food that is not exposed to the environment in proposed § 110.5 (discussed in section X.D of this document) and proposed § 110.206 (discussed in section XII.B of this document).

V. Regulatory Approach

As noted in section II.B of this document, section 103 of FSMA amends the FD&C Act and creates a new section 418 (Hazard Analysis and Risk Based Preventive Controls) that applies to facilities that manufacture, process, pack or hold food. FDA is proposing to establish its implementing regulations for hazard analysis and risk based preventive controls for human foods in part 110. In sections II.A.1 and II.A.2 of this document, we discuss the food safety regulations currently in place, including the CGMPs currently established in part 110 and other food safety regulations established in other parts, including those that apply to acidified foods,

LACF, bottled drinking water, infant formula, seafood, juice, dietary supplements, and shell eggs. In considering whether to establish the requirements for hazard analysis and risk-based preventive controls within part 110 or in a new part, we tentatively conclude that the broad applicability of the requirements of section 418 of the FD&C Act to many types of foods makes it appropriate to establish implementing regulations within a regulation already considered to be an "umbrella" regulation. We also tentatively conclude that establishing an implementing regulation within part 110 would emphasize the role of CGMPs as a "prerequisite program" for preventive controls, which would be consistent with domestic and international recommendations for HACCP systems (Refs. NACMF and Codex). Moreover, the definition of preventive controls in section 418(o)(3) of the FD&C Act establishes that the procedures, practices and processes that constitute preventive controls may include CGMPs.

VI. Highlights of the Proposed Rule

A. Overview

The proposed rule would revise FDA's current regulations in part 110 regarding the manufacturing, processing, packing, or holding of human food in two fundamental ways. First, it would add new provisions to current part 110 to implement section 103 of FSMA. Second, it would update, revise, or otherwise clarify certain requirements of our current regulations in part 110, largely to modernize the regulations consistent with the CGMP Working Group Report.

As required by section 103(c) of FSMA, the proposed rule also would revise and clarify certain definitions in FDA's current regulations in part 1, subpart H (21 CFR part 1, subpart H) (Registration of Food Facilities) to clarify the types of activities that are included as part of the definition of the term "facility" under section 415 of the FD&C Act and to clarify the scope of the exemption for "farms" provided by section 415 of the FD&C Act. The proposed rule would

make corresponding changes in part 1, subpart I (Prior Notice of Imported Food) and in part 1, subpart J (Establishment, Maintenance, and Availability of Records).

Under the proposed rule, part 110 would be divided into the following subparts:

- Subpart A--General Provisions;
- Subpart B--Current Good Manufacturing Practice;
- Subpart C--Hazard Analysis and Risk-Based Preventive Controls;
- Subpart D--Modified Requirements;
- Subpart E--Withdrawal of an Exemption Applicable to a Qualified Facility; and
- Subpart F--Requirements Applying to Records That Must Be Established and Maintained.
- Subpart G would be reserved.

In the remainder of this section, we highlight key provisions of the proposed rule.

B. Proposed Revisions to 21 CFR Part 1

The proposed rule would clarify or otherwise revise definitions in current part 1, subpart H and would make corresponding changes to current part 1, subpart J. It also would add new definitions to subparts H and J, and make conforming revisions to subpart I of part 1. More specifically, the proposed rule would:

- Add new definitions for the terms "Mixed-type facility" and "Harvesting" in § 1.227 of current part 1, subpart H and § 1.328 of current part 1, subpart J;
- Clarify or otherwise revise the definitions for the terms "Farm," "Holding," "Manufacturing/processing," and "Packing" in §§ 1.227 and 1.328;
- Redesignate the definitions in current § 1.227 so that the definitions would appear in alphabetical order and would no longer bear numerical paragraph designations; and

- Revise current part 1, subpart I so that a cross-reference in part 1, subpart I to current § 1.227 conforms with the proposed paragraph reordering and redesignations for § 1.227.

C. Revisions to 21 CFR Part 110 (Part 110) Subpart A--General Provisions

The proposed rule would both revise current provisions of subpart A of part 110 and add new provisions to subpart A. More specifically, the proposed rule would:

- Add a provision establishing that the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States is a prohibited act under section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)) if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or subparts C, D, E, or F of part 110 (proposed § 110.1(b));
- Establish specified exemptions for certain facilities, or for certain activities conducted by facilities, from the proposed requirements for hazard analysis and preventive controls that would be established in proposed subpart C. The proposed exemptions would be consistent with requirements established by FSMA or discretion provided by FSMA. The subjects of the specified exemptions, and corresponding statutory provisions, relate to:
  - A "qualified" facility (proposed § 110.2(a); under section 418(l) of the FD&C Act);
  - Activities subject to our HACCP regulation for seafood in part 123 (proposed § 110.2(b); under section 418(j)(1)(A) of the FD&C Act);
  - Activities subject to our HACCP regulation for juice in part 120 (proposed § 110.2(c); under section 418(j)(1)(B) of the FD&C Act);
  - Activities applicable to the microbiological hazards that are regulated under part 113 for LACF (proposed § 110.2(d); under section 418(j)(1)(C) of the FD&C Act);

- Activities of a facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement (proposed § 110.2(e); under section 103(g) of FSMA);
- Activities of a facility that are subject to the Standards for Produce Safety in section 419 of the FD&C Act (proposed § 110.2(f); section 418(k) of the FD&C Act);
- Certain low-risk packing or holding activity/food combinations conducted on a farm by a small or very small business (proposed § 110.2(g)); under section 103(c)(1)(D) of FSMA);
- Certain low-risk manufacturing/processing activity/food combinations conducted on a farm by a small or very small business (proposed § 110.2 (h)); under section 103(c)(1)(D) of FSMA);
- The receipt, manufacturing, processing, packing, holding, and distribution of alcoholic beverages and other food (proposed § 110.2(i)); under section 116 of FSMA);
- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (proposed § 110.2(j); under section 418(m) of the FD&C Act); and
- Facilities solely engaged in the storage of packaged food that is not exposed to the environment, although the storage of such food that requires time/temperature control to prevent the growth of, or toxin formation by, pathogenic microorganisms would be subject to modified requirements that would be established in proposed subpart D (proposed § 110.5; under section 418(m) of the FD&C Act).
- Redesignate the current "RAC exemption" in current § 110.19 to co-locate it with other exemptions relevant to part 110 (those associated with FSMA) and adjust and revise it

based on experience and changes in related areas of the law since issuance of current part 110 (e.g., issuance of farm definition under part 1, subparts H and J and concomitant development of categories of activities done on farm other than "harvest") (proposed § 110.2(k)); and

- Clarify or otherwise revise a number of definitions of terms that currently are established in § 110.3 and add a number of new definitions as an aid to implementation of the proposed new requirements.

D. Revisions to Part 110 Subpart B--Current Good Manufacturing Practice

In general, the proposed rule would revise current part 110 by:

- Redesignating certain sections;
- Moving one requirement established in current subpart A, and several requirements established in current subparts C, E, and G, into proposed subpart B;
- Modernizing the language throughout (e.g., by replacing the word "shall" with the word "must");
- Either changing to requirements, or deleting, provisions containing recommendations;
- Clarifying that certain CGMP provisions requiring protection against contamination require protection against cross-contact of food as well; and
- Revising or clarifying certain requirements to use certain terms consistently throughout part 110 (e.g., consistently referring to the same four types of activities – manufacturing, processing, packing, and holding).

More specifically, the proposed rule would revise particular provisions of current part 110 as follows:

- Personnel: Proposed § 110.10 would revise current § 110.10 to require, rather than recommend, appropriate training and to require that records documenting required training be establish and maintained.

- Plant and grounds: Proposed § 110.20 would revise current § 110.20 to clarify that plant buildings and structures must be constructed, designed, ventilated, maintained, and controlled to reduce the potential for food cross-contact and to require that all outdoor bulk vessels (rather than only outdoor bulk fermentation vessels) be constructed and designed to permit the taking of proper precautions to protect food.

- Sanitary operations: Proposed § 110.35 would revise current § 110.35 to:

    - Clarify that all food-contact surfaces and all non-food contact surfaces of equipment and utensils used in the operation of a food plant must be cleaned, sanitized and stored in a manner and as frequently as necessary to protect against cross-contact of food and of food-contact surfaces;

    - Require, rather than recommend, appropriate storage of single-service articles and sanitized portable equipment with food-contact surfaces and utensils to protect food and food-contact surfaces from contamination and cross-contact; and

    - Require, rather than recommend, that non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against contamination of food and food-contact surfaces.

- Sanitary facilities and controls: Proposed § 110.37 would revise current § 110.37 to:

- Remove recommended practices for compliance from the current requirements for toilet facilities (§ 110.37(d)) and instead require that toilet facilities be kept clean and not be a potential source of contamination of food and food-contact surfaces; and
- Remove recommended practices for compliance from the current requirements for hand-washing facilities (§ 110.37(e)) and instead require that hand-washing facilities be designed to ensure that an employee's hands are not a source of contamination for food or food-contact surfaces.

- Equipment and utensils: Proposed § 110.40 would revise current § 110.40 to:
  - Require, rather than recommend, that all equipment be installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces;
  - Clarify that food-contact surfaces must be maintained to protect food from cross-contact; and
  - Require that certain instruments and controls be precise as well as accurate.
- Processes and controls: Proposed § 110.80 would revise current § 110.80 to:
  - Include language from the definition of "food," by referring to "raw materials and ingredients" rather than "raw materials and other ingredients";
  - Clarify that requirements directed to controls on processes, raw materials, work-in-progress, rework and finished food must protect against both contamination and cross-contact;
  - Require that work-in-process and rework be handled in a manner that protects against cross-contact, contamination, and growth of undesirable microorganisms;

- Require, rather than recommend, certain practices for protection of food from contamination (and cross-contact), including practices related to:
    - The inspection of containers and carriers of raw materials and ingredients; and
    - The receipt, inspection, segregation, and storage of raw materials, including in bulk form;
- Require that manufacturing steps provide adequate physical protection of food from contaminants that may drip, drain, or be drawn into food;
- Require, rather than recommend, certain practices regarding blanching;
- Require that filling, assembling, packaging, and other operations be performed in such a way that the food is protected against the growth of undesirable microorganisms as well as against contamination;
- Require, rather than recommend, that food-manufacturing areas and equipment used for manufacturing human food not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food;
- Delete an option to reexamine adulterated food, find that it is not adulterated, and incorporate it into other food (e.g., if a food tests positive for a contaminant in one test and negative in one or more additional tests);
- Delete requirements to comply with action levels and defect action levels; and
- Delete a number of recommended practices for compliance with current § 110.80, including those for compliance of raw materials with applicable regulations; compliance

with controls to minimize the potential for growth of microorganisms (e.g., specific temperature controls) during manufacturing, processing, packing and holding; and protecting against metal contamination.

- Warehousing and distribution: Proposed § 110.93 would revise current § 110.93 by:
  - Adding explicit requirements for food to be stored and transported under conditions that would protect against cross-contact and against radiological contamination; and
  - Specifying that these storage and transport requirements apply to all food, regardless of whether it is in finished form or as a raw material.
- Defect Action Levels: Proposed § 110.110 would revise current § 110.110 by clarifying restrictions on the mixing of food that contains defects with food that does not contain defects.
- List of required records: Proposed § 110.120 would add a new section that would list the records that would be required by provisions in subpart B and require that such records be established and maintained in accordance with general recordkeeping requirements that would be established in proposed subpart F. The listed records would be those that document the training of personnel, as would be required by proposed § 110.10(c)(3).

E. New Part 110 Subpart C--Hazard Analysis and Risk-Based Preventive Controls

Proposed subpart C would implement various provisions of section 103 of FSMA and would include the following requirements.

- Food safety plan: Proposed § 110.126 would require that the owner, operator, or agent in charge of a facility prepare a written food safety plan (or have the written food safety plan prepared on its behalf). Proposed § 110.126 also would require that the owner, operator, or

agent in charge of a facility implement the written food safety plan. The written food safety plan would include:

- A written hazard analysis as would be required by proposed § 110.130(a)(2);
- Written preventive controls as would be required by proposed § 110.135(b) (including a written recall plan that would be specified in proposed § 110.137 and a written supplier approval and verification program that would be specified in proposed § 110.152);
- Written monitoring procedures as would be required by proposed § 110.140(a);
- Written corrective action procedures as would be required by proposed § 110.145(a)(1); and
- Written verification procedures as would be required by proposed § 110.150(e)(1).

- Hazard analysis: Proposed § 110.130 would require that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur, including biological, chemical, physical, and radiological hazards.
- Preventive controls: Proposed § 110.135 would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls (including at critical control points, if any) to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented and that the food manufactured, processed, packed or

held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. The preventive controls would include, as appropriate:

- Parameters associated with the control of the hazard and the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur;
- Process controls;
- Food allergen controls;
- Sanitation controls;
- A recall plan (which would be established in proposed § 110.137 for food for which there are hazards that are reasonably likely to occur);
- A supplier approval and verification program (which would be established in proposed § 110.152); and
- Any other necessary controls.

- Recall Plan: Proposed § 110.137 would require that the owner, operator, or agent in charge of a facility establish a written recall plan for food in which there is a hazard that is reasonably likely to occur.
- Monitoring: Proposed § 110.140 would establish requirements for monitoring of the preventive controls to provide assurance that they are consistently performed, including requirements to establish and implement written monitoring procedures and establish and maintain records documenting the implementation of the monitoring procedures.
- Corrective actions: Proposed § 110.145 would establish requirements for corrective actions, including requirements to establish and implement written corrective action

procedures that would be used if preventive controls are not properly implemented, requirements to take corrective actions in the event of an unanticipated problem, and requirements for corrective actions related to the results of environmental monitoring.

- Verification: Proposed § 110.150 would establish requirements for verification activities, including:
    - Validation that the preventive controls identified and implemented in accordance with proposed § 110.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so;
    - Verification of monitoring and corrective actions;
    - Verification that the preventive controls are consistently performed and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, including:
        - Review of complaints to determine whether a complaint relates to the effectiveness of the food safety plan;
        - Calibration of instruments;
        - Performance of scientifically valid finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur;
        - Performance of environmental monitoring for a microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur; and
        - Review of certain records within specified timeframes;

- Written procedures for finished product testing and environmental monitoring;
- Reanalysis of the food safety plan at least once every three years and more often when circumstances warrant; and
- Documentation of verification activities.

- Supplier approval and verification program: Proposed § 110.152 would require that the owner, operator, or agent in charge of a receiving facility establish and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur and for which the receiving facility does not have a preventive control to significantly minimize or prevent the hazard. The program must include:
  - A written list of approved suppliers;
  - A written determination of which designated food safety regulation(s), if any, the supplier is subject to;
  - Verification activities, including, as appropriate, audits and other activities such as periodic sampling and testing.
- Requirements applicable to the qualified individual: Proposed § 110.155 would establish qualification requirements for a "qualified individual," who would be required to prepare the food safety plan, validate preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the reanalysis of a food safety plan.
- List of records required for subpart C: Proposed § 110.175 would list the records that would be required by proposed provisions in subpart C and require that such records be

established and maintained in accordance with general recordkeeping requirements that would be established in proposed subpart F. The listed records would include:

- The written food safety plan;
- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification;
- Records that document the supplier approval and verification program; and
- Records that document applicable training for the qualified individual.

F. New Part 110 Subpart D--Modified Requirements

Proposed subpart D would implement certain provisions in sections 418(l) and (m) of the FD&C Act for modified requirements with respect to:

- Qualified facilities: Proposed § 110.201 would implement the modified requirements specified in section 418(l) of the FD&C Act for facilities that satisfy the statutory criteria for a "qualified facility," including:
  - Submission to FDA of documentation that the facility is a qualified facility; and
  - Either:
    - Submission to FDA of documentation demonstrating that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

- Submission to FDA of documentation that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.
- A qualified facility that does not submit documentation must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed.
- A qualified facility would be required to maintain those records relied upon to support the documentation required.

- Facilities solely engaged in the storage of packaged food that is not exposed to the environment: Proposed § 110.206 would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment conduct certain activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance, including:
  - Establishing and implementing temperature controls
  - Monitoring the temperature controls;
  - Taking appropriate corrective actions when there is a problem with temperature controls;
  - Verifying that temperature controls are consistently implemented; and
  - Establishing and maintaining:
    - Records that document the monitoring of temperature controls;
    - Records of corrective actions taken when there is a problem with the control of temperature; and

- Records documenting verification activities.

G. New Part 110 Subpart E--Withdrawal of an Exemption From a Qualified Facility

Proposed subpart E would establish the conditions under which an exemption granted to a "qualified facility" in proposed § 110.2(a) could be withdrawn, and the procedures that would be followed to withdraw such an exemption.

H. New Subpart F--Requirements Applying to Records That Must Be Established and Maintained

Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of part 110, including:

- General requirements: Proposed § 110.305 would establish that records:
  - May be kept as original records, true copies, or electronic records;
  - Must contain the actual values and observations obtained during monitoring, be created concurrently with performance of the activity documented, and be as detailed as necessary to provide history of work performed; and
  - Must be accurate, indelible, and legible and include:
    - The name and location of the plant or facility;
    - The date and time of the activity documented and the signature or initials of the person performing the activity; and
    - Where appropriate, the identity of the product and the production code, if any.
- Additional requirements specific to the food safety plan: Proposed § 110.310 would require that the food safety plan be signed and dated by the owner, operator, or agent in charge of the facility, upon initial completion and upon any modification.

- Requirements for record retention: Proposed § 110.315 would:
    - Require that records be retained for two years after the date they were prepared, or for two years after their use is discontinued, depending on the nature of the record and
    - Provide that records may be kept offsite, provided that they can be made available for official review within 24 hours of request, and except that the food safety plan would be required to remain onsite.
- Requirements for official review of records by FDA: Proposed § 110.320 would require that all required records be made promptly available to a duly authorized representative of FDA upon oral or written request; and
- Public disclosure: Proposed § 110.325 would inform persons subject to part 110 that required records are subject to the disclosure requirements under part 20.

VII. Compliance Dates

Section 103(i)(1) of FSMA, General Rule, provides that "[t]he amendments made by this section shall take effect 18 months after the date of enactment" (i.e., by July 4, 2012). Section 103(i)(2) of FSMA, Flexibility for Small Businesses, provides that "[n]otwithstanding paragraph (1)," the amendments made by this section "shall apply" to a small business and very small business beginning on the dates that are 6 months and 18 months, respectively, "after the effective date" of FDA's final regulation.

FDA is implementing the amendments made by section 103 to the FD&C Act through this rulemaking (except as relates to animal food and intentional contamination). FDA does not anticipate that a final regulation will be published sufficiently in advance of July 4, 2012, to provide adequate time for businesses to comply by that date. FDA tentatively concludes that it is

appropriate to begin enforcement of section 418 only after providing a sufficient time period following publication of the final regulation for facilities to come into compliance. The final regulation will contain provisions that affect which facilities are subject to section 418 and which provisions apply to particular facilities. Without these provisions of the regulation in effect, facilities would be uncertain as to the applicability of certain requirements to them. Further, FDA tentatively concludes that compliance with section 418 will be facilitated greatly by the detail and explanation that will be provided by the final regulation.

As discussed in section XVII (Analysis of Economic Impacts), the current practices of many businesses are sufficient to satisfy some of the proposed requirements. However, the majority of businesses will need to make at least some changes if the proposed regulations are adopted. FDA recognizes that it takes time to change existing CGMP programs and to implement a system of preventive controls. The proposed regulation would require, among other things, performance of a hazard analysis, development of preventive controls, and training.

FDA is proposing that the final rule would be effective 1 year after publication in the Federal Register, and businesses would be required to comply with the rule on the effective date. However, we recognize that small and very small businesses may need more time to comply with the requirements. FDA believes that it is reasonable to allow for 6 months for small businesses and 18 months for very small businesses to come into compliance after the effective date of the final rule. FDA intends to work closely with the food industry, extension and education organizations, and state partners to develop the tools and training programs needed to facilitate implementation of this rule.

VIII. Section 103(c) of FSMA: On-Farm Activities

A. Section 103(c) of FSMA

Section 103(c)(1)(A) of FSMA requires the Secretary to "publish a notice of proposed rulemaking in the Federal Register to promulgate regulations with respect to-- (i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 350d), as amended by [FSMA]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415." Section 103(c)(1)(B) of FSMA stipulates that such rulemaking "shall enhance the implementation of such section 415 and clarify the activities that are included as part of the definition of the term "facility" under such section." Accordingly, in this document we are proposing to clarify the treatment of activities that are included as part of the definition of the term "facility" in section 415 of the FD&C Act in order to enhance the implementation of section 415. By doing so, we also clarify the coverage of section 418 of the FD&C Act, because section 418 applies to domestic and foreign facilities that are required to register under section 415 (see section 418(o)(2)) except where exemptions from section 418 apply.

Section 103(c)(1)(C) of FSMA directs the Secretary to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover "(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under

common ownership." In section VIII.G of this document we describe the risk evaluation we performed to satisfy this requirement.

Section 103(c)(1)(D)(i) of FSMA requires that, as part of the section 103(c) rulemaking, "the Secretary shall consider the results of the science-based risk analysis… and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by [section 103 of FSMA]) including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201 [of FSMA]), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk." Section 103(c)(1)(D)(ii) of FSMA provides that the exemptions or modifications described in section 103(c)(1)(D)(i) "shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by [FSMA], if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act[.]" In section VIII.H of this document we set forth our tentative conclusions regarding combinations of on-farm manufacturing, processing, packing, and holding activities and foods determined to be low risk, considering the results of the science-based risk evaluation; and in section X.B.6 of this document we propose to exempt such combinations of activities and foods from the requirements of section 418 of the FD&C Act when performed on farms that are small or very small businesses as defined in section X.C.4 of this document. In section VIII.H of this document, we

discuss a proposed approach to using the results of the risk evaluation for the purposes of section 421 of the FD&C Act.

B. The Current Legal Framework

Section 415 of the FD&C Act directs the Secretary to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. Our regulations implementing section 415 are established in part 1 (21 CFR part 1), subpart H (Registration of Food Facilities). We have issued guidance to assist food facilities in complying with part 1, subpart H (hereinafter "Food Facility Registration Guidance"). (Ref. Guidance for Industry: Questions and Answers Regarding Registration of Food Facilities (Edition 4)).

The legal and regulatory framework provided in sections 415 and 418 of the FD&C Act, our regulations in part 1, subpart H, and the Food Facility Registration Guidance is relevant to the FSMA section 103(c) rulemaking and the FD&C Act section 418(n) rulemaking that are the subjects of this document. That framework determines which establishments and activities are subject to the requirements of section 418 of the FD&C Act. We describe key aspects of the current framework below.

- Under § 1.227(b)(2), for the purposes of section 415 of the FD&C Act, a facility is, in relevant part, any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States.

- Under § 1.225, the owner, operator, or agent in charge of either a domestic or foreign facility must register in accordance with part 1, subpart H if the facility is engaged in the

manufacturing/processing, packing, or holding of food for consumption in the United States, unless the facility qualifies for one of the exemptions in § 1.226.

- Under § 1.226(b), farms are not subject to the registration requirement in § 1.225.
- Under § 1.227(b)(3), farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.
- Under § 1.227(b)(5), holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
- Under § 1.227(b)(6), manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.
- Under § 1.227(b)(8), packaging (when used as a verb) means placing food into a container that directly contacts food and that the consumer receives.
- Under § 1.227(b)(9), packing means placing food into a container other than packaging the food.

- Under section 418(o)(2) of the FD&C Act, a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act is subject to the requirements of section 418.

Together, this framework establishes that a business qualifies as a "farm" that is exempt from the section 415 registration requirement if it satisfies the definition of "farm" in § 1.227(b)(3), including the activities performed, where the activities take place, where the food used in the activities comes from, and where the food is consumed:

- A farm is devoted to the growing and harvesting of crops. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.
- A farm can pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership.
- A farm can manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

In addition, because farms are excluded from FDA's authority to establish recordkeeping requirements under section 414(b) of the FD&C Act, FDA established the same definitions of the terms facility, farm, holding, manufacturing/processing, packaging, and packing in the regulations implementing section 414 at part 1, subpart J, § 1.328.

C. Why This Rulemaking Is Needed

Farms are establishments that conduct activities described in the farm definition in §§ 1.227(b)(3) and 1.328 and do not conduct other activities that would trigger the requirement to register as a food facility under section 415 of the FD&C Act. Because farms are not required to register under section 415, they are not subject to section 418 of the FD&C Act because they do

not satisfy the definition of "facility" in section 418(o)(2) ("a domestic or foreign facility that is required to register under section 415").

Farms are subject to many provisions of the FD&C Act and FDA's authorities thereunder, such as FDA's inspection authority under section 704 and the general adulteration provisions for food in section 402. FDA has long recognized that regulation of farms should be sensitive to the agricultural setting. As early as 1969, FDA exempted establishments "engaged solely in the harvesting, storage, or distribution" of raw agricultural commodities from certain regulatory requirements. See 34 FR 6977 at 6980; April 26, 1969. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188) ("BT Act"), provided FDA with the authority to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA, and to issue regulations regarding the establishment and maintenance of certain records (codified as sections 415 and 414 of the FD&C Act, respectively). Sections 415 and 414 explicitly exclude "farms," but do not define that term. In notice and comment rulemaking implementing these provisions, FDA developed a definition of the term "farm." FDA first proposed to define "farm" as:

> a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term "farm" includes: (i) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and (ii) Facilities that manufacture/process food, provided that all food

used in such activities is consumed on that farm or another farm under the same ownership.

(68 FR 5377 at 5418; February 3, 2003). FDA received comments on this proposed definition stating that it was too narrow because it would not include farms that engage in activities traditionally performed on farms for nearly all commodities, such as washing, trimming outer leaves, and cooling. See 68 FR 58893 at 58905; October 10, 2003. Accordingly, to reflect Congress's intent to exempt establishments engaging in activities farms traditionally perform from the section 415 registration requirement, FDA revised the first part of the farm definition in § 1.227(b)(3) to state that a farm is a facility in one general location that is devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both, and that washing, trimming outer leaves, and cooling of food are considered part of harvesting (Id.) (emphasis added). FDA also established the same definition of "farm" at § 1.328 for the purpose of exempting farms from its regulation implementing the section 414 recordkeeping requirement. See 69 FR 71561 at 71652; December 9, 2004. In post-rulemaking guidances implementing the section 415 and 414 requirements, FDA further interpreted the farm definition with the goal of doing so in a manner recognizing the traditional activities of establishments commonly recognized to be farms. See Food Facility Registration Guidance; and Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4), September 2006 (hereinafter "Recordkeeping Guidance"). (Ref. Food Facility Registration Guidance; and Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4)).

"Farm mixed-type facilities" are establishments that grow and harvest crops or raise animals and may conduct other activities within the farm definition, but that also conduct

activities that trigger the registration requirement under section 415 of the FD&C Act. FDA proposes to codify this term and its definition in the proposed revisions to part 1 set forth in section VIII.E of this document. Section 418 of the FD&C Act does not explicitly address whether farm mixed-type facilities are subject to section 418 with respect to all of their activities or only with respect to the activities they conduct that trigger the section 415 registration requirement. Considering the text of section 103 of FSMA and the statute as a whole, FDA tentatively concludes that farm mixed-type facilities are subject to section 418 only with respect to their activities that trigger the section 415 registration requirement, and not with respect to activities they conduct that are within the farm definition. Put another way, FDA proposes to apply section 418 only to the "non-farm" portion of these establishments' activities, and not to the "farm" portion of their activities.

Because section 418(o)(2) of the FD&C Act defines the term "facility" for the purposes of section 418 to mean only those facilities required to register under section 415 of the FD&C Act, FDA tentatively concludes that Congress intended the exemptions from the registration requirement set forth in section 415 and FDA's implementing regulations in part 1, subpart H (including the farm exemption in § 1.226(b)) to be meaningful for the purposes of defining section 418's applicability. Section 418(a) requires the owner, operator, or agent in charge of a facility that is required to register under section 415 to "evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility" and to take other steps discussed more fully elsewhere in this document including identifying and implementing preventive controls, monitoring preventive controls, and maintaining records. The use of the phrase "food manufactured, processed, packed, or held by the facility" in section 418(a) parallels the language in section 415(a)(1) providing that "[t]he Secretary shall by regulation require that any facility

engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary." FDA tentatively concludes that only a facility's manufacturing, processing, packing, or holding activities that trigger registration under our regulations in part 1, subpart H should be considered to be manufacturing, processing, packing, or holding of food by a facility for the purposes of section 418. Put another way, FDA tentatively concludes that mixed-type facilities are only subject to section 418 with respect to their manufacturing, processing, packing, or holding of food that actually triggers the section 415 registration requirement, and not with respect to all of their manufacturing, processing, packing, or holding of food. To conclude otherwise would mean that, for example, the farm exemption from registration would be rendered irrelevant to the coverage of section 418, except for activities on farms that will be subject to requirements under section 419 of the FD&C Act (as a result of the exemption from section 418 for such activities in section 418(k)). Under such an interpretation many "farm" portions of farm mixed-type facilities would be subject to section 418, including, for example, dairies, egg farms, farms raising livestock for food, and farms growing produce that is not subject to requirements under section 419. However, section 103(c)(1)(D) of FSMA, which directs FDA to consider exempting or modifying the requirements of section 418 for activities outside the farm exemption conducted by farm mixed-type facilities, seems to mean that while Congress intended the "non-farm" portions of farm mixed-type facilities to be subject to section 418 (including under modified requirements) if FDA concluded that it was appropriate to do so after conducting a science-based risk evaluation on that topic, Congress did not intend the "farm" portion of such facilities to be covered by section 418.

Therefore, unless an exemption from section 418 of the FD&C Act applies, FDA tentatively concludes that facilities required to register under section 415 of the FD&C Act are

subject to section 418 with respect to all activities they conduct that trigger the section 415 registration requirement, but not with respect to activities that would not trigger the registration requirement (such as activities within the farm definition set forth in § 1.227(b)(3)). Thus, it is particularly important to clarify the classification of various activities included in the "facility" definition in section 415 as manufacturing, processing, packing, or holding -- and in doing so to clarify the scope of the farm definition in § 1.227(b)(3) -- to make clear the extent to which farm mixed-type facilities must comply with section 418.

At the time FDA developed the farm definition and its interpretations of that definition, the practical impact of an activity's classification as inside or outside that definition was limited to the potential to trigger the registration and recordkeeping requirements under sections 415 and 414 of the FD&C Act. With the advent of FSMA, the scope of the farm definition has taken on more importance because, for example and as discussed in this section, activities within the farm definition are not subject to section 418 of the FD&C Act, but activities outside the farm definition are subject to section 418. Therefore, it is important that FDA clarify and adjust the scope of the farm definition as needed to clearly and accurately establish which activities are subject to section 418. Accordingly, FDA is now proposing a process by which to classify activities in order to establish a coherent approach that will more accurately reflect the scope of activities traditionally conducted by farms and allow for more certainty among industry with regard to how their activities will be regulated. In sections VIII.D, VIII.E, and VIII.F of this document, we address certain activities and their classifications on farms, on farm mixed-type facilities, and off-farm for the purposes of section 415, and propose revisions to the regulations in part 1, subpart H, implementing section 415, to enhance and clarify their application. At the same time, we also propose to make the same revisions to the regulations in part 1, subpart J,

implementing section 414, because section 414 also excludes farms and FDA uses the same approach to define "farm" and related terms in subpart J (at § 1.328) as it does in subpart H (at § 1.227).

D. Raw Agricultural Commodities, Processed Foods, and Farms

To clarify the scope of the farm definition, FDA considered how the activities of farms relate to the concept of a raw agricultural commodity ("RAC"). The FD&C Act defines "raw agricultural commodity" and "processed food" in relation to each other, and identifies certain activities that transform a RAC into a processed food and others that do not. Section 201(r) of the FD&C Act (21 U.S.C. 321(r)) defines "raw agricultural commodity" to mean "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." Section 201(gg) of the FD&C Act (21 U.S.C. 321(gg)) defines "processed food" to mean "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling." In addition, section 201(q)(1)(B)(i)(II) of the FD&C Act, defining pesticide chemicals, contains the following language regarding activities that do not transform a RAC into a processed food: "the treatment [with pesticide chemicals] is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner)."

The status of a food as a RAC or processed food is relevant for many different purposes under the FD&C Act. For example, under section 403(q)(4) of the FD&C Act (21 U.S.C. 343(q)(4)), FDA has established a voluntary nutrition labeling program for RACs that is not applicable to processed foods. Under 403(w) of the FD&C Act (21 U.S.C. 343(w)), labeling

requirements related to major food allergens do not apply to RACs. Under sections 201(q), 403(k), 403(l), and 408 of the FD&C Act (21 U.S.C. 321(q), 343(k), 343(l), and 346a), the status of a food as a RAC has an impact on the manner in which pesticide chemicals and their residues are regulated. FSMA created more provisions in the FD&C Act and elsewhere that take status as a RAC or processed food into account, including section 417(f) of the FD&C Act (21 U.S.C. 350f(f)), establishing notification requirements for reportable foods that do not apply to fruits and vegetables that are RACs; section 418(m) of the FD&C Act, which authorizes FDA to exempt or modify the requirements for compliance under section 418 with respect to facilities that are solely engaged in the storage of RACs other than fruits and vegetables intended for further distribution or processing; section 419(a)(1)(A) of the FD&C Act (21 U.S.C. 350h(a)(1)(A)), which authorizes FDA to establish minimum science-based standards applicable to certain fruits and vegetables that are RACs; and section 204(d)(6)(D) of FSMA (21 U.S.C. 2223(d)(6)(D)), which contains special provisions for commingled RACs applicable to FDA's authority under section 204 of FSMA to establish additional recordkeeping requirements for high risk foods. FDA has also established by regulation an exemption from the current CGMP requirements applicable to establishments engaged solely in the harvesting, storage, or distribution of one or more RACs (§110.19 (21 CFR 110.19)). This exemption is discussed in detail in section X.B.9 of this document.

Because the status of a food as a RAC or processed food is of great importance in defining the jurisdiction of FDA and EPA over antimicrobial substances, FDA and EPA have developed guidance regarding whether or not various activities transform RACs into processed foods. FDA and EPA jointly issued a legal and policy interpretation of the agencies' jurisdiction under the FD&C Act over antimicrobial substances used in or on food (hereinafter "1998 Joint

EPA/FDA Policy Interpretation") (63 FR 54541; October 9, 1998). In 1999, FDA issued guidance addressing several of the issues discussed in the 1998 Joint EPA/FDA Policy Interpretation. See Guidance for Industry: Antimicrobial Food Additives, July 1999 (hereinafter "Antimicrobial Guidance"). (Ref. Guidance for Industry: Antimicrobial Food Additives, July 1999). As discussed in these documents, FDA and EPA agreed that the following "post-harvest" activities do not transform a RAC into processed food within the meaning of that term in section 201(gg) of the FD&C Act: "washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems, and husks" (63 FR 54541 at 54541; Antimicrobial Guidance, section 7). FDA and EPA also agreed that the following activities do transform a RAC into a processed food: "canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting, or peeling" (63 FR 54541 at 54541; Antimicrobial Guidance, section 7). In addition, these documents set forth the conclusion of EPA and FDA that drying RACs causes them to become processed foods, unless the drying is for the purpose of facilitating storage or transportation of the commodity (63 FR 54541 at 54541-2; Antimicrobial Guidance, section 7). This conclusion was based on EPA's policy statement on the status of dried commodities as RACs (61 FR 2386; January 25, 1996). FDA and EPA also identified slaughter of animals for food and activities done to carcasses post-slaughter as "processing" for the purposes of the processed food definition (63 FR 54541 at 54542; Antimicrobial Guidance, section 7). Table 2 summarizes activities that cause food RACs to become processed foods and activities that do not change the status of a food RAC, as provided in the FD&C Act and addressed in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance.

Table 2. –The Effect of activities on RACs that are foods	
Activity changes a RAC into a processed food	Activity does not change the status of a RAC

Canning	Application of pesticides (including by washing, waxing, fumigation, or packing)
Chopping	Coloring
Cooking	Drying for the purpose of storage or transportation
Cutting	Hydro-cooling
Drying that creates a distinct commodity	Otherwise treating fruits in their unpeeled natural form
Freezing	Packing
Grinding	Refrigeration
Homogenization	Removal of leaves, stems, and husks
Irradiation	Shelling of nuts
Milling	Washing
Pasteurization	Waxing
Peeling	Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant
Slaughtering animals for food and activities done to carcasses post-slaughter, including skinning, eviscerating, and quartering	
Slicing	
Activities that alter the general state of the commodity	

This summary demonstrates that the activities that transform a RAC into a processed food (and are sometimes therefore referred to as "processing" in the context of a food's status as a RAC or processed food) are not coextensive with the definition of "manufacturing/processing" for the purposes of food facility registration and recordkeeping under §§ 1.227(b)(6) and 1.328. "Manufacturing/processing" in part 1 includes most food-handling activities because it is satisfied by any degree of "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food." In contrast, transforming a RAC into a processed food seems to require meeting a threshold of altering the general state of the commodity (63 FR 54541 at 54541; Antimicrobial Guidance, section 7) sometimes referred to as transformation of the RAC into a new or distinct commodity (61 FR 2386 at 2388). This means that a given activity may be manufacturing/processing under the current definition in §§ 1.227(b)(6) and 1.328 without transforming a RAC into a processed food. Examples of such activities include coloring, washing, and waxing.

The term "raw agricultural commodity" and similar terms also appear in other Federal statutes. While these statutes are not implemented or enforced by FDA and do not directly impact the interpretation of the definitions in sections 201(r) and 201(gg) of the FD&C Act, they do provide some suggestions about what "raw agricultural commodity" and related concepts can mean in various circumstances. For example, the Secretary of Transportation may prescribe commercial motor vehicle safety standards under 49 U.S.C. 31136, but the Motor Carrier Safety Improvement Act of 1999 (Pub. L. 106-159, title II, Sec. 229, Dec. 9, 1999), as added and amended by the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (Pub. L. 109-59, title IV, Sec. 4115, 4130, Aug. 10, 2005), provided an exemption from maximum driving or on-duty times for drivers transporting "agricultural commodities" or farm supplies within specific areas during planting and harvest periods. In that circumstance, "agricultural commodity" is defined as "any agricultural commodity, non-processed food, feed, fiber, or livestock… and insects" (49 U.S.C. 31136 note). Another example is 19 U.S.C. 1677(4)(E), which provides for certain circumstances in which producers or growers of raw agricultural products may be considered part of the industry producing processed foods made from the raw agricultural product for the purposes of customs duties and tariffs related to such processed foods. In that circumstance, "raw agricultural product" is defined as "any farm or fishery product" (19 U.S.C. 1677(4)(E)). These statutes are informative in that they suggest that the "raw agricultural commodity" concept describes and signifies the products of farms in their natural states, or, in other words, that which a farm exists to produce on a basic level. These statutes, relevant sections of the FD&C Act, and past interpretations of the RAC concept as set forth in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance lead FDA to tentatively conclude that RACs are the essential products of farms. FDA proposes to

incorporate this concept into its rules for classifying activities related to foods on farms and farm mixed-type facilities in order to more accurately reflect which activities of these establishments fall within the farm definition.

FDA's current regulations in part 1 and related guidances already demonstrate that some activities may be classified differently on farms and off farms. For example, "washing" is an example of manufacturing/processing under the definition of that term in §§ 1.227(b)(6) and 1.328, but "washing" produce is identified as part of harvesting under the farm definition in §§ 1.227(b)(3) and 1.328, so washing on farms is harvesting, not manufacturing/processing. To date, FDA has not articulated an organizing principle explaining these differences. We are now tentatively articulating the following principles to explain and clarify the method used to classify activities on and off-farm in the regulations in part 1 and related guidances.

As discussed above, the basic purpose of farms is to produce RACs, and RACs are the essential products of farms. Accordingly, activities involving RACs that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of "farm" in §§ 1.227(b)(3) and 1.328 in order to appropriately implement Congress's intent that FDA exempt "farms" from the registration and recordkeeping authorities provided in sections 415(b)(1) and 414(b) of the FD&C Act. This is the case even if the same activities off farm would be considered to be manufacturing/processing under the definition of that term in §§ 1.227(b)(6) and 1.328 because those activities involve "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food." This special classification of on-farm activities, however, should only apply to RACs because only RACs, not processed foods, are the essential products of farms. Farms that choose

to transform their RACs into processed foods should be considered to have chosen to expand their business beyond the traditional business of a farm, thereby opting to become farm mixed-type facilities subject to the section 415 registration requirement, section 414 recordkeeping requirements, and other requirements linked to the section 415 registration requirement by FSMA (such as compliance with section 418 of the FD&C Act). Similarly, this special classification of on-farm activities should only apply to RACs grown or raised on the farm itself or on other farms under the same ownership because the essential purpose of a farm is to produce its own RACs, not to handle RACs grown on unrelated farms for distribution into commerce. (For the purposes of this discussion, FDA will refer to RACs grown or raised on a farm or another farm under the same ownership as a farm's "own RACs," in contrast to RACs grown on a farm under different ownership, which FDA refers to as "others' RACs.") Notably, when FDA first undertook to define "farm," it received a comment implicitly recognizing this, urging the agency to define farms to include typical post-harvesting operations, <u>if all food is grown on the farm</u> (emphasis added) (68 FR 5377 at 5379; February 3, 2003). Therefore, activities farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce. In general, when a farm opts to perform activities outside the farm definition, becoming a farm mixed-type facility, the establishment's activities that are within the farm definition should be classified as manufacturing/processing, packing, or holding in the same way as for farms that are not mixed-type facilities, but the activities that are outside the farm definition should be classified according to the rules applied to off-farm food establishments. Finally, packing, holding, or manufacturing food-- RACs or processed foods, from any source-- for consumption on the farm should remain within the farm definition because

otherwise farms could not feed people and animals on the farm without being required to register under section 415 of the FD&C Act.

E. Proposed Changes to Part 1, Subparts H, I, and J

FDA proposes to revise §§ 1.227 and 1.328 to reflect the principles articulated above and to clarify how the definitions in those regulations apply to specific activities depending on the location in which the activity is performed, the food on which the activity is performed, and the source of the food. In addition, FDA is proposing to redesignate all definitions in current § 1.227 as proposed § 1.227 and eliminate paragraph designations (such as (a), (b), (1), (2), and (3)). Paragraph designations are not necessary when definitions are presented in alphabetical order. As a technical amendment, FDA is proposing to delete the definition of "Act" in current § 1.227 and revise all definitions in current § 1.227 to refer to "the Federal Food, Drug, and Cosmetic Act" rather than "the act" for clarity and for consistency with our current approach to citing the FD&C Act in new regulations. As a conforming change, FDA is proposing to revise current § 1.241 to refer to "the Federal Food, Drug, and Cosmetic Act" rather than "the act." New definitions that FDA proposes to add to §§ 1.227 and 1.328 would be added in alphabetical order. As a conforming change, FDA proposes to revise § 1.276(b)(9) in part 1, subpart I, to cross-reference § 1.227 (without any paragraph designations) rather than to cross-reference § 1.227(b)(6).

FDA proposes to add a new definition of the term "Mixed-type facility" to §§ 1.227 and 1.328. Mixed-type facility would mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. This term and its definition were initially developed in the preamble to the proposed rule on food facility registration (68 FR 5377 at 5381) and in the

interim final rule on food facility registration (68 FR 58893, at 58906-7, 58914, 58934-8) and would be codified in our proposed revisions to §§ 1.227 and 1.328 with the same meaning. The proposed definition would also provide, as an example of such a facility, a definition of a "farm mixed-type facility." A "farm mixed-type facility" would be defined as an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. FDA tentatively concludes that it is necessary to define this term to satisfy FSMA section 103(c)'s directives to enhance the implementation of section 415 of the FD&C Act, clarify the activities that are included as part of the term facility under that section, and to conduct this rulemaking addressing activities that constitute on-farm packing or holding of food not grown, raised, or consumed on such farm or another farm under the same ownership and activities that constitute on-farm manufacturing or processing of food not consumed on that farm or another farm under common ownership. Because the specific classes of activities mentioned in FSMA section 103(c) are, by definition, on-farm activities that do not fall within the farm definition, Congress has explicitly directed FDA to engage in rulemaking addressing establishments that conduct activities on farms that are outside the farm definition. Accordingly, FDA proposes to define the term "farm mixed-type facilities" to refer to these establishments.

FDA proposes to add a new definition of the term "Harvesting" to §§ 1.227 and 1.328. Harvesting would apply to farms and farm mixed-type facilities and be defined as activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting would be limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting would not include

activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership would be listed as examples of harvesting. This proposed definition would include the same examples of "harvesting" that were previously part of the farm definition (washing, trimming of outer leaves, and cooling) and would add other examples to help clarify the scope of the definition of harvesting. FDA also proposes to make clear that these activities are "harvesting" when conducted on any of a farm's own RACs, not just "produce." For example, unpasteurized shell eggs are RACs, and washing such eggs on the farm on which the eggs were produced would be part of harvesting the eggs. "Harvesting" is a category of activities that is only applicable to farms and farm mixed-type facilities. Activities that would be "harvesting" when performed on a farm on the farm's own RACs would be classified differently under other circumstances, such as at a processing facility that is not on a farm, or when performed by a farm on others' RACs. For example, at an off-farm processing facility that pasteurizes eggs, washing the unpasteurized shell eggs after they are received would not be "harvesting" because it is not being performed on the farm that produced the eggs (or another farm under the same ownership). Instead, washing eggs at the off-farm processing facility would be "manufacturing," because it involves preparing, treating, modifying or manipulating food.

FDA proposes to revise the definition of "Farm" in current §§ 1.227(b)(3) and § 1.328 to delete examples of harvesting that currently appear in that definition. FDA is proposing to include these and other examples in a new, separate definition of harvesting, described above. This is a non-substantive change.

FDA proposes to revise the definition of "Holding" in current §§ 1.227(b)(5) and 1.328 by adding to the existing definition an expanded definition applicable to farms and farm mixed-type facilities. The proposed revision would state that, for farms and farm mixed-type facilities, holding would also include activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just storage of food would be classified as "holding" when a farm or farm mixed-type facility performs those activities on its own RACs. For example, fumigating or otherwise treating a farm's own RACs against pests for the purpose of safe and effective storage would be "holding" under this proposed definition. However, fumigating or otherwise treating food against pests under other circumstances (such as off-farm or by a farm handling others' RACs) would not be "holding" food because it is not storage of food, which would remain the definition of holding applicable to most circumstances.

FDA proposes to revise the definition of "Manufacturing/processing" in current §§ 1.227(b)(6) and 1.328 by adding to the existing definition a criterion applicable to farms and farm mixed-type facilities. The proposed revision would state that, for farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. Under this proposal, expanded definitions of "packing" and "holding," and the extra category "harvesting" would apply to activities performed by farms and farm mixed-type facilities on their own RACs. These expanded and extra categories would not apply off-farm or to foods other than farms' or farm mixed-type facilities' own RACs. Thus, some activities that would otherwise be manufacturing/processing would instead be defined as

packing, holding, or harvesting by virtue of being performed by a farm or farm mixed-type facility on its own RACs. Accordingly, these activities would not be manufacturing/processing because they would already be classified into the expanded definitions of packing or holding, or into the extra category of harvesting.

FDA proposes to revise the definition of "Packing" in current §§ 1.227(b)(9) and 1.328 by adding to the existing definition an expanded definition applicable to farms and farm mixed-type facilities. The proposed revision would state that, for farms and farm mixed-type facilities, packing would also include activities traditionally performed by farms to prepare RACs grown or raised on the same farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just placing food into a container other than packaging would be classified as "packing" when a farm or farm mixed-type facility performs those activities on its own RACs. For example, packaging (placing food into a container that directly contacts the food and that the consumer receives) a farm's own RACs would be "packing" under this definition because farms traditionally do this to provide greater protection for fragile RACs than would be possible if the RACs were placed in containers other than the consumer container, and this activity does not transform a RAC into a processed food. However, packaging food under other circumstances would not be "packing" food because packaging is explicitly excluded from the definition of packing applicable to most circumstances (placing food into a container other than packaging). Other examples of activities that could be packing when performed by a farm or farm mixed-type facility on its own RACs include packaging or packing a mix of RACs together (e.g., in a bag containing three different colored bell peppers, or a box of mixed produce for a community

sponsored agriculture program farm share); coating RACs with wax, oil, or resin coatings used for the purposes of storage or transport; placing stickers on RACs; labeling packages containing RACs; sorting, grading, or culling RACs; and drying RACs for the purpose of storage or transport.

F. Impact of Proposed Changes to Part 1, Subparts H and J

1. Rationale or Classification Changes That Do Not Affect Whether or Not an Activity Falls Within the Farm Definition

FDA has previously considered whether various activities fall within the farm definition or not, and has provided guidance on these issues in the rulemakings establishing the regulations in part 1, subparts H and J, and in the Food Facility Registration Guidance and the Recordkeeping Guidance. For most of the activities FDA has previously addressed in these discussions, applying the rules set forth in the proposed revisions to Part 1 would result in the same answers with respect to whether the activities are within the farm definition or not. Because we have not articulated these principles before, there may be some activities FDA previously discussed for which the rationale for their classifications, or their specific classifications (e.g., packing, holding, or harvesting) may be different under this proposal. Where an activity that FDA has previously considered to be within the farm definition would still be within the farm definition under this proposal, but for a different reason, we do not consider this to be a change and do not specifically discuss it in this section. Similarly, we do not discuss in this section situations in which an activity would be outside the farm definition and FDA has previously considered the activity to be outside the farm definition, but for a different reason. FDA anticipates making revisions to the guidance documents addressing these topics

after FDA issues a final rule on this topic to make clear how the revised definitions in part 1 would apply in these situations.

2. Application of Pesticides to a Farm or Farm Mixed-Type Facility's Own Raw Agricultural Commodities

The general term "treating" is part of the definition of manufacturing/processing in current §§ 1.227(b)(6) and 1.328, and the proposed revision to that definition. FDA addressed "treating against pests" on farms and farm mixed-type facilities in the preamble to the interim final rule on food facility registration (68 FR 58894 at 58905), the Food Facility Registration Guidance (Questions 2.5, 2.6, and 11.1) (Ref. Registration Q&A), and the preamble to the Establishment and Maintenance of Records final rule (69 FR 71562, 71587; December 9, 2004). In those documents, FDA concluded that treating crops against pests by applying pesticides prior to harvest is an integral part of growing crops and is therefore "growing" within the farm definition. FDA concluded that other applications of pesticides post-harvest are manufacturing/processing because such applications are directed at the food, and not at the entire plant. For one specific pesticide (chlorine) used in wash water, however, FDA concluded that farms using chlorinated water from public or other water supplies chlorinated for other purposes are washing; and farms adding their own chlorine to wash water at levels below 200 parts per million (ppm) total chlorine are washing; but farms adding their own chlorine to wash water levels above 200 ppm are manufacturing/processing because such levels constitute treating the crop against pests rather than washing.

Some but not all of these conclusions would change under the proposed revisions to part 1. Treatment of food crops against pests that occurs before harvest, while the crop is still in the growing area, would still be considered an inherent part of the growing process and their

classification would not be affected by the proposed revisions to part 1. Such treatments are and would remain within the farm definition.

Under the proposed revisions to part 1, FDA would consider some treatments of farm and farm mixed-type facilities' own RACs against pests to be holding: those treatments being for the purpose of safe or effective storage. An example of such activity is fumigating a farm's own raw nuts to prevent insect infestation and damage during the nuts' potentially long storage period. Such treatments would be within the farm definition under the proposed revisions to part 1. FDA is aware that such treatments are traditionally performed by farms and may be a practical necessity for the preservation of some crops during storage, and such treatments do not transform a RAC into a processed food. Thus, these treatments fit the proposed definition of "holding" applicable to farms and farm mixed-type facilities with respect to their own raw agricultural commodities.

Under the proposed revisions to part 1, FDA would consider other treatment of farm and farm mixed-type facilities' own RACs against pests to be harvesting: those treatments for the purpose of removing the crop from the growing area and preparing it for use as food. An example of such activity is washing a crop in water containing antimicrobial chemicals after removing the crop from the growing area. Generally, the antimicrobial chemicals are intended only to ensure the safety of the wash water, but if the antimicrobial chemicals were also intended to reduce the microbial load on the crop itself as a safety measure, such treatments would be within the farm definition under the proposed revisions to part 1. FDA is aware that such treatments are traditionally performed by farms and that they are part of preparing the crop for safe use as food, and such treatments do not transform a RAC into a processed food. Thus, these

treatments fit the proposed definition of "harvesting" applicable to farms and farm mixed-type facilities with respect to their own RACs.

Continuing to use the general term "treating" in the proposed definition of manufacturing/processing in §§ 1.227 and 1.328 is not in conflict with these conclusions. First, the general term "treating" refers broadly to treatments of any kind, and not specifically "treating against pests." Second, when considering farms and farm mixed-type facilities conducting operations on their own RACs under the proposed revisions to part 1, only activities that do not satisfy the expanded definitions of packing or holding, or the definition of harvest, would be considered under the manufacturing/processing definition. Thus, pesticide treatments of farms' own RACs that fall into the categories of holding, or harvesting, as discussed above, would be excluded from the proposed definition of manufacturing. Off-farm, such treatments would be considered to be manufacturing/processing, because the exclusion applicable to farms and farm mixed-type facilities operating on their own RACs would not apply.

3. Coating a Farm or Farm Mixed-Type Facility's Own Raw Agricultural Commodities for Storage or Transport (e.g., Wax, Oil, or Resin Coatings)

FDA has addressed "waxing" on farms and farm mixed-type facilities in the preamble to the interim final rule on Food Facility Registration (68 FR 58894 at 58912), and the preamble to the Establishment and Maintenance of Records final rule (69 FR 71561 at 71587). In those documents, FDA concluded that on-farm waxing was manufacturing/processing. In addition, FDA lists "waxing" as an example of a manufacturing/processing activity in the definition of that term in current §§ 1.227(b)(6) and 1.328, and in the proposed revision to that definition.

This conclusion would change for certain types of waxing under the proposed revisions to part 1. Coatings applied to a farm or farm mixed-type facility's own RACs for the purpose of

protecting them during storage or transport, and not to create a distinct commodity, would be within the expanded definition of packing. Examples of such coatings are waxes, oils, and resins applied to fresh produce such as cucumbers, apples, and avocados. Applying such coatings would be within the farm definition under the proposed revisions to part 1. FDA is aware that such treatments are traditionally performed by farms to prepare crops for storage or transport. These coatings do not transform a RAC into a processed food. Thus, these treatments fit the proposed definition of "packing" applicable to farms and farm mixed-type facilities with respect to their own RACs. By contrast, if a farm applies a coating to its own RACs that creates a distinct commodity (e.g., coating nuts in chocolate or coating apples in caramel), that activity would create a processed food, would not fit the expanded definition of packing and would be manufacturing/processing. Thus, unless such coatings were applied to a farm's own RACs for its own consumption, the act of applying the coating would be outside the farm definition.

Continuing to use "waxing" as an example in the proposed definition of manufacturing/processing in §§ 1.227 and 1.328 is not in conflict with these conclusions. As explained with respect to pesticide treatments, activities on farms and farm mixed-type facilities that are within the expanded definitions of packing and holding, or the definition of harvest, would be excluded from the proposed definition of manufacturing/processing. The existing definitions of manufacturing/processing and harvesting in §§ 1.227(b)(6) and 1.328 demonstrate that FDA has consistently cited some activities as examples of manufacturing/processing as a general matter, but classified them differently in specific situations based on relevant circumstances. Washing, trimming, and cooling are all examples of manufacturing/processing in current §§ 1.227(b)(6) and 1.328, but washing, trimming outer leaves of, and cooling produce are part of harvesting in the farm definition in current §§ 1.227(b)(3) and 1.328. Use of an activity

as an example of manufacturing/processing in current §§ 1.227(b)(6) and 1.328, or the proposed revision of that definition, does not represent a conclusion that the activity is always classified as manufacturing/processing under all circumstances. FDA expects that its proposed revisions to part 1 will clarify this.

4. Drying a Farm or Farm Mixed-Type Facility's Own Raw Agricultural Commodities to Create a Distinct Commodity

FDA has addressed drying on farms and farm mixed-type facilities in the Food Facility Registration Guidance (Q&A 2.19, February 2004) and the Recordkeeping Guidance (Q&A 4.2 and 4.5, September 2006). In those documents, FDA concluded that drying peppermint naturally during storage in a barn would not be manufacturing/processing; that drying hay naturally or artificially is an essential part of harvesting hay to prevent spontaneous combustion and is therefore not manufacturing/processing; and that drying alfalfa would be part of harvesting if it was an activity traditionally performed during the removing of the crop from the field through the safe storage of the crop.

Some but not all of these conclusions would change under the proposed revisions to part 1. As discussed in section VIII.D of this document, FDA tentatively concludes that the question of whether an activity transforms a RAC into a processed food should be part of defining what activities are within the farm definition, because RACs are essential products of farms and processed foods are not. Thus, activities that transform foods from RACs into processed foods would not be within the expanded definitions of packing or holding, or the definition of harvesting, that apply to farms and farm mixed type facilities conducting activities on their own RACs. Instead, anything that transforms a RAC into a processed food must be

manufacturing/processing, which is outside the farm definition unless it is done only for consumption on the farm.

In the Antimicrobial Guidance, FDA approved of and referenced the 1996 EPA interpretive ruling entitled "Pesticides; Status of Dried Commodities as Raw Agricultural Commodities" (61 FR 2386). As discussed briefly in section VIII.D of this document, in the 1998 EPA/FDA Joint Policy Interpretation and the Antimicrobial Guidance, FDA and EPA concluded that a RAC becomes a processed food when it is dried, unless the purpose of the drying is to facilitate transportation or storage of the commodity prior to processing. As a practical matter, this means that some RACs become processed food when they are dried, because the drying creates a distinct commodity from the RAC. An example of this kind of drying is drying grapes to create raisins; raisins are processed foods (61 FR 2386 at 2388). When the drying is for the purpose of storage or transport and does not create a distinct commodity, however, such as for grains, nuts, legumes, hays, other grasses, hops, rice, beans, and corn, the dried commodity remains a RAC (61 FR 2386 at 2388).

Accordingly, drying hay and alfalfa would be considered part of packing or holding under the proposed revisions to part 1, depending on how the drying is conducted (before storage or during storage, respectively), because these crops are traditionally dried by farms for the purpose of preparing for storage or transport (for packing) or for safe and effective storage (for holding), and drying these crops does not create a distinct commodity, so the dried commodity is still a RAC. In contrast, drying herbs such as peppermint would be considered to be manufacturing/processing under the proposed revisions to part 1, because drying an herb creates a distinct commodity and therefore a processed food, just as drying a fruit creates a distinct

commodity and therefore a processed food. Drying peppermint would not be within the farm definition unless it was done for consumption on the farm.

5. Off-Farm Packaging of Raw Agricultural Commodities

In current §§ 1.227(b)(8) and 1.328, and the proposed revision to those sections, "packaging" (when used as a verb) is defined as placing food into a container that directly contacts the food and that the consumer receives. Packaging is listed as an example of manufacturing/processing in current §§ 1.227(b)(6) and 1.328 and the proposed revision to that definition, as well as in § 1.226(a). "Packing," by contrast, is currently defined in §§ 1.227(b)(9) and 1.328 as placing food into a container other than packaging the food. FDA has addressed packaging on farms and farm mixed-type facilities, and off-farm, in the Food Facility Registration Guidance (Q&A 2.10 - 2.14, February 2004), the preamble to the Establishment and Maintenance of Records final rule (69 FR 71562 at 71587), and the Recordkeeping Guidance (Q&A 4.3, 28.9, 28.10, June 2006). In those documents, FDA concluded that placing RACs into consumer-ready containers (e.g., placing strawberries in clamshell packages, placing eggs in a carton) both on the farm that grew them and at off-farm packing houses is "more akin to packing" than packaging (despite meeting the definition of packaging) because it does not alter the form of the food, so it is not manufacturing/processing; bottling wine (placing it in a container that touches the food and that the consumer receives) is packaging and therefore manufacturing/processing because it preserves the manufactured condition of the wine; placing cereal in a plastic cereal box liner is packaging and therefore manufacturing/processing; and placing apples received from elsewhere in bulk into plastic bags is packaging and therefore manufacturing/processing.

Most of these conclusions remain the same under the proposed revisions to part 1, although the reasoning for those conclusions would instead be based on the rules articulated in the proposed revisions to part 1. Specifically, a farm or farm mixed-type facility placing its own RACs in consumer containers that contact the food would be packing because farms traditionally do this to prepare their RACs for storage or transport, and this activity does not transform the RACs into a processed food. Examples of this kind of activity include an egg farm putting its own eggs in cartons, and a strawberry farm placing its own strawberries in clamshell packages. Such activities would be within the farm definition. Bottling wine and placing cereal in plastic box liners would still be packaging and therefore manufacturing/processing, regardless of where such activities are performed, because those foods are processed foods to which the expanded proposed definition of packing would not be applicable.

Under the proposed revisions to part 1, there would be a change in how FDA considers the act of placing RACs into consumer containers (1) off-farm and (2) on farms or farm mixed-type facilities with respect to others' RACs. Off-farm, the expanded definition of packing would not apply, so this activity would be packaging and therefore manufacturing/processing. As a practical matter, this change should have no practical impact because off-farm establishments that conduct this activity are required to register under section 415 of the FD&C Act, and are therefore subject to section 418 of the FD&C Act, whether this activity is considered packing or manufacturing/processing. On farms and farm mixed-type facilities that place others' RACs into consumer containers, this activity would be packaging and therefore manufacturing/processing, because the expanded definition of packing would only apply to a farm's own RACs. This result is consistent with the principles articulated in section VIII.D of this document because, while it may be a practical necessity for a farm to place its own fragile RACs in consumer packages to

protect them during storage and transport, packaging others' RACs is not part of the essential purpose of a farm (producing the farm's own RACs). Farms that conduct such activities are acting as distributors for other farms' products and FDA considers that the activities they conduct on others' RACs should be classified as manufacturing/processing, packing, or holding in the same manner as are activities performed by off-farm distributors of RACs. Therefore FDA tentatively concludes that these activities should be outside the farm definition.

G. Science-Based Risk Evaluation of On-Farm Activities Outside of the Farm Definition

Sections 103(c)(1)(C)-(D) of FSMA require FDA to analyze activity/food combinations that are likely to be conducted on farms, but that are outside the definition of farm in § 1.227. Such activities trigger the registration requirement in Section 415 of the FD&C Act, and in turn, are subject to requirements under Section 418 of the FD&C Act and Section 421 of the FD&C Act (Targeting of Inspection Resources). FSMA Sections 103(c)(1)(C)-(D) direct FDA to consider whether any of these activity/food combinations may be considered to be low risk. If FDA determines that any such activity/food combinations are low risk, FDA may exempt small or very small businesses (as defined in section X.C.4 of this document) that only engage in these activity/food combinations from the requirements of sections 418 and/or 421 of the FD&C Act, or may establish modified requirements under those sections.

FDA has conducted the science-based risk evaluation required by section 103(c)(1)(C) of FSMA and is making it available for public comment in the docket established for this proposed rule (Ref. risk evaluation). In the risk evaluation, FDA considered the risk of activity/food combinations likely to be performed at farm mixed-type facilities that are outside the scope of the farm definition (as proposed in § 1.227). FDA considered low-risk activities to be those that, for a particular food, were not reasonably likely to introduce a hazard and that do not

significantly minimize or prevent a hazard that is reasonably likely to occur. Using this definition, we assessed whether a specific activity was low risk for each specific food category. Based on this assessment, we identified a set of low-risk activity/food combinations.

We will consider comments regarding the risk evaluation in any final rule based on this proposed rule. As discussed in section II.B.2.d of this document, we will subject the risk evaluation to peer review after considering public comments we may receive on that document.

H. Conclusions of the Science-Based Risk Evaluation

In this section, FDA states the conclusions of its science-based risk evaluation, as required under section 103(c)(1)(C) of FSMA. Based on the proposed revisions to definitions in part 1, subparts H and J discussed in section VIII.E of this document, the same activity may be classified differently (among the categories of harvesting, manufacturing/processing, packing, or holding) depending on whether the food being operated upon is a RAC and whether the RAC was grown or raised on the farm or farm mixed-type facility performing the activity or a farm under the same ownership. We therefore arranged our results in three lists shaped by these factors and the resulting activity classifications. References to "farms" in these lists should be understood to include farm mixed-type facilities.

1. List of low-risk on-farm packing and holding activity/food combinations when conducted on food not grown, raised, or consumed on that farm or another farm under the same ownership

Based on the risk evaluation, FDA tentatively concludes that the following are low-risk packing and holding activity/food combinations when conducted on a farm on food not grown, raised, or consumed on that farm or another farm under the same ownership. (The same activities performed on a farm's own RACs, or food consumed on the farm or another farm

under the same ownership, would be within the farm definition and therefore outside the scope of the risk evaluation.)

- Packing or re-packing (including weighing or conveying incidental to packing or re-packing) of
    - Intact fruits and vegetables (Seeds for consumption, peanuts, and tree nuts would generally be considered to be “fruits and vegetables,” but for the purposes of the risk evaluation, they have been addressed separately.)
        - Grains and grain products
        - Seeds for consumption
        - Peanuts and tree nuts
        - Honey (raw and pasteurized)
        - Maple sap for syrup and maple syrup
        - Acid foods made into jams, jellies and preserves
- Sorting, culling, or grading incidental to packing or storing of
    - Intact fruits and vegetables
    - Grains and grain products
    - Seeds for consumption
    - Peanuts and tree nuts
    - Honey (raw and pasteurized)
    - Maple sap for syrup and maple syrup
- Storing (ambient, cold and controlled atmosphere) of
    - Intact fruits and vegetables
    - Grains and grain products

- Seeds for consumption
- Peanuts and tree nuts
- Honey (raw and pasteurized)
- Maple sap for syrup and maple syrup
- Acid foods made into jams, jellies and preserves

2. List of low-risk on-farm manufacturing/processing activity/food combinations when conducted on the farm's own raw agricultural commodities for distribution into commerce

Based on the risk evaluation, FDA tentatively concludes that the following are low-risk manufacturing/processing activity/food combinations when conducted on a farm on the farm's own RACs for distribution into commerce. (As discussed earlier in this section of this document, some activities that would be manufacturing/processing when performed on foods other than a farm's own RACs are not manufacturing/processing when performed on a farm's own RACs because when performed on the farm's own RACs, those activities are instead classified as packing, holding, or harvesting and are within the farm definition, making them outside the scope of this risk evaluation. As a result, this list of low-risk manufacturing/processing activity/food combinations for a farm's own RACs is shorter than the list that follows for low risk manufacturing/processing for foods other than a farm's own RACs.)

- Artificial ripening of intact fruits and vegetables
- Boiling/evaporation of maple sap to make maple syrup
- Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables, seeds for consumption, and peanuts and tree nuts (e.g., coating apples with caramel, coating seeds or nuts with spices)
- Chopping peanuts and tree nuts

- Drying/dehydrating intact fruits and vegetables where the drying creates a distinct commodity (e.g., drying fruits or herbs)
- Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., cracking tree nuts)
- Making jams, jellies and preserves from acid foods (e.g., acid fruits)
- Salting seeds for consumption, raw peanuts, and raw tree nuts

3. List of low-risk on-farm manufacturing/processing activity/food combinations when conducted on food other than the farm's own raw agricultural commodities, for distribution into commerce

Based on the risk evaluation, FDA tentatively concludes that the following are low-risk manufacturing/processing activity/food combinations when conducted on a farm on food other than the farm's own RACs, for distribution into commerce.

- Making honey (including extraction and filtration)
- Making maple syrup (including filtration and boiling/evaporation)
- Artificial ripening of intact fruits and vegetables
- Cooling intact fruits and vegetables using cold air
- Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables, seeds for consumption, and peanuts and tree nuts (e.g., coating apples with caramel, coating seeds or nuts with spices)
- Chopping peanuts and tree nuts
- Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables and seeds for consumption

- Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts)
- Labeling (including stickering) intact fruits and vegetables, grain and grain products, seeds for consumption, intact single-ingredient peanuts or tree nuts (shelled and unshelled), honey, and maple sap or syrup
- Making jams, jellies and preserves from acid foods (e.g., acid fruits)
- Mixing/blending intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup
- Packaging (other than modified atmosphere or vacuum packaging) intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup
- Packaging peanuts or tree nuts using modified atmosphere or vacuum methods
- Salting seeds for consumption and peanuts and tree nuts
- Sifting grain or grain products and seeds for consumption
- Shelling intact fruits and vegetables (e.g., beans and peas such as black-eyed peas, kidney, lima, and pinto beans), seeds for consumption, and peanuts and tree nuts
- Sorting, culling and grading (other than when incidental to packing or storage) intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup
- Treating intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (e.g., fumigation)
- Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables

4. Proposed decisions regarding results of the risk evaluation for purposes of section 418 and 421 of the FD&C Act

Based on our tentative conclusions that the activity/food combinations described above are low risk, we are proposing in §§ 110.2(g)(1) and (g)(2) to exempt farm mixed-type facilities that are small or very small businesses as defined in proposed § 110.3 from requirements under section 418 of the FD&C Act if the only activities subject to section 418 that the business conducts are low-risk activity/food combinations, as discussed in section X.B.6 of this document. This exemption would not exempt eligible facilities from the requirement to register under section 415 of the FD&C Act.

We tentatively conclude that FDA should consider the low risk on-farm activity/food combinations for small/very small businesses identified in the risk evaluation as a factor in identifying high-risk facilities and allocating inspection resources under Section 421 of the FD&C Act, Targeting of Inspectional Resources for Domestic Facilities. However, at this time, FDA tentatively concludes that it should not exempt or modify the frequency requirements under 421 based solely upon whether a facility only engages in such low-risk activity/food combinations and is a small or very small business. Current data limitations impact our ability to accurately identify such facilities, and we must be able to identify such facilities in order to implement an exempted or modified inspection frequency schedule. We request comment on whether we should establish data submission requirements that would allow us to identify these types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act. Examples of data elements that we might need in order to identify these facilities include: identification of a facility as a farm mixed-type facility, annual monetary value of sales, number of employees,

food category/activity type. We also request comment on these possible data elements and any other criteria that may be appropriate for the purposes of allocating inspection resources to these facilities.

IX. Proposed General Revisions to Current Part 110

A. Proposed Change to the Title of Current Part 110

FDA is proposing to revise the title of current subpart B from "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" to "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." The proposed title would reflect that part 110 would include both CGMP requirements (including those established prior to the enactment of FSMA) and requirements for risk-based preventive controls for domestic and foreign facilities that are required to register under section 415 of the FD&C Act. As proposed, the title of part 110 would no longer identify specific activities (i.e., manufacturing, packing, and holding). The activities covered by the CGMP requirements would be identified within the requirements themselves and are not necessary to include in the title of part 110. We request comment on the proposed revision of the title of part 110.

B. Proposed Redesignations in Current Part 110

FDA is proposing to redesignate the subparts of current part 110 and to include in proposed subpart B the CGMP provisions already established in part 110. The proposed redesignation will clearly separate current CGMP requirements, and any newly proposed CGMP requirements, from newly proposed requirements that would implement section 418 of the FD&C Act. The proposed redesignation is intended to make it easy for persons who would be

exempt from requirements established under section 418 of the FD&C Act to identify the CGMP requirements that apply to them.

FDA also is proposing a general reorganization and redesignation of the provisions currently in part 110. The proposed revisions are intended to enhance the clarity of part 110 as a whole. Table 3 shows the proposed reorganization and redesignation of current provisions. In sections X and XI of this document, we discuss proposed changes to the current provisions of part 110 in the order in which they would appear in a final rule based on this proposed rule.

Table 3. Proposed Rearrangement of Provisions and Subparts of Current Part 110

Current Designation	Current Subpart Location	Proposed Redesignation	Proposed Subpart Location
§ 110.3--Definitions	Subpart A	Proposed § 110.3	Proposed Subpart A
§ 110.5--Current good manufacturing practice	Subpart A	Proposed § 110.1	Proposed Subpart A
§ 110.10--Personnel	Subpart A	Proposed § 110.10	Proposed subpart B
§ 110.19--Exclusions	Subpart A	Proposed § 110.2(k)	Proposed subpart A
§ 110.20--Plant and grounds	Subpart B	Proposed § 110.20	Proposed subpart B
§ 110.35--Sanitary operations	Subpart B	Proposed § 110.35	Proposed subpart B
§ 110.37--Sanitary facilities and controls	Subpart B	Proposed § 110.37	Proposed subpart B
§ 110.40--Equipment and utensils	Subpart C	Proposed § 110.40	Proposed subpart B
§ 110.80--Processes and controls	Subpart E	Proposed § 110.80	Proposed subpart B
§ 110.93--Warehousing and distribution	Subpart E	Proposed § 110.93	Proposed subpart B
§ 110.110--Natural or unavoidable defects in food for human use that present no health hazard	Subpart G	Proposed § 110.110	Proposed subpart B

C. Proposed Revisions for Consistency With Terms Used in Section 418 of the FD&C Act

1. Activities Subject to Part 110

FDA is proposing to revise current part 110 to make clear that the activities subject to part 110 include manufacturing, processing, packing and holding. We describe each of these proposed revisions elsewhere in this document, in an order consistent with the placement of the current or revised provision. Section 418 of the FD&C Act uses this group of terms to broadly

identify activities that take place in food facilities. In addition, we have previously described activities that may be considered "manufacturing, processing, packing, or holding" by establishing definitions for "manufacturing/processing" in current §§ 1.227(b)(6) and 1.328, "packing" in current §§ 1.227(b)(9) and 1.328, and "holding" in current §§ 1.227(b)(5) and 1.328. This proposed rule proposes certain revisions to these existing definitions (see section VIII.E of this document) and would incorporate the revised definitions of manufacturing/processing, packing, and holding in part 110. We tentatively conclude there is no meaningful distinction between "manufacturing/processing," "packing," and "holding" as defined in our proposed revisions to §§ 1.227 and 1.328 and those terms as they have been used in current part 110. We also tentatively conclude that consistent use of these terms throughout part 110, in reference to activities taking place in food facilities, establishments, or plants, would make the regulations more clear and have no substantive effect on the current requirements. We request comment on this proposed revision.

2. The term "facility"

FDA is proposing to replace the term "facility" or "facilities" in current part 110 with the term "establishment" or "plant" whenever the term "facility" or "facilities" could be confused with the firms that are subject to the proposed requirements for hazard analysis and risk-based preventive controls required by section 418 of the FD&C Act. FDA is proposing this change to distinguish between the requirements of current part 110 (Current Good Manufacturing Practices) and requirements that we are proposing to establish under section 103 of FSMA. The term "facility" as used in current part 110 reflects the common meaning of that term as something designed, built, or installed to serve a specific function. However, after issuance of current part 110, in our regulation implementing section 415 of the FD&C Act, "Registration of

Food Facilities" (§ 1.227(b)(2) in part 1, subpart H), we defined the term "facility" to have a very specific meaning for the purpose of that regulation as follows:

Current section 1.227(b)(2) provides in part that "[f]acility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States." Part 1, subpart H broadly defines the term "facility" for the purposes of that subpart, and provides that facilities must register unless they qualify for one of the exemptions in that subpart. For example, current § 1.227(b)(3) defines "farm" as a type of facility, and § 1.226(b) provides that farms do not need to register.

Section 418(o)(2) of the FD&C Act defines "facility" for the purposes of section 418 to mean "a domestic facility or a foreign facility that is required to register under section 415" of the FD&C Act, and proposed § 110.3 would define "facility" to incorporate this statutory definition. Under proposed § 110.3, the term "facility" would have a meaning for the purposes of proposed part 110 that is more narrow than the common meaning of the term or the definition of facility in current § 1.227(b)(2), in that it would encompass only those facilities that are required to register under section 415 of the FD&C Act (and part 1, subpart H). Our proposal to replace the term "facility" in current part 110 with "establishment" or "plant" is intended to avoid confusion about the applicability of current part 110 to plants or establishments that satisfy the definition of the term "facility" in current § 1.227(b) but are exempt from the requirement to register. We describe each of these proposed revisions elsewhere in this document, in an order consistent with the placement of the current or revised provision. We request comment on this proposed revision.

We are not proposing to replace the use of the term "facilities" in current requirements directed to specific functional parts of a plant or establishment, such as "toilet facilities" and "hand-washing facilities." We tentatively conclude that the use of the term "facilities" in these contexts would not create confusion. We request comment on whether there is potential for confusion such that we should eliminate all use of the term "facility" or "facilities" in current part 110 irrespective of context.

3. Owner, operator, or agent in charge

Section 418 of the FD&C Act establishes requirements applicable to the "owner, operator, or agent in charge" of a facility. Current part 110 establishes requirements for persons not explicitly identified as "owner, operator, or agent in charge" of a food plant or establishment. For example, current § 110.10 establishes requirements applicable to "plant management" and current § 110.20(a) establishes requirements for the "operator" of a food plant. We request comment on whether there is any meaningful difference between the persons identified in current part 110 and the "owner, operator, or agent in charge" identified in section 418 of the FD&C Act. We also request comment on whether it would be appropriate to refer to the "owner, operator, or agent in charge" of a plant, establishment, or facility throughout part 110 and, if so, whether the requirements would be clear if we revise the proposed rule to use pronouns (such as "you" and "your") within part 110. Pronouns are commonly used in contemporary regulations and simplify the presentation of the requirements.

D. Proposed Additions Regarding Cross-Contact

Proposed § 110.3 would define the term "cross-contact" to mean the unintentional incorporation of a food allergen into a food. "Food allergen" would be defined as a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. As

discussed in section X.C.4 of this document, it has been estimated that food allergies affect four to six percent of children and two to three percent of adults in the U.S. Food allergies can cause life threatening reactions to foods. Because there is no cure for food allergy, sensitive consumers and their families must practice avoidance to prevent reactions. To do so they must rely on food labels to be complete, clear, and accurate. Manufacturers can provide consumers with the food labels they need by using controls to ensure that labels declare all the food allergens that are intended to be present, controls to ensure that the correct label is applied to the product, and controls that prevent the unintended presence of food allergens through cross-contact.

Comments submitted to the Food CGMP Modernization Working Group emphasized the importance of controls to prevent cross-contact (Ref. CGMP Working Group Report). After considering the comments, the CGMP Working Group report recommended that food processing establishments that handle any of the major food allergens be required to develop and adopt a food allergen control plan that addresses six areas of control, one of which is "[p]revention of cross-contact during processing" (Ref. CGMP Working Group Report). FDA interprets current part 110 to require protection against cross-contact, which can constitute insanitary conditions that may cause a food to be adulterated under section 402(a)(4) of the FD&C Act if the food may have been rendered injurious to health. Consistent with this interpretation, FDA issued a Notice to Manufacturers titled "Allergy Warning Letter" on June 10, 1996, advising with regard to cross-contact that adhering to CGMPs is essential for effective reduction of adverse reactions, and urging manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of unintended food allergens (Ref. to warning letter). In the past, inadvertent incorporation of an allergen into a food was referred to as "contamination" or "cross contamination" (Ref. Deibel et al. JFP 60:436-441,1997), and in many instances these terms are

still used (Ref. Taylor, S.L. Cross-Contamination of Foods and Implications for Food Allergic Patients). More recently, the term "cross-contact" has been applied with respect to unintentional transfer of allergenic proteins from a food containing the proteins to one that does not (Ref. FARRP Allergen Control Plan (no date); Jackson et al. 2008), because an allergen is a normal component of food, and not itself a contaminant. Given this shift in the scientific literature distinguishing "cross-contact" from "contamination," FDA tentatively concludes that it should begin using the term "cross-contact" to describe inadvertent incorporation of an allergen into food, rather than the general term "contamination," for purposes of clarity. To make it clear that CGMPs require protection against cross-contact, and to ensure that CGMPs continue to address health concerns related to allergens, FDA is proposing to revise several provisions of part 110 to explicitly address cross-contact.

We describe each of these proposed additions elsewhere in this document, in an order consistent with the placement of the current or revised provision. We request comment on this proposed revision to the CGMPs in current part 110.

E. Proposed Revisions for Consistency With the Definition of "Food"

Current § 110.3 defines "food" to mean food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients. We are proposing to retain that definition in this proposed rule. There is an overlap between raw materials and ingredients. Not all raw materials are ingredients. For example, under section 201(f) of the FD&C Act, a food additive is food and, thus, the manufacture of a food additive is subject to part 110. An example of a food additive is sucrose fatty acid esters. Under § 172.859, sucrose fatty acid esters are the mono-, di-, and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or hydrogenated edible tallow or edible vegetable oils. The only solvents which may be used in the preparation of

sucrose fatty acid esters are those generally recognized as safe in food or regulated for such use by an appropriate section in this part. Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters. The regulation for sucrose fatty acid esters identifies a number of raw materials used in the production of sucrose fatty acid esters. Because the production process transforms those raw materials into the substance "sucrose fatty acid esters," those raw materials generally would not be viewed as "ingredients" of the final chemical product. Likewise, if a facility adds the food additive "sucrose fatty acid esters" to a food product, the facility would view that food additive as an ingredient of its food product, but would not view the chemicals used to produce sucrose fatty acid esters as ingredients of its food product.

The title of current § 110.80(a) and several provisions within current 110.80 refer to "raw materials and other ingredients" rather than to "raw materials and ingredients" as in the definition of "food." For consistency with the definition of food, we are proposing to change the title of current § 110.80(a) to "Raw materials and ingredients." As a companion change to this change in title, we are proposing to substitute "ingredients" for "other ingredients" throughout provisions in § 110.80 that refer to both raw materials and ingredients. We do not list every instance where this proposed revision would apply.

F. Proposed Deletion or Revision of Guidance From Current Part 110

In 2000, we codified our policies and procedures for the development, issuance, and use of guidance documents in § 10.115 (21 CFR 10.115) (65 FR 56468, September 19, 2000). Under § 10.115(b), guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe our interpretation of or policy on a regulatory issue. They include documents that relate to the design, production, labeling, promotion,

manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies. Under § 10.115(d), guidance documents do not establish legally enforceable rights or responsibilities and do not legally bind the public or FDA.

Comments submitted to the Food CGMP Modernization Working Group noted that several provisions of current part 110 use non-binding language such as "should" and recommended that we revise part 110 to express all provisions using binding language (e.g., "shall" in place of "should") (Ref. CGMP Working Group Report). Consistent with these comments and with 21 CFR 10.115, we are proposing to either delete non-binding provisions of current part 110 (e.g., provisions using "should" or "compliance may be achieved by") or revise them to establish new requirements. We describe each of these proposed deletions or revisions elsewhere in this document, in an order consistent with the placement of the revised provision.

G. Proposed Editorial Changes to Current Part 110

FDA is proposing to revise current part 110 to make several changes that are editorial in nature. These editorial changes have no substantive effect on the current requirements of part 110 and, thus, we do not list every instance where these proposed editorial changes would apply. We are proposing to:

- Refer to the "Federal Food, Drug, and Cosmetic Act" rather than to "the act" for clarity and for consistency with our current approach to citing the FD&C Act in new regulations;
- Replace the term "shall" with the term "must". The term "must" is a more common word than "shall," and we are using "must" in new regulations.

- Replace the phrase “includes, but is not limited to” with “includes,” because the use of the word “includes” indicates that the specified list that follows is not exclusive. The phrase “but is not limited to” is unnecessary. (72 FR 34751 at 34765, June 25, 2007)

- Replace the phrase “adulteration within the meaning of the act” with the single term “adulteration” because “within the meaning of the act” is not needed for the term “adulteration” to have the meaning assigned by section 402 of the FD&C Act (21 U.S.C. § 342 (Adulterated food).

X. Subpart A--General Provisions

A. Proposed § 110.1 - Applicability and Status

FDA is proposing to redesignate current § 110.5(a) as proposed § 110.1(a) with associated editorial changes described in section X.C.1 of this document. Current § 110.5(a) establishes that the criteria and definitions in part 110 apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the FD&C Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Current § 110.5(a) also establishes that the criteria and definitions in part 110 apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264). FDA is proposing to retain the provisions of current § 110.5(a) in proposed § 110.1(a). The provisions of current § 110.5(a) as re-established in proposed § 110.1(a) would continue to apply to all provisions of current part 110. Under this proposed rule, proposed § 110.1 also would apply to new provisions of part 110, including provisions that would be added under the authority of sections 402(a)(3), 402(a)(4), or 418 of the

FD&C Act, section 361 of the PHS Act, or a combination of those authorities. We note that section 418(a) of the FD&C Act provides that facilities subject to that section must "identify and implement preventive controls to … provide assurances that … food is not adulterated under section 402 [of the FD&C Act]" and that similar references to preventing adulteration under section 402 of the FD&C Act also appear in section 418(c) and (e). In section III of this document, we explain how the proposed provisions are necessary to protect against contamination with hazards that may adulterate food. We tentatively conclude that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 110 in determining whether, under particular circumstances, a food is adulterated under section 402(a)(3) or (a)(4) or in violation of section 361 of the PHS Act.

Section 103(e) of FSMA amends section 301 of the FD&C Act (21 U.S.C. 331) by adding a new section - (uu) - to the list of acts and the causing thereof that are prohibited. Under section 301(uu), the following act, and the causing thereof, is prohibited: "[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act]." To clearly communicate that failure to comply with regulations established under section 418 is a prohibited act, proposed § 110.1(b) would establish that the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or subparts C, D, E, or F of part 110 is a prohibited act under section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)).

FDA is proposing to redesignate current § 110.5(b) as proposed § 110.1(c) with no changes. Current § 110.5(b) establishes that food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations. As discussed in sections II.A.1 and II.A.2 of this document, following the establishment of the umbrella CGMPs in 1969 (34 FR 6977), FDA established additional CGMP requirements, including CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (proposed rule, 41 FR 30444, July 23, 1976; final rule, 44 FR 16209, March 16, 1979; currently established in part 113) and CGMP requirements for acidified foods (proposed rule, 41 FR 30457, July 23, 1976; final rule, 44 FR 16230, March 16, 1979; currently established in part 114). In the preamble to the proposed rule to establish current § 110.5(b), we explained that this provision was intended to communicate that foods covered by such specific CGMPs are still subject to part 110 (44 FR 33238, at 33239, June 8, 1979). Since current § 110.5(b) was established, we have established additional food safety regulations, such as the 1995 HACCP regulations in part 123 for fish and fishery products (60 FR 65096, December 18, 1995) and the 2001 HACCP regulations in part 120 for juice (66 FR 6138, January 19, 2001). As with foods that are subject to part 113 or part 114, foods that are subject to part 123 or part 120 are subject to the requirements of part 123 or 120 even though they are foods covered by the current good manufacturing practice requirements of part 110. See section II.A of this document for a discussion of other food safety regulations for specific foods to which this would also apply.

Importantly, section 418 of the FD&C Act requires that we establish regulations to implement requirements for hazard analysis and risk-based preventive controls for human food. As discussed in section V of this document, we tentatively conclude that it is appropriate to

establish these requirements for hazard analysis and risk-based preventive controls in part 110. As discussed in section IX.A of this document, we are proposing to revise the title of part 110 to reflect the addition of these new requirements. As discussed more fully in section X.B of this document, section 418 of the FD&C Act establishes several exemptions from the proposed requirements for hazard analysis and risk-based preventive controls. For example, section 418(j)(1) of the FD&C Act provides that section 418 of the FD&C Act "shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with… (A) [t]he Seafood Hazard Analysis Critical Control Points Program…" (We interpret "Seafood Hazard Analysis Critical Control Points Program" to mean the requirements of part 123 for fish and fishery products.) As discussed below, consistent with section 418(j)(1)(A), proposed § 110.2(b) would provide that proposed subpart C of part 110 would not apply with respect to activities that are subject to part 123 at a facility, if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with part 123. However, under current § 110.5(b) and proposed § 110.1(c), all activities at that facility have been, and would continue to be, subject to the CGMP requirements in proposed subpart B and the requirements of part 123. That facility also would be required to establish and maintain records that would be required under subpart B (proposed § 110.120) in accordance with recordkeeping requirements that would be required under proposed subpart F. The same would be true for establishments and facilities that are subject to other food safety regulations, consistent with the exemptions that would be established in proposed § 110.2.

B. Proposed § 110.2 - Exemptions

1. Proposed § 110.2(a)--Exemption Applicable to a Qualified Facility

Section 418(l) of the FD&C Act establishes modified requirements for "qualified facilities." We describe what a qualified facility is in section XIII.A of this document, where we propose the modified requirements for such a facility (proposed § 110.201). We also define the term "qualified facility" in proposed § 110.3 (see the discussion of definitions in section X.C.4 of this document). Section 418(l)(2)(A) of the FD&C Act provides that a qualified facility "shall not be subject to the requirements under [sections 418(a) through (i) and (n) of the FD&C Act];" as a practical matter with respect to the provisions of this proposed rule, section 418(l)(2)(A) of the FD&C Act provides that a qualified facility would be exempt from the proposed requirements of subpart C. Importantly, section 418(l)(3) of the FD&C Act provides that the Secretary of HHS may withdraw the exemption provided in section 418(l)(2)(A) under certain circumstances. We discuss the withdrawal provisions of section 418(l)(3), and our proposed provisions to implement section 418(l)(3) (proposed subpart E), in section XIV of this document.

We tentatively conclude that we should include the exemption provided in section 418(l)(2)(A) of the FD&C Act in the proposed rule to establish by regulation the reach of the provision. Proposed § 110.2(a) would provide that subpart C would not apply to a qualified facility, except as provided by subpart E (i.e., except as provided by the proposed provisions for withdrawal), and that qualified facilities are subject to the modified requirements in § 110.201.

2. Proposed § 110.2(b) and (c)--Exemptions Applicable to Food Subject to HACCP Requirements for Fish and Fishery Products or for Juice

As discussed above, section 418(j)(1)(A) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility that is required to comply with, and is in compliance

with, the Seafood Hazard Analysis Critical Control Points Program. Likewise, section 418(j)(1)(B) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, "[t]he Juice Hazard Analysis Critical Control Points Program…." (We interpret "Juice Hazard Analysis Critical Control Points Program" to mean the requirements of part 120 for juice.)

The purpose of sections 418(j)(1)(A) and (B) appears clear--to exclude food covered by and in compliance with current HACCP requirements (parts 120 and 123) from section 418 of the FD&C Act. The exclusion likely reflects a determination that the similarity of the existing HACCP requirements in parts 120 and 123 to the preventive control requirements in section 418 makes application of section 418 unnecessary to foods currently subject to and in compliance with part 120 or 123. Although the purpose of the exemption appears clear, FDA considers the language of sections 418(j)(1)(A) and (B) to be ambiguous with regard to application of the exemption. The language of sections 418(j)(1)(A) and (B) premise exemption from section 418 on an owner, operator, or agent in charge of a facility being required to comply with, and being in compliance with, part 120 or 123 "with respect to such facility[.]" However, parts 120 and 123 do not apply to "facilities," establishments, or plants. Rather, they apply to the specified foods (juice and fish and fishery products, respectively) and to persons defined as "processors" who conduct certain activities involving those foods. See, e.g., § 120.1 ("The requirements of this part shall apply to any juice…"), § 120.3(k) (definition of "Processor"), § 123.3(l) (definition of "Processor"), and § 123.6(b) ("The purpose of this part is to set forth requirements specific to the processing of fish and fishery products"). Thus, it is unclear for purposes of sections 418(j)(1)(A) and (B) under what circumstances a juice or seafood processor is required

to comply with parts 120 or 123 "with respect to [a] facility," especially when such a person also conducts activities involving other foods not subject to parts 120 or 123 at the same facility. Because of this ambiguity, FDA considered three possible interpretations.

First, we could interpret sections 418(j)(1)(A) and (B) to exempt all food manufactured, processed, packed, or held by a facility from section 418 of the FD&C Act if the owner, operator, or agent in charge of the facility is required to comply with and is in compliance with part 123 or 120 with respect to any activities in the facility. Under this interpretation, food manufactured, processed, packed, or held by a facility that is not subject to part 120 or 123 would be excluded from section 418 if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 or 123 for any food manufactured, processed, packed, or held by the facility. For example, if a facility processes juice products and the owner, operator, or agent in charge is in compliance with the juice HACCP regulation (part 120), all food manufactured, processed, packed, or held by the facility--both the juice subject to part 120 and food not subject to part 120 (e.g., dairy products)--would be exempt from section 418. The exclusion for juice appears consistent with the purpose of section 418(j)(1)(B) because the juice is already subject to the HACCP requirements in part 120. The resulting exclusion for dairy products, however, does not serve the purpose of the exclusion because the dairy products are not subject to the HACCP requirements in parts 120 or 123. Further, the exclusion of food not subject to part 120 or 123 (e.g., dairy products) would create a gap in the coverage of preventive controls, and therefore not be protective of public health.

For example, there could be hazards reasonably likely to occur with regard to the dairy products, including environmental pathogens such as L. monocytogenes, but such hazards would not trigger any preventive control requirements because the facility would be excluded from

section 418 of the FD&C Act. Finally, there is no apparent reason to regulate the same type of food not subject to part 120 or 123 (e.g., dairy products) differently depending on whether the food is manufactured, processed, packed, or held by a facility that manufactures, processes, packs, or holds other food that is subject to part 120 or 123. Therefore, we tentatively conclude that this interpretation results in an exclusion that is too broad.

Second, we could interpret sections 418(j)(1)(A) and (B) to exempt an entire facility from section 418 only if the owner, operator, or agent in charge of the facility is subject to and in compliance with part 120 or 123 with regard to all food manufactured, processed, packed, or held by the facility. Under this interpretation, juice and seafood in a facility would, in addition to being subject to part 120 or 123, be subject to the requirements in section 418 if the facility manufactures, processes, packs, or holds any food not subject to part 120 or 123. For example, juice processing activities subject to part 120 at a facility that processes juice and dairy products would be subject to section 418 because the facility manufacturers, processes, packs, or holds food not subject to part 120 or 123. The resulting application of section 418 to the dairy products in the example is a logical outcome--the dairy products are not subject to any other preventive control-type requirements. Further, the coverage gap created by the first possible interpretation is avoided. The application of section 418 to the juice in the example, however, is problematic. The juice is subject to part 120, thus application of section 418 to the juice would result in a circumstance that the exclusion in sections 418(j)(1)(A) and (B) was likely intended to avoid--subjecting food covered by current HACCP requirements to additional preventive control requirements in section 418. Therefore, we tentatively conclude that this interpretation results in an exclusion that is too narrow.

Finally, we considered a third interpretation. We could interpret sections 418(j)(1)(A) and (B) of the FD&C Act to exempt those activities of a facility that are subject to part 120 or 123, and only those activities, regardless of whether the facility manufactures, processes, packs, or holds other food. This interpretation would fulfill the apparent goal of the exemption-- to exclude food covered by and in compliance with current HACCP requirements (parts 120 and 123) from section 418. Further, this interpretation is neither too broad (because it does not exclude food that is not subject to part 120 or 123) nor is it too narrow (because it does not result in overlapping requirements when food not subject to part 120 or 123 is processed in the same facility as food that is subject to part 120 or 123). This is the interpretation that seems most reasonable and that we propose to adopt in this proposed rule. We request comment on our interpretation of sections 418(j)(1)(A) and (B).

We tentatively conclude that we should include the exemptions provided in sections 418(j)(1)(A) and (B) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption as we have interpreted it. Proposed § 110.2(b) would provide that Subpart C would not apply with respect to activities that are subject to part 123 (Fish and Fishery Products) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 with respect to such activities. Likewise, proposed § 110.2(c) would provide that Subpart C would not apply with respect to activities that are subject to part 120 (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 with respect to such activities. Proposed § 110.2(b) and (c) would make clear that the exemptions provided by sections 418(j)(1)(A) and (B) of the FD&C Act would apply to particular activities at a facility rather than to the facility as a whole. For

example, a facility producing juice and dairy beverages would be exempt only with respect to juices subject to, and in compliance, with part 120. Such a facility would be subject to subpart C with respect to its dairy beverages, unless it qualified for another exemption.

We request comment on the criteria that should be used to determine whether a facility is in compliance with part 123 or part 120.

3. Proposed § 110.2(d)--Exemption Applicable to Food Subject to Part 113 - Thermally Processed Low-Acid Foods Packaged In Hermetically Sealed Containers

Section 418(j)(1)(C) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, "[t]he Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the [FDA] (or any successor standards)." (We interpret "Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards" to mean the requirements of part 113.) Importantly, section 418(j)(2) of the FD&C Act limits the express exemption associated with part 113 to microbiological hazards that are regulated under part 113 (or any successor regulations). FDA considers the language of section 418(j)(1)(C) of the FD&C Act to be ambiguous with regard to application of the exemption. As discussed with regard to sections 418(j)(1)(A) and (B) above, the language of section 418(j)(1)(C) premises exemption from section 418 of the FD&C Act on an owner, operator, or agent in charge of a facility being required to comply with, and being in compliance with, part 113 "with respect to such facility[.]" However, part 113 does not apply to "facilities," establishments, or plants. Rather, it applies to the specified foods (low-acid canned foods) and to persons defined as "commercial processors" who conduct certain activities involving those foods. See, e.g., § 113.3(d) (definition of "Commercial processor"), and section 404 of the

FD&C Act (21 U.S.C. 344), which provides FDA with legal authority to issue part 113 ("[The Secretary] shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food [presenting specific risks defined in the section] in such locality of permits to which shall be attached such conditions governing the manufacture, processing, or packaging of such class of food…"). Thus, it is unclear for purposes of section 418(j)(1)(C) under what circumstances a low-acid canned food processor is required to comply with part 113 "with respect to [a] facility," especially when such a person also conducts activities involving other foods not subject to part 113 at the same facility.

We considered the same three interpretations of section 418(j)(1)(C) of the FD&C Act as we considered for sections 418(j)(1)(A) and (B) of the FD&C Act for the purpose of proposed § 110.2(b) and (c). We tentatively conclude that we should interpret section 418(j)(1)(C) in the same manner as we interpreted sections 418(j)(1)(A) and (B) – i.e., to exempt those activities of a facility that are subject to part 113, and only those activities. Such an interpretation would fulfill the apparent goal of the exemption without being too narrow or too broad. We also tentatively conclude that we should include the exemption provided in section 418(j)(1)(C) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption as we have interpreted it. Proposed § 110.2(d)(1) would provide that Subpart C would not apply with respect to activities that are subject to part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 113 with respect to such activities. For example, a facility producing both low-acid foods packaged in hermetically sealed containers and acidified foods subject to part 114 would be exempt only with respect to low-acid foods subject to, and in compliance with, part 113. Consistent with section 418(j)(2) of

the FD&C Act, proposed § 110.2(d)(2) would establish that the exemption in proposed § 110.2(d)(1) would be applicable only with respect to the microbiological hazards that are regulated under part 113. A facility that is required to comply with, and is in compliance with, part 113 would be subject to the requirements in proposed subpart C for hazards such as chemical hazards (e.g., pesticide residues), physical hazards (e.g., metal fragments that could be introduced from equipment) and radiological hazards (e.g., high concentrations of radium-226, radium-228 or uranium in well water used in product). A facility that is required to comply with, and is in compliance with, part 113 also would be subject to the requirements in proposed subpart C for biological hazards not regulated under part 113. For example, the heat-stable toxin produced by the Staphylococcus aureus is a biological hazard that would not be inactivated or destroyed by the processing required under part 113 (Refs. Anderson et al 1996. JFP and Bennett and Berry 1987 J Food Sci).

We request comment on the criteria that should be used to determine whether a facility is in compliance with part 113.

4. Proposed § 110.2(e)--Exemption Applicable to a Facility That Manufactures, Processes, Packs, or Holds a Dietary Supplement

Section 103(g) of FSMA provides that "[n]othing in the amendments made by [section 103 of FSMA] shall apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of sections 402(g)(2) and 761 of the [FD&C Act] (21 U.S.C. 342(g)(2), 379aa-1)." Section 402(g)(2) of the FD&C Act authorizes FDA to issue regulations to require good manufacturing practices for dietary supplements. FDA has issued such a regulation at part 111 (21 CFR 111) (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for

Dietary Supplements). Section 761 of the FD&C Act requires serious adverse event reporting for dietary supplements. FDA has issued guidance implementing section 761 (Ref. DS Adverse Event Reporting Guidance).

We interpret section 103(g) of FSMA in a manner analogous to our interpretation of sections 418(j) and (k) of the FD&C Act – i.e., as an exemption from the requirements for hazard analysis and preventive controls that we are proposing to establish in subpart C of part 110. We interpret the reference in section 103(g) of FSMA to "compliance with section 402(g)(2)" to mean compliance with part 111 (i.e., the regulation authorized by section 402(g)(2) of the FD&C Act). We tentatively conclude that Congressional intent regarding the reach of section 103(g) of FSMA is unambiguous in that section 103(g) of FSMA directly limits the provision "with regard to the manufacturing, processing, packing, or holding of a dietary supplement ...." We also tentatively conclude that we should include a provision implementing section 103(g) of FSMA in the proposed rule to establish by regulation the reach of the provision. Proposed § 110.2(e) would provide that Subpart C would not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of Part 111 (Current good manufacturing practice in manufacturing, packing, labeling, or holding operations for dietary supplements) and section 761 of the FD&C Act (Serious Adverse Event Reporting for Dietary Supplements).

We request comment on the criteria that should be used to determine whether a facility is in compliance with part 111 and with section 761 of the FD&C Act.

5. Proposed § 110.2(f)--Exemptions Applicable to Activities Subject to Standards for Produce Safety in Section 419 of the FD&C Act

Section 418(k) of the FD&C Act provides that section 418 of the FD&C Act "shall not apply to activities of a facility that are subject to section 419 [of the FD&C Act]". Section 419, "Standards for Produce Safety," requires FDA to establish by regulation "science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which [FDA] has determined that such standards minimize the risk of serious adverse health consequences or death." Section 419(h) of the FD&C Act provides that section 419 of the FD&C Act "shall not apply to activities of a facility that are subject to section 418 [of the FD&C Act]." In an upcoming rulemaking to implement section 419, FDA expects to apply section 419 to "farms" as would be defined in proposed §§ 1.227 and 1.328 that are not required to register under section 415 of the FD&C Act. FDA also expects to apply section 419 to farms that conduct an activity (or activities) that triggers the section 415 registration requirement ("farm mixed-type facilities"), but only with respect to their activities that are within the farm definition and therefore do not trigger the registration requirement. See section VIII.E of this document for a discussion of our proposed revisions and additions to the definitions in current §§ 1.227(b) and 1.328.

Establishments that are exempt from registration under section 415 of the FD&C Act as "farms" would not be subject to section 418 of the FD&C Act when conducting activities within the farm definition. Farm mixed-type facilities would be subject to section 418 of the FD&C Act when conducting those activities that trigger the section 415 registration requirement. We tentatively conclude that Congressional intent regarding the reach of section 418(k) of the FD&C

Act is unambiguous in that section 418(k) directly limits the exemption to activities of the facility that are subject to section 419 of the FD&C Act. We also tentatively conclude that we should include a provision implementing section 418(k) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption. Proposed § 110.2(f) would provide that Subpart C would not apply to activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety).

As discussed immediately below in section X.B.6 of this document, proposed § 110.2(g) and (h) would provide for an exemption from the requirements of proposed subpart C for certain on-farm, low-risk manufacturing, processing, packing or holding activities by a small or very small business.

6. Proposed § 110.2(g) and (h)--Exemption Applicable to Certain On-farm Manufacturing, Processing, Packing or Holding Food by a Small or Very Small Business

a. Requirements of section 103 of FSMA. As discussed in section VIII.A of this document, section 103(c)(1)(A) of FSMA requires that the Secretary publish a proposed rule to promulgate regulations with respect to "(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the [FD&C Act]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of section 415." Section 103(c)(1)(B) of FSMA directs that the rulemaking "shall enhance the implementation of such section 415 [of the FD&C Act] and clarify the activities that are included as part of the definition of the term "facility" under such section 415." In section VIII of this document, we discuss clarifications of certain on-farm activities and whether they trigger the section 415 registration requirement in order to enhance

the implementation of section 415 by clarifying the treatment of various activities for purposes of section 415, including activities conducted on farms.

As discussed in section VIII.A of this document, section 103(c)(1)(C) of FSMA requires that the Secretary conduct a science-based risk analysis of "(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership." As discussed in section VIII.G of this document, we have evaluated the risk of such activity/food combinations (Ref. risk evaluation).

Section 103(c)(1)(D)(i) of FSMA requires that, in promulgating the regulations under Section 103(c)(1)(A), "the Secretary shall consider the results of the science-based risk analysis conducted under [Section 103(c)(1)(C) of FSMA], and shall exempt certain facilities from the requirements in section 418 of the [FD&C Act]…, including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of [the FD&C Act]… or modify the requirements in [sections 418 or 421 of the FD&C Act], as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk." Section 103(c)(1)(D)(ii) of FSMA provides that "[t]he exemptions or modifications under [section 103(c)(1)(D)(i) of FSMA] shall not include an exemption from the requirement to register under section 415 of the [FD&C Act]… if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the [FD&C Act]."

b. FDA's interpretation of section 103(c)(1)(D)(i) of FSMA. FDA considers the language of section 103(c)(1)(D)(i) of FSMA to be unambiguous with regard to the reach of the exemption. The language of section 103(c)(1)(D)(i) includes the requirement "if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk." FDA tentatively concludes that this language is unambiguous and means that Congress intended us to exempt a facility from, or modify the requirements of, section 418 of the FD&C Act under this authority if the facility only conducts a limited set of low-risk activity/food combinations that would otherwise be subject to section 418, that is, to the extent the facility is subject to section 418, it "is engaged only in" the identified activities involving the identified foods. This interpretation seems both protective of public health and consistent with the preventive purpose of section 418 of the FD&C Act. This interpretation would mean that a facility would be required to conduct a hazard analysis and establish and implement risk-based preventive controls for all activities conducted on all foods (including low-risk activity/food combinations) if a facility conducts a single activity subject to section 418 of the FD&C Act that is not a low-risk activity/food combination, unless the facility qualifies for another exemption from subpart C.

c. Proposed § 110.2(g)--Exemptions for on-farm low-risk packing or holding activity/food combinations. Proposed § 110.2(g) would provide that subpart C would not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the following low-risk packing or holding activity/food combinations on food not grown, raised, or

consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership:

- (1) Packing or re-packing (including weighing or conveying incidental to packing or re-packing) of:

(i) Intact fruits and vegetables (for purposes of proposed §§ 110.2(g) and (h) only, "intact fruits and vegetables" refers only to fruits and vegetables other than seeds for consumption, peanuts, and tree nuts);

(ii) Grains and grain products;

(iii) Seeds for consumption;

(iv) Peanuts and tree nuts;

(v) Honey (raw and pasteurized);

(vi) Maple sap for syrup and maple syrup; and

(vii) Acid foods made into jams, jellies and preserves;

- (2) Sorting, culling, or grading incidental to packing or storing of:

(i) Intact fruits and vegetables;

(ii) Grains and grain products;

(iii) Seeds for consumption;

(iv) Peanuts and tree nuts;

(v) Honey (raw and pasteurized); and

(vi) Maple sap for syrup and maple syrup; and

- (3) Storing (ambient, cold and controlled atmosphere) of:

(i) Intact fruits and vegetables;

(ii) Grains and grain products;

(iii) Seeds for consumption;

(iv) Peanuts and tree nuts;

(v) Honey (raw and pasteurized);

(vi) Maple sap for syrup and maple syrup; and

(vii) Acid foods made into jams, jellies and preserves.

The low-risk on farm packing and holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership reflect the findings of the risk evaluation (Ref. risk evaluation) required by section 103(c)(1)(C) of FSMA, discussed in section VIII.H of this document. For purposes of proposed §§ 110.2(g) and (h) only, "intact fruits and vegetables" refers only to fruits and vegetables other than seeds for consumption, peanuts, and tree nuts. Peanuts, tree nuts, and seeds for consumption can be considered part of "fruits and vegetables" as a general matter, but FDA has addressed those foods separately for the purpose of the risk evaluation and the proposed §§ 110.2(g) and (h) exemptions in order to accurately reflect differences in activity/food combinations likely to be performed on farm mixed-type facilities on those foods as compared to other fruits and vegetables, as well as differences in risk across those activity/food combinations.

d. Proposed § 110.2(h)--Exemptions for on-farm low-risk manufacturing/processing activity/food combinations. Proposed § 110.2(h) would provide that subpart C would not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the following:

(1) When conducted on a farm mixed-type facility's own raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (those grown or raised on that farm mixed type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:

(i) Artificial ripening of intact fruits and vegetables

(ii) Boiling/evaporation of maple sap to make maple syrup

(iii) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables, seeds for consumption, or peanuts or tree nuts (e.g., coating apples with caramel, coating seeds or nuts with spices)

(iv) Chopping peanuts and tree nuts

(v) Drying/dehydrating intact fruits and vegetables where the drying creates a distinct commodity (e.g., drying fruits or herbs)

(vi) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts)

(vii) Making jams, jellies and preserves from acid foods (e.g., acid fruits)

(viii) Salting seeds for consumption, raw peanuts, and raw tree nuts;

(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:

(i) Making honey (including extraction and filtration);

(ii) Making maple syrup (including filtration and boiling/evaporation);

(iii) Artificial ripening of intact fruits and vegetables;

(iv) Cooling intact fruits and vegetables using cold air;

(v) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables, seeds for consumption, and peanuts and tree nuts (e.g., coating apples with caramel, coating seeds or nuts with spices);

(vi) Chopping peanuts and tree nuts;

(vii) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables and seeds for consumption;

(viii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);

(ix) Labeling (including stickering) intact fruits and vegetables, grain and grain products, seeds for consumption, intact single-ingredient peanuts or tree nuts (shelled and unshelled), honey, and maple sap or syrup;

(x) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

(xi) Mixing/blending intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup;

(xii) Packaging (other than modified atmosphere or vacuum packaging) intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup;

(xiii) Packaging peanuts or tree nuts using modified atmosphere or vacuum methods;

(xiv) Salting seeds for consumption and peanuts and tree nuts;

(xv) Sifting grain or grain products and seeds for consumption;

(xvi) Shelling intact fruits and vegetables (e.g., beans and peas such as black-eyed peas, kidney, lima, and pinto beans), seeds for consumption, and peanuts and tree nuts;

(xvii) Sorting, culling and grading (other than when incidental to packing or storage) intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup;

(xviii) Treating intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (e.g., fumigation); and

(xix) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

The low-risk on-farm manufacturing/processing activity/food combinations reflect the findings of the risk evaluation (Ref. risk evaluation) required by section 103(c)(1)(C) of FSMA, discussed in section VIII.H of this document.

7. Proposed § 110.2(i)-- Exemptions Related to Alcoholic Beverages

a. Requirements of FSMA. Section 116(a) of FSMA (21 U.S.C 2206(a)) provides that, except as provided by certain listed sections in FSMA, nothing in FSMA, or the amendments made by FSMA, "shall be construed to apply to a facility that- (1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and (2) under section 415 of the [FD&C Act] is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages."

Section 116(b) of FSMA (21 U.S.C. 2206(b)) provides that section 116(a) of FSMA "shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food,

except that [section 116(a) of FSMA] shall apply to a facility described in [section 116(a) of FSMA] that receives and distributes non-alcohol food, provided such food is received and distributed- (1) in a prepackaged form that prevents any direct human contact with such food; and (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury."

Section 116(c) of FSMA (21 U.S.C. 2206(c)) provides that, "[e]xcept as provided in [sections 116(a) and (b) of FSMA], [section 116] shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of [FSMA] (including the amendments made by [FSMA])."

b. FDA's interpretation of Section 116(a)(1) of FSMA. FDA is aware that some facilities that manufacture, process, pack, or hold alcoholic beverages are required to obtain what is technically called a "permit" from the Secretary of the Treasury ("Treasury") and some are required to "register" (such as "dealers" under 26 U.S.C. 5124) with Treasury. Others must adhere to functionally similar requirements by submitting a notice or application and obtaining approval from Treasury prior to commencing business. As examples, distilled spirits plants require a Federal Alcohol Administration Act (FAA Act) basic permit (27 U.S.C. 203-204) and must register under the Internal Revenue Code of 1986 (IRC) (26 U.S.C. 5171-72); wineries must obtain an FAA Act basic permit to produce or blend wine and as a bonded wine cellar must obtain approval of an application under the IRC (26 U.S.C. 5351 and 5356); and breweries must file a brewer's notice under the IRC and must obtain approval of that notice from Treasury (26 U.S.C. 5401). Because Treasury informs FDA that these are functionally similar requirements, and because FDA has not identified a public health basis or an indication that Congress intended

for these various facilities to be treated differently for the purposes of section 116 of FSMA, FDA tentatively concludes that the phrase "obtain a permit or register" is ambiguous and should be interpreted broadly, to include not only facilities that must obtain what is technically named a "permit" or must "register" with Treasury, but also those facilities that must adhere to functionally similar requirements as a condition of doing business in the United States, namely, by submitting a notice or application to Treasury and obtaining Treasury approval of that notice or application. Proposed § 110.2(i)(1)(i) would provide that obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States under the relevant statutes would be treated the same as obtaining a permit or registering with Treasury under those statutes for the purposes of section 418 of the FD&C Act.

FDA understands that all of the facilities described in FSMA section 116(a)(1) are located in the United States (including Puerto Rico under the FAA Act). In isolation, therefore, section 116(a)(1) of FSMA appears to operate to exempt only certain domestic facilities from the requirements of section 418 of the FD&C Act. Under this interpretation, while domestic facilities would be exempt from section 418 of the FD&C Act if they met all of the required criteria, foreign facilities would not be exempt because they do not satisfy section 116(a)(1) of FSMA.

This raises the question of whether such a construction of section 116(a)(1) of FSMA would be consistent with the risk-based public health principles underlying section 418 of the FD&C Act and FSMA generally; and raises concerns related to U.S. trade obligations, for example, those found in the World Trade Organization Agreements. See, e.g., The General Agreement on Tariffs and Trade 1994, (GATT 1994) Art. III(4) ("The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded

treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale…."); Agreement on the Application of Sanitary and Phytosanitary Measures, (SPS Agreement), Art. 2(3) ("Member shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members."). Importantly, section 404 of FSMA provides that "Nothing in this Act… shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party."

As a result, FDA considers the language of section 116 of FSMA, read together with the language of section 404 of FSMA, to be ambiguous with regard to foreign facilities that manufacture, process, pack, or hold alcoholic beverages. There are multiple possible interpretations of this provision. For example, section 116 of FSMA could be read to exempt only domestic facilities from the requirements of section 418 of the FD&C Act, or section 404 of FSMA could be read to make the section 116(a)(1) exemption inapplicable for all facilities for the purposes of section 418 of the FD&C Act. In considering sections 116 and 404 together, FDA tentatively concludes that it is reasonable to construe section 116(a)(1) to refer not only to domestic firms, but also to foreign firms in order to be consistent with the risk-based public health principles underlying section 418 of the FD&C Act and FSMA generally, and to avoid any inconsistency with treaties or international agreements to which the United States is a party. Accordingly, proposed § 110.2(i)(1)(i) would apply the exemption not only to domestic facilities that are required to secure a permit, registration, or approval from Treasury under the relevant

statutes, but also to foreign facilities of a type that would require such a permit, registration, or approval if they were domestic facilities.

c. FDA's interpretation of Section 116(b) of FSMA. FDA also considers the language of section 116 of FSMA to be ambiguous with regard to the reach of the exemption for facilities that manufacture, process, pack, or hold alcoholic beverages and also receive, manufacture, process, pack, hold, or distribute non-alcohol food (for clarity FDA is using the term "food other than alcoholic beverages" rather than "non-alcohol food" in the codified and discussion that follows). Section 116(b) of FSMA provides that section 116(a) "shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food," except when the non-alcohol food is "received and distributed-- (1) in a prepackaged form that prevents any direct human contact with such food; and (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury."

In order to interpret the application of section 116 to food other than alcoholic beverages, FDA must interpret the meaning of the phrase "received and distributed … in a prepackaged form that prevents any direct human contact with such food" in section 116(b) of FSMA. FDA tentatively concludes that this phrase refers to food that is completely enclosed in packaging during the entire time it is under the facility's direct control, such that direct human contact with such food is prevented. Under this interpretation, facilities that conduct activities using such packaged food without opening the packaging after receiving the food and before distributing it are receiving and distributing food in prepackaged form that prevents any direct human contact with such food. For example, a winery that assembles gift baskets containing bottles of its own wine and prepackaged boxes of crackers purchased from a supplier, without opening the boxes

of crackers, would be receiving and distributing the food other than alcoholic beverages (crackers) in prepackaged form that prevents direct human contact with such food.

Considering this interpretation and the fact that alcohol-related facilities also handle food other than alcoholic beverages in other ways, one interpretation of section 116(b) could be that facilities described in 116(a) that also receive and distribute any food other than alcoholic beverages would be entirely ineligible for the exemption, and therefore wholly subject to section 418 of the FD&C Act, unless such food is received and distributed in prepackaged form and in amounts that constitute no more than 5 percent of a facility's overall sales. For example, if a brewery receives grain and distributes spent grain as animal feed, the entire brewery and all of its activities, including the manufacturing, processing, packing, and holding of beer, would be subject to section 418 of the FD&C Act under this interpretation because it receives and distributes food other than alcoholic beverages that is not in prepackaged form. However, if the same brewery simply disposed of its spent grain as waste, the brewery's manufacturing, processing, packing, and holding of beer would not be subject to section 418 of the FD&C Act. In other words, under this interpretation, whether the facility's manufacturing, processing, packing, or holding of alcohol would be subject to section 418 of the FD&C Act would depend on the facility's activities relating to food other than alcoholic beverages.

When considering the provision as a whole and in its statutory context, FDA tentatively concludes that another interpretation is more reasonable. The agency understands section 116 of FSMA, in general, to indicate that the manufacturing, processing, packing, or holding of alcoholic beverages at most alcohol-related facilities should not be subject to section 418 of the FD&C Act. FDA understands section 116(b) of FSMA to indicate that the receipt and distribution of food other than alcoholic beverages, including any manufacturing, processing,

packing, or holding of such food occurring at the facility between receipt and distribution, should be subject to section 418 of the FD&C Act, unless that food is received and distributed in prepackaged form and in amounts that constitute 5 percent or less of the facility's overall sales. Thus, activities related to alcoholic beverages (including the manufacturing, processing, packing, or holding of alcoholic beverages) at facilities within the scope of 116(a) of FSMA would not be subject to section 418 of the FD&C Act. Activities related to food other than alcoholic beverages (including the receiving, manufacturing, processing, packing, holding, and distributing of such foods) would be subject to section 418 of the FD&C Act even if those activities occur at facilities that are otherwise within the scope of 116(a) (unless they qualify for another exemption or are in prepackaged form and constitute 5 percent or less of the facility's overall sales). For example, if an alcoholic beverage distillery also makes non-alcoholic beverages, under this interpretation the alcoholic beverage distilling activities would be exempt from section 418 of the FD&C Act, but the activities related to non-alcoholic beverages would be subject to section 418 (assuming the non-alcoholic beverages are not in prepackaged form and constitute less than 5 percent of the facility's overall sales) unless they qualify for another exemption. This interpretation is also consistent with the rule of construction in section 116(c) of FSMA, which states, "except as provided in [sections 116(a) and (b) of FSMA], [section 116 of FSMA] shall not be construed to exempt any food, other than alcoholic beverages, . . . from the requirements of this Act."

When considering the statute as a whole, including its underlying purpose, this interpretation of section 116 also provides a more consistent, risk-based approach supported by public health principles. FDA concludes that Congress must have considered identifying hazards and implementing preventive controls for the manufacturing, processing, packing, and holding of

alcoholic beverages to warrant lower priority from a public health perspective than other foods. Congress may have made such a conclusion in light of the potential antimicrobial function of the alcohol content in such beverages and the concurrent regulation of alcoholic beverage-related facilities by both FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB). The definition of "food" under the FD&C Act includes "articles used for food or drink" and thus includes alcoholic beverages. See 21 U.S.C. 321(f). As such, alcoholic beverages are subject to the FD&C Act adulteration provisions, and implementing regulations, related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the requirements of current part 110. In addition, alcoholic beverages are regulated by TTB under the Federal Alcohol Administration Act and Chapter 51 of the Internal Revenue Code, which together establish “a comprehensive system of controls of alcoholic beverages, including on-site inspections and procedures that require the advance approval of statements of process and of formulas showing each ingredient to be used in the product” (Ref. FDA TTB/ATF MOU at II.B). FDA tentatively concludes that Congress intended to exempt certain alcohol-related facilities from section 418 of the FD&C Act because it found that, in light of the relatively low public health risk presented by the manufacturing, processing, packing, and holding of alcoholic beverages and their joint regulation by both FDA and TTB, the current regulatory scheme was sufficient to control the hazards associated with the manufacturing, processing, packing, and holding of alcoholic beverages. At the same time, FDA tentatively concludes that Congress did not intend to exempt manufacturing, processing, packing, or holding of food other than alcoholic beverages from section 418 except in the very limited circumstances set forth in section 116(b)(1) and (2) of FSMA.

At times, the manufacturing, processing, packing, or holding of alcoholic beverages is inseparable from the manufacturing, processing, packing, or holding of food other than alcoholic beverages. For example, a brewery that sells its spent grains as animal feed may be manufacturing beer and animal feed simultaneously for at least part of the brewing process. FDA tentatively concludes that section 418 of the FD&C Act does not apply to such inseparable activities. FDA tentatively concludes that section 418 applies to the food other than alcoholic beverages starting at the point at which it becomes physically separate from the alcoholic beverage because section 116(c) demonstrates Congress's intent to limit the reach of the exemption to alcoholic beverages. Thus, in the case of the brewery manufacturing animal feed, section 418 of the FD&C Act would apply to the spent grain sold as animal feed once the spent grain is physically separated from the beer, but not before that point.

Proposed § 110.2(i)(1) would provide that subpart C would not apply with respect to alcoholic beverages at facilities meeting the criteria in proposed § 110.2(i)(1)(i) and (ii). Proposed § 110.2(i)(2) would provide that subpart C would not apply with respect to food other than alcoholic beverages at facilities described in proposed § 110.2(i)(1), provided such food is in prepackaged form that prevents direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

We tentatively conclude that we should include a provision implementing section 116 of FSMA in the proposed rule to establish by regulation the reach of the provision. We request comment on our interpretation of section 116 of FSMA.

8. Proposed § 110.2(j)--Exemption Applicable to Facilities Solely Engaged in Storage of Raw Agricultural Commodities Other than Fruits and Vegetables Intended for Further Distribution or Processing

Section 418(m) of the FD&C Act provides in relevant part that FDA may by regulation "exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in… the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing".

Proposed 110.2(j) would exempt facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing from the requirements of subpart C. This provision would exempt, for example, facilities that only store whole grains (such as corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, and soybeans), unpasteurized shell eggs, and unpasteurized milk from subpart C. This would include facilities such as grain elevators and silos, provided that such facilities do not conduct other activities subject to section 418 of the FD&C Act. FDA notes that the proposed rule titled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" does not contain a similar exemption, but tentatively concludes that this exemption is appropriate. Outbreaks of foodborne illness have not been traced back to storage facilities solely engaged in the storage of non-fruit or vegetable RACs. In addition, as discussed in section X.B.9 of this document, facilities that are solely engaged in the storage of RACs are exempt from the current CGMP regulation, and FDA proposes to maintain this exemption from the CGMPs. FDA tentatively concludes that there would not be significant public health benefit to be gained by subjecting facilities that solely store non-fruit and vegetable RACs intended for further distribution or processing to the requirements of subpart C. Such

facilities would remain subject to the requirements of the FD&C Act. For example, if storage is done under insanitary conditions whereby the food may become contaminated with filth or rendered injurious to health, the food would be adulterated under section 402(a)(4) of the FD&C Act.

9. Proposed § 110.2(k)--Exemption Applicable to Farms, Activities of "Farm Mixed-type Facilities" Within the Definition of "Farm," and the Holding or Transportation of One or More Raw Agricultural Commodities

Current § 110.19(a) provides that establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the FD&C Act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public, are exempt from the requirements of part 110. The exemption in current § 110.19(a) is commonly referred to as the "RAC exemption." Current § 110.19(b) states that we will issue special regulations if it is necessary to cover operations excluded under current § 110.19(a). In section VIII.D of this document, we discuss the meaning of the term "raw agricultural commodity" (RAC).

FDA is proposing a series of changes to current § 110.19. As discussed more fully below, FDA is proposing to:

- Redesignate current § 110.19(a) as proposed § 110.2(k);
- Delete current § 110.19(b);
- Make clear that the exemption from requirements in current part 110 remains limited to the current requirements (which presently are established in current part 110, subparts B, C, E, and G and would be re-established in proposed subpart B under this proposed rule); and

- Adjust and clarify what activities fall within this exemption based on experience and changes in related areas of the law since issuance of the CGMP regulation.

Proposed § 110.2(k) would provide that Subpart B does not apply to "farms" (as would be defined in proposed § 1.227), activities of farm mixed-type facilities (as would be defined in proposed § 1.227) that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the FD&C Act.

Redesignating current § 110.19(a) as proposed § 110.2(k) would simplify the rule by listing all exemptions in a single place. Deleting current § 110.19(b) would have no substantive effect, because current § 110.19(b) establishes no binding requirement on FDA or on persons that would be subject to part 110 and is unnecessary to retain in part 110. We may issue special regulations if it is necessary to do so irrespective of whether such a possibility is provided for in part 110. Making clear that the exemption from requirements in current part 110 remains limited to the current requirements is necessary because establishments that previously qualified for the RAC exemption would be subject to section 418 of the FD&C Act if they are required to register under section 415 of the FD&C Act, unless they otherwise qualify for an exemption from section 418 (in proposed § 110.2(a) through (h)).

Based on FDA's experience since issuance of the CGMP regulation and changes in related areas of the law since that time, FDA proposes to modify the existing language so that this exemption would apply to farms (as would be defined in proposed § 1.227), activities of farm mixed-type facilities that fall within the farm definition, and activities related to holding or transporting RACs.

FDA proposes to explicitly apply this exemption to "farms" within the meaning of that term in proposed § 1.227. In current § 110.19(a), FDA used the term "harvesting" to describe

one type of activity that could qualify for the exemption. Current § 110.19(a) and its use of the term "harvesting" predated the BT Act of 2002, which exempted "farms" from the new authorities in sections 414 and 415 of the FD&C Act. As discussed in section VIII.C of this document, FDA developed a definition of the term "farm" through notice and comment rulemaking implementing those authorities. Through those rulemakings, FDA learned that the terms "growing" and "harvesting" were not enough to capture the scope of the activities traditionally done on farms, and expanded the farm definition accordingly. Further, in this rulemaking, FDA is proposing to further clarify the scope of the farm definition. FDA recognizes today that farms within the definition of "farm" in proposed § 1.227 grow/raise and harvest their own RACs, pack and hold their own RACs or any food they may consume themselves, and/or manufacture food for their own consumption. The term "harvesting" in current § 110.19(a) is narrower than the current farm definition, but FDA concludes that the RAC exemption should apply to all activities within the farm definition and not merely to harvesting because other controls (such as the forthcoming produce safety rule under section 419 of the FD&C Act, and the statutory adulteration provision for food, section 402 of the FD&C Act) are more appropriate to apply to farms and their activities than is the CGMP regulation, which was developed and established for establishments other than farms. This is consistent with how FDA has interpreted the RAC exemption with respect to farms. For example, our "Guide to Produce Farm Investigations" (Ref. to FDA inspection guides document) advises FDA staff that "[f]arming operations, and subsequent operations in packing sheds and buildings, may not meet all requirements outlined in 21 CFR 110 or recommendations in the GAP Guide (Ref. FDA's GAPs Guide). However these documents serve as a useful tool in assessing whether raw agricultural products are handled under conditions that may adulterate the food." Farms within

the proposed § 1.227 definition are also not covered by section 418 of the FD&C Act because they do not have to register under section 415 of the FD&C Act, so they are not covered by any of proposed part 110. Activities within the farm definition are addressed by the adulteration provisions of the FD&C Act and the requirements in part 118 for egg producers (as applicable), and will also be addressed (as applicable) in an upcoming rulemaking for produce safety standards under section 419 of the FD&C Act.

FDA also proposes to exclude activities of farm mixed-type facilities that fall within the farm definition in proposed § 1.227 from subpart B. See section VIII.C of this document for a discussion of the term "farm mixed-type facility." FDA tentatively concludes that the portion of a farm mixed-type facility that is within the farm definition should be treated the same for the purposes of subpart B as are the same activities on farms that only conduct activities within the farm definition. FDA also proposes to exclude activities related to holding or transporting RACs, whether or not such activities are performed on farms. The term "holding" would have the same meaning here as in the revisions we are proposing to current § 1.227(b)(5). Current § 110.19(a) uses the term "storage" to describe these activities. In proposed § 1.227, "holding" is defined as "storage of food" for establishments other than farms and farm mixed-type facilities. The term "transportation" would be used instead of the current term "distribution" to make clear that the scope of the activities exempted by that term is limited to movement of RACs in commerce by a motor vehicle or rail vehicle, and does not extend to other activities, such as packing, that might be considered to be part of the broader term "distribution." Entities that would be entirely exempted by these terms in the proposed revised provision would include warehouses, silos, or other entities that only store RACs and transporters that only handle RACs. Because section 418 of the FD&C Act applies to any facility that is required to register under

section 415 unless an exemption from section 418 applies, it is a separate question whether these entities would be subject to subpart C. Many of the establishments that are exempted from subpart B by this proposed provision are also likely to be exempt from subpart C or subject to modified requirements under section 418 of the FD&C Act, either because they do not have to register under section 415 (e.g., common carriers), or they qualify for an exemption or modified requirements under section 418 (e.g., modified requirements for certain warehouses under proposed § 110.5, exemption for small or very small businesses performing only on-farm low-risk activity/food combinations under proposed § 110.2(g) and (h), exemption for facilities that are solely engaged in the storage of raw agricultural commodities other than fruits and vegetables intended for further distribution or processing under proposed § 110.2(j)).

By removing the term "distribution" from current § 110.19(a), FDA proposes to exclude packing of RACs from the revised exemption, i.e., to subject packing of RACs to the requirements of subpart B. As discussed in section II.A.1 of this document, the CGMP working group recommended that the agency consider removing the RAC exclusion entirely, and recommended that the agency request further comments on the appropriate application of CGMP controls to raw agricultural product harvesting, packing, storage and distribution (Ref. CGMP working group report). These concerns were based on investigations of outbreaks linked to fresh produce that had "identified contamination during production and harvest, initial processing and packing, distribution, and final processing as the likely source of product contamination." (Ref. CGMP working group report). Since issuance of the CGMP working group report, FDA has continued to investigate foodborne illness outbreaks and contamination events associated with fresh produce and other RACs, and continues to be concerned about sanitation practices at establishments that pack RACs. Packing of RACs has been implicated as a likely source of

contamination in multi-state foodborne illness outbreaks associated with RACs (Ref. Tauxe, R. E. 1997. Emerging Foodborne Diseases: An evolving Public Health Challenge. Emerging Infect. Dis. -3(4):425-434) (Ref. Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis, FDA, Oct. 2011) (Ref. CDC MMWR 9/7/07, 56(35); 909-911 Multistate Outbreaks of Salmonella infections Associated with Raw Tomatoes Eaten in Restaurants-- United States, 2005-2006).

Accordingly, FDA tentatively concludes that packing of RACs should be subject to the CGMP requirements in proposed subpart B, but that the other activities discussed above for RACs are sufficiently addressed, or will be addressed, by FDA in other ways. Growing/raising and harvesting of RACs, and all activities within the farm definition, such as on-farm packing and holding of a farm's own RACs, will continue to be addressed through the statutory adulteration provisions in the FD&C Act, the requirements of part 118 for egg producers (as applicable), and the upcoming rulemaking establishing produce safety standards (as applicable) under section 419 of the FD&C Act. FDA tentatively concludes that it is appropriate to address food safety on farms in this fashion, rather than by requiring farms to comply with subpart B. Manufacturing/processing steps conducted on RACs are already subject to the current CGMP regulation and will continue to be subject to the requirements of subpart B, which applies to manufacturing/processing, including when such activities are performed on RACs. This includes manufacturing/processing steps that may occur at establishments that are commonly known as "packinghouses," such as washing and treating fruits and vegetables. "Distribution" is a term that might include activities such as transportation and packing (including re-packing). For clarity, we now discuss those two steps separately. Transportation of non-RACs is subject to the

CGMP requirements in current § 110.93, and FDA expects to address transportation of food in more detail in rulemaking to implement the Sanitary Food Transportation Act of 2005 (Pub. L. 109-59) and section 416 of the FD&C Act (75 FR 22713, Apr. 30, 2010). Section 416(b) of the FD&C Act requires FDA to promulgate regulations to "require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated." In addition, FDA is not currently aware of foodborne illness outbreaks related to RACs that were likely to have been caused by insanitary conditions during transportation conditions. This leaves only packing as a step of concern that is not being sufficiently addressed, either through application of the CGMP requirements or in another way. Therefore, FDA tentatively concludes that packing of RACs that does not fall within the farm definition should be subject to the requirements in proposed subpart B. We request comment on this conclusion and on whether there any aspects of proposed subpart B that should not apply to the packing of RACs.

Because the current exemption in §110.19(a) is limited to "establishments engaged solely in" the listed activities, it does not exempt establishments that conduct any activities relating to food for human consumption other than the specifically identified activities for RACs. FDA tentatively concludes that would be reasonable to revise the exemption so that it would exempt the specifically identified activities when performed on RACs, regardless of whether the establishment that conducts those activities also conducts other activities that do not qualify for the exemption. This is because, as in the section 418(j)(1) exemptions discussed in sections X.B.2 and X.B.3 of this document (for activities covered by parts 120, 123, and 113), it is more appropriate to subject these activities to controls other than those in proposed subpart B, and

these activities should be regulated in the same way whether or not other activities subject to proposed subpart B take place at the same establishment. If activities subject to proposed subpart B do take place at the same establishment, compliance with proposed subpart B with respect to those activities should provide the necessary protection for food subject to those activities regardless of whether RACs are also stored or transported by the same establishment, or if activities inside the farm definition are conducted at the same establishment.

FDA also proposes to delete "which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public" from the current exemption. While this phrase captured FDA's original reasoning for providing the RAC exemption, it is confusing because many RACs are not so processed (as is often the case for fresh produce, for example) and the operative part of the exemption is that it applies to RACs, not only some RACs depending on whether they receive later manipulation.

C. Proposed § 110.3 - Definitions

1. Redesignation

FDA is proposing to redesignate all definitions in current § 110.3(a) through (r) as proposed § 110.3, eliminate paragraph designations (such as (a), (b), and (c)), and add new definitions in alphabetical order. Paragraph designations are not necessary when the definitions are presented in alphabetical order. Proposed § 110.3 would remain within subpart A.

2. Current Definitions That FDA Is Proposing to Delete

Current § 110.3(p) defines "shall" to be used to state mandatory requirements. FDA is proposing to delete the definition of "shall" and use "must" instead, as discussed in section IX.G of this document.

Current § 110.3(q) defines "should" to be used to state recommended or advisory procedures or identify recommended equipment. FDA is proposing to delete the definition "should." As discussed in section IX.F of this document, FDA is proposing to either delete non-binding provisions of current part 110 (e.g., provisions using "should") or revise them to establish new requirements. Consequently, the definition for "should" is not needed.

3. Current Definitions That FDA Is Proposing to Revise

Current § 110.3(e) defines "critical control point" to mean a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food. Current § 110.3(e) was established in 1986. Current § 110.3(e) preceded various currently used definitions of "critical control point" (CCP) – e.g., in the NACMCF HACCP guidelines (Ref. NACMCF), the Codex HACCP Annex (Ref. Codex 2003), and Federal HACCP regulations for seafood (part 123), juice (part 120), and meat and poultry (9 CFR 417). Proposed § 110.3 would revise the current definition of "critical control point" to match the statutory definition in section 418(o)(1) of the FD&C Act and to be consistent with definitions in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Proposed § 110.3 would define "critical control point" to mean a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

A non-substantive difference between the definition of CCP in proposed § 110.3 and the definition of CCP in § 120.3(d) is that proposed § 110.3 would incorporate the phrase "food safety hazard" into the definition of CCP, whereas § 120.3(d) uses the phrase "food hazard." We see no meaningful difference between "food safety hazard" and "food hazard," whether

comparing proposed § 110.3 to § 120.3(d) or whether comparing § 120.3(d) to § 123.3(b) (which uses the phrase "food safety hazard" in its definition of CCP). In fact, we see no meaningful difference between "food safety hazard" and "hazard" and are proposing to define the term "hazard" rather than "food safety hazard" for the purpose of part 110 (see the discussion of our definition of the term "hazard" in section X.C.4 of this document). Section 418 of the FD&C Act largely refers to "hazards" and the single reference to "food safety hazard" is in the statutory definition of CCP. Because the phrase "food safety hazard" appears in so many current definitions of CCP, we tentatively conclude it is appropriate to propose to establish the statutory definition of CCP into the proposed rule, even though this will be the only place in the proposed rule where we use the term "food safety hazard."

There are slight differences in wording among the various currently used definitions of CCP – e.g., whether the definition uses the term "control" or the phrase "control measure" and in how the definition incorporates concepts such as "essential," "preventing," eliminating" or "reducing to acceptable level" hazards. As already discussed (see section II.C.1 of this document), part 120 preceded the 1998 NACMCF guidelines and, thus, has the most differences. For the purpose of this proposed rule, we do not see these differences as meaningful and tentatively conclude that the statutory definition of CCP in section 418(o)(1) of the FD&C Act is, for practical purposes, consistent with existing definitions and that our proposed definition of CCP would present no conflict with existing recommendations.

The definition of CCP in proposed § 110.3 would also differ from the definition of CCP in current § 110.3(e) in that the definition of CCP would no longer explicitly address filth. Deleting filth from the definition of CCP is consistent with section 418(o)(1) of the FD&C Act, and with the various current definitions of CCP, to emphasize food safety hazards generally

rather than specifically identifying filth, which may or may not present a food safety hazard, depending on the circumstances. Similarly, the definition of CCP in proposed § 110.3 also would no longer explicitly address decomposition of the final food. However, section 418(b)(1) of the FD&C Act refers to decomposition among the hazards to be identified and evaluated and, thus, decomposition is considered within the term "hazard" when it affects the safety of the product.

Current § 110.3(g) defines "food-contact surfaces" as those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Current § 110.3(g) also specifies that "food-contact surfaces" includes utensils and food-contact surfaces of equipment. FDA is proposing to revise the definition for "food-contact surfaces" to include the phrase "or other transfer" after "drainage." FDA is proposing this revision to clarify that surfaces from which any transfer involving liquids or non-liquids onto the food or onto surfaces that contact the food are food-contact surfaces. Proposed § 110.3 would define "food-contact surfaces" to mean those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Proposed § 110.3 would also specify that "food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Current § 110.3(i) defines "microorganisms" to mean yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. Current § 110.3(i) also specifies that the term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning

of the act. Current § 110.3(i) also states that, occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism. FDA is proposing to revise the definition for "microorganisms" to also include protozoa and microscopic parasites. FDA is proposing this revision to clarify that FDA considers not only yeasts, molds, bacteria and viruses, but also protozoa and microscopic parasites, to be microorganisms of importance in the safe and sanitary production of foods. As discussed in section IX.G of this document, FDA is proposing to delete the phrases "but is not limited to," and "within the meaning of the act." FDA also is proposing to delete the last sentence in the definition because it is not needed. Proposed § 110.3 would define "microorganisms" to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. Proposed § 110.3 would also specify that the term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Current § 110.3(k) defines "plant" to mean the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food. FDA is proposing to revise the definition for "plant" by adding "processing" and "packing" and deleting "labeling" and "packaging" so that activities listed in the definition are consistent with activities covered by part 110. As discussed in section IX.C.2 of this document, FDA is proposing to consistently use the terms "manufacturing, processing, packing and holding" to reflect the group of terms used in section 418(a) of the FD&C Act to broadly identify activities that take place in food facilities. As discussed later in this section, "labeling" and "packaging" would be included in the definition of manufacturing/processing and do not need to be repeated

in the definition of "plant." As discussed above in section IX.C.2 of this document, FDA also is proposing to replace the term "facility" with the term "establishment." Proposed § 110.3 would define "plant" to mean the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Current § 110.3(n) defines "safe-moisture level" as a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. Current § 110.3(n) also specifies that the maximum safe moisture level for a food is based on its water activity (a_w), and that an a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms. FDA is proposing to revise the definition for "safe-moisture level" to:

- Delete the hyphen between "safe" and "moisture." The hyphen is not necessary.
- Remove the word "maximum" before "safe moisture level." FDA tentatively concludes that this word is not needed, since the word "maximum" is implicit when referring to "safe" with respect to moisture level.
- Replace the phrase "based on" with "related to." FDA tentatively concludes that the term "related to" is more appropriate because moisture level is not the only factor that determines water activity.
- Replace the phrase "manufacturing, storage, and distribution" with the phrase "manufacturing, processing, packing, and holding." As discussed in section IX.C.1 of this document, we are proposing to use this group of terms to broadly identify activities that take place in food facilities.

With these proposed changes, proposed § 110.3 would define "safe moisture level" to mean a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. Proposed § 110.3 would also specify that the safe moisture level for a food is related to its water activity (a_w), and that an a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Current § 110.3(o) defines "sanitize" to mean to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer. FDA is proposing to revise the definition for "sanitize" to include the term "cleaned" before "food-contact surfaces." It is well established that sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces (Ref. Troller, J. A. 1993. Sanitation in Food Processing). Proposed § 110.3 would define "sanitize" to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

4. New Definitions

FDA is proposing to define the term "affiliate" to mean any facility that controls, is controlled by, or is under common control with another facility. The proposed definition would incorporate the definition in section 418(l)(4)(A) of the FD&C Act and would make the meaning of the term clear when used in the proposed definition of "qualified facility."

FDA is proposing to define "calendar day" to mean every day shown on the calendar.

FDA is proposing to define the term "cross-contact" to mean the unintentional incorporation of a food allergen into a food. We discuss cross-contact in more detail in section IX.D of this document.

FDA is proposing to define the term "designated food safety regulation" to mean a regulation contained in part 106 (Infant Formula Quality Control Procedures), part 107 (Infant Formula), subpart B (Current Good Manufacturing Practice) or subpart C (Hazard Analysis And Risk-Based Preventive Controls) of part 110, part 111 (Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements), part 113 (Thermally Processed Low-Acid Foods Packaged In Hermetically Sealed Containers), part 114 (Acidified Foods), part 118 (Production, Storage, And Transportation Of Shell Eggs), part 120 (Hazard Analysis and Critical Control Point Systems), part 123 (Fish And Fishery Products), or part 129 (Processing And Bottling Of Bottled Drinking Water). We are proposing to define "designated food safety regulation" as a concise term to be used to reference multiple regulations in the proposed provisions for a supplier approval and verification program (proposed § 110.152). We explain the basis for including the named regulations within the term "designated food safety regulation" in section XII.H of this document (i.e., in the discussion of the applicable provision of proposed § 110.152).

FDA is proposing to define the term "environmental pathogen" to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. Examples of environmental pathogens include Salmonella spp. and Listeria monocytogenes. FDA requests comment on this definition and the types of organisms that should be considered environmental pathogens,

including whether spores of pathogens such as Clostridium perfringens or Bacillus cereus should be considered environmental pathogens.

FDA is proposing to define the term "facility" to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act in accordance with the requirements of 21 CFR part 1, subpart H. The proposed definition would incorporate the definition in section 418(o)(2) of the FD&C Act.

FDA is proposing to define the term "farm" by reference to the definition of that term in proposed §1.227. See section VIII of this document for detailed discussion of farms and mixed-type facilities. We are proposing to cross-reference the definition of "farm" rather than to define it in part 110 because the definition of "farm," under both current § 1.227(b)(3) and proposed § 1.227, includes the word "facility" with a meaning that is broader than the meaning of "facility" in section 418(o)(2) of the FD&C Act. Under part I, subpart H, the term "facility" is not limited to entities that are required to register under section 415 of the FD&C Act. We are proposing to cross-reference the definition to reduce the potential confusion that could result if we used the term "facility" to have two different meanings within part 110.

FDA is proposing to define the term "food allergen" to mean a major food allergen as defined in section 201(qq) of the FD&C Act. Section 201(qq) defines the term "major food allergen" to mean any of the following: milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans, or a food ingredient that contains protein derived from one of these foods, with certain exceptions. The proposed definition would be consistent with the requirement in section 418(a) of the FD&C Act that the owner, operator, or agent in charge of a facility "identify and implement preventive controls to significantly minimize or prevent the occurrence

of ... hazards and provide assurances that [food manufactured, processed, packed, or held by the facility] is not ... misbranded under section 403(w) [of the FD&C Act]." Section 403(w) of the FD&C Act provides certain labeling requirements for foods that bear or contain a major food allergen, with certain exceptions.

FDA is proposing to define the term "harvesting" as applicable to farms and farm mixed-type facilities and meaning activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. The proposed definition would also specify that harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership; and that harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. The proposed definition would state that gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting. We are proposing to use the same definition of "harvesting" as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of "harvesting."

FDA is proposing to define "hazard" to mean any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines (Ref. NACMCF) and our HACCP regulation for juice (§120.3(g)) define "hazard" and "food hazard," respectively as a biological, chemical, or

physical agent that is reasonably likely to cause illness or injury in the absence of its control. The Codex HACCP Annex defines "hazard" as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (Ref. Codex). Our HACCP regulation for seafood (§123.3(f)) and the FSIS HACCP regulation for meat and poultry (9 CFR 417.1) define "food safety hazard" as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. A difference between the proposed definition of "hazard" and the definitions established in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry is that the proposed definition would include radiological agents whereas the various definitions of "hazard," "food hazard" and "food safety hazard" under these HACCP systems do not. We are proposing to include radiological agents to implement section 418(b)(1)(A) of the FD&C Act, which includes radiological hazards as an example of known or reasonably foreseeable hazards that may be associated with the facility. We describe biological, chemical, radiological, and physical hazards in sections II.D and XII.B.3 of this document.

FDA is proposing to define the term "hazard that is reasonably likely to occur" to mean a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls. The proposed definition is consistent with Federal HACCP regulations for seafood, juice, and meat and poultry. Our HACCP regulation for seafood describes a food safety hazard that is reasonably likely to occur as one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that

there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls (§123.6(a)). Our HACCP regulation for juice describes a food hazard that is reasonably likely to occur as one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed (§ 120.7(a)(2)). The FSIS HACCP regulation for meat and poultry describes a food safety hazard that is reasonably likely to occur as one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls (9 CFR 417.2(a)). In section XII.B.4 of this document, we explain how the term "hazard that is reasonably likely to occur" would implement section 418(b)(1) of the FD&C Act and relate this term to the NACMCF HACCP guidelines and the Codex HACCP Annex.

FDA is proposing to define the term "hazard that is reasonably likely to occur, in the context of supplier controls" to mean a hazard for which a prudent owner, operator, or agent in charge of a receiving facility would establish controls or verify that the supplier has controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being received in the absence of those controls. We are proposing to distinguish the term "hazard that is reasonably likely to occur" in the context of supplier controls to make clear that, in some cases, a receiving facility may verify that a supplier has controls for a hazard rather than establish controls at the receiving facility. For example, the owner, operator, or agent in charge of a receiving facility that manufactures cheese may rely on the supplier of milk to pasteurize the

milk as a control on biological hazards rather than pasteurize the milk at the receiving facility. We also are proposing to distinguish the term "hazard that is reasonably likely to occur" in the context of supplier controls to emphasize that, in the proposed supplier approval and verification program (see discussion of proposed § 110.152 in section XII.H of this document), the focus would be in the context of whether the hazard would be in the food as it is received by the receiving facility.

FDA is proposing to define the term "holding" to mean the storage of food. The proposed definition would also state that holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks; and that, for farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. We are proposing to use the same definition of "holding" as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of "holding."

FDA is proposing to define the term "manufacturing/processing" to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. The proposed definition would also state that examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. The proposed definition would also specify that, for farms and farm mixed-type

facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. We are proposing to use the same definition of "manufacturing/processing" as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of "manufacturing/processing."

FDA is proposing to define the term "mixed-type facility" to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. The proposed definition would also state that an example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. We are proposing to use the same definition as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of "mixed-type facilities."

FDA is proposing to define the term "monitor" to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The proposed definition is the same as the definition in our HACCP regulation for juice (§ 120.3(i)). The NACMCF guidelines define "monitor" to mean to conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification (Ref. NACMCF 1998). The Codex HACCP Annex defines "monitor" to mean the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (Ref. Codex 2003). Our HACCP regulation for seafood, and the

FSIS HACCP regulation for meat and poultry were each established before the current NACMCF HACCP guidelines and do not define the term "monitor." However, as discussed in section XII.E of this document, both of these regulations establish requirements that are consistent with the definition of "monitor" in proposed § 110.3 and in the NACMCF HACCP guidelines, the Codex HACCP Annex, and our HACCP regulation for juice.

FDA is proposing to define the term "packaging" to mean (when used as a verb) placing food into a container that directly contacts the food and that the consumer receives. FDA is proposing to use the same definition of "packaging" as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of "packaging."

FDA is proposing to define the term "packing" to mean placing food into a container other than packaging the food. The proposed definition would also specify that, for farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. We are proposing to use the same definition of "packing" as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of "packing."

FDA is proposing to define the term "preventive controls" to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at

the time of the analysis. The proposed definition would incorporate the definition in section 418(o)(3) of the FD&C Act.

FDA is proposing to define the term "qualified end-user" to mean, with respect to a food, the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that (1) is located (a) in the same State as the qualified facility that sold the food to such restaurant or establishment; or (b) not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. The proposed definition would incorporate the definition in section 418(l)(4)(B) of the FD&C Act.

FDA is proposing to define the term "qualified facility" to mean (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility as to which both of the following apply:

- During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
- The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

The proposed definition would incorporate the description of "qualified facility" in section 418(l)(1) of the FD&C Act with editorial changes to improve clarity .

FDA is proposing to define the term "qualified individual" to mean a person who has successfully completed training in the development and application of risk-based preventive

controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system. FDA is proposing to define the term "qualified individual" to have a concise term to use in proposed provisions that would require that an activity be performed by such an individual. We are proposing to establish requirements for a qualified individual in proposed section § 110.155 (see section XII.I of this document).

FDA is proposing to define the term "ready-to-eat food (RTE food)" to mean any food that is normally eaten in its raw state or any other food, including processed food, for which the food is normally eaten, or it is reasonably foreseeable that the food would be eaten, without further processing that will significantly minimize biological hazards. Our proposed definition is consistent with the definition in the Codex Guidelines On The Application Of General Principles Of Food Hygiene To The Control Of Listeria Monocytogenes In Foods (Ref. Codex 2007 Listeria guidelines), which defines an RTE food as any food which is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further listericidal steps. By referring to "any other food, including processed food," our proposed definition for RTE food, in combination with our proposed definition of "manufacturing/processing," would incorporate the concepts in the Codex guidelines for control of Listeria that RTE food includes foods that have been processed, mixed, cooked, or otherwise prepared into a form that can be eaten without processing in a manner that adequately reduces pathogens. Our proposed definition would generalize the Codex definition established for the purpose of guidelines directed to a single hazard – i.e., the environmental pathogen L. monocytogenes – to any biological hazard that would be addressed under section 418 of the FD&C Act. In so doing, our proposed definition would state that RTE foods are

normally eaten without further "processing that will significantly minimize biological hazards," rather than "listericidal steps." In a draft guidance directed to the control of L. monocytogenes in refrigerated or frozen RTE foods (Ref. draft Listeria processing guidance), we defined RTE food to mean "a food that is customarily consumed without cooking by the consumer, or that reasonably appears to be suitable for consumption without cooking by the consumer." We are proposing a definition of RTE food that is more closely aligned to the definition in the Codex guidelines on the control of Listeria than the definition in our draft guidance regarding the control of Listeria to emphasize that RTE foods include foods that are already processed to some degree but have reached the point at which no further steps to significantly minimize biological hazards will be applied by the processor. This emphasis is needed for clarity with respect to proposed requirements that would be directed to control of environmental pathogens at a facility. As discussed in section XII.B.4.b of this document, proposed § 110.130(c)(2) would require that a hazard analysis include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a RTE food is exposed to the environment prior to packaging. As discussed in section XII.G.5.d of this document, proposed § 110.150(d)(4) would require performance of environmental monitoring, for a microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur.

Our proposal to include in the proposed definition of RTE food the concept that it includes food that "is reasonably foreseeable that the food would be eaten without further processing to significantly minimize biological hazards" would retain the concept, in the draft guidance directed to the control of L. monocytogenes in refrigerated or frozen RTE foods, that an RTE food includes food that "reasonably appears to be suitable for consumption without

cooking by the consumer." For example, it is well known that consumers eat raw cookie dough; an outbreak of foodborne illness caused by E. coli O157:H7 has been linked to consumption of raw cookie dough (Ref. cookie dough recall notice). It also is well known that consumers use dried soup mix in RTE form as a component of a dip; multiple dried soup mix products were recalled due to the potential for contamination with Salmonella from an ingredient (hydrolyzed vegetable protein) (Ref. HVP list of 177 products recalled).

FDA is proposing to define the term "reasonably foreseeable hazard" to mean a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food. The term "reasonably foreseeable hazard" is not used in NACMCF HACCP guidelines, the Codex HACCP Annex, or Federal HACCP regulations for seafood, juice, or meat and poultry. However, the term is used in FSMA and, as discussed in section XII.B.2.a of this document, the concept is grounded in the hazard evaluation process in HACCP systems.

FDA is proposing to define the term "receiving facility" to mean, for an article of food, a facility that is subject to subpart C of part 110 and that manufactures/processes a raw material or ingredient that it receives from a supplier. We are proposing to define "receiving facility" as a concise term to be used in the proposed provisions for a supplier approval and verification program (proposed § 110.152). Some receiving facilities obtain food from suppliers who are part of the same corporate structure and who may, along with the receiving facility, be subject to a single, integrated, company-wide approach to food safety in which hazards are controlled and verified by a common supply chain management system. We request comment on whether receiving facilities should not be required to conduct supplier verification when receiving food from entities under the same corporate ownership and, if so, the specific justifications and conditions under which supplier verification should not be required.

FDA is proposing to define the term "significantly minimize" to mean to reduce to an acceptable level, including to eliminate. The specific terms "significantly minimize" and "preventive control" are not used in the NACMCF HACCP guidelines, the Codex HACCP Annex, or Federal HACCP regulations for seafood, juice, or meat and poultry. However, these terms are used in FSMA and are consistent with the definition of "control measure" in the NACMCF HACCP guidelines, the Codex HACCP Annex, and our HACCP regulation for juice. The NACMCF HACCP guidelines define "control measure" as any action or activity that can be used to prevent, eliminate or reduce a significant hazard (Ref. NACMCF). The Codex HACCP Annex defines "control measure" as any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Ref. Codex). Our HACCP regulation for juice defines "control measure" as any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard (§ 120.3(c)). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry, which were established prior to the current NACMCF HACCP guidelines, do not define "control measure." However, these Federal HACCP regulations nonetheless reflect the same concept that would be established in the proposed definition of "significantly minimize" in the definition of "critical control point," which is defined in the HACCP regulation for seafood as a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels (§ 123.3(b)) and in the FSIS HACCP regulation for meat and poultry as a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels (9 CFR 417.1).

FDA is proposing to define the term "small business" to mean, for the purposes of part 110, a business employing fewer than 500 persons. The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. We are proposing to establish the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR 121 for most food manufacturers. This is also the same definition for small business as we used to define a small business in our juice HACCP regulation (§ 120.1). The proposed definition is consistent with the findings of a study that we conducted as required by section 418(l)(5) of the FD&C Act. Based on the study we estimate that businesses employing fewer than 500 employees produce approximately 40 percent of all manufactured food produced in the United States. Using this definition, section 418(i)(2)(A) of the FD&C Act delays compliance with these regulations for 6 months after the effective date. That study is available in the docket established for this proposed rule (Ref. to the study). After considering comments and determining whether to revise the study in light of the comments, and consistent with the requirements of the Information Quality Act (Pub. L. 106–554, section 515(a)) and the Final Information Quality Bulletin for Peer Review issued by the Office of Management and Budget (70 FR 2664, January 14, 2005), we will subject the document to peer review. We request comment on that study. We will consider comments regarding the study, as well as comments regarding our proposed definition for small business, in any final rule based on this proposed rule.

FDA is proposing to define the term "subsidiary" to mean any company which is owned or controlled directly or indirectly by another company. The proposed definition would incorporate the definition in section 418(l)(4)(D) of the FD&C Act.

FDA is proposing to define the term "supplier" to mean, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food (other than a farm that harvests a raw agricultural commodity that is a fruit or vegetable) that is provided to a receiving facility without further manufacturing/processing, except for further manufacturing/processing by another establishment that consists solely of the addition of labeling or similar activity of a de minimis nature. We are proposing to define the term "supplier" to make the meaning of the term clear in the proposed requirements for a supplier approval and verification program (proposed § 110.152). We are proposing to specify that the supplier could be an "establishment" rather than a "facility" because a supplier may be an entity that is not required to register under section 415 of the act and, thus, would not be a "facility" as that term would be defined for the purpose of this rule. We are proposing to identify establishments that manufacture/process food, raise an animal, or harvest food to address types of establishments that could be suppliers of ingredients under proposed § 110.152. Under the proposed definition of "supplier," we would not consider a facility that packs or holds the food without any type of manufacturing/processing to be a supplier.

FDA is proposing to define the term "validation" to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and our HACCP regulation for juice. The NACMCF guidelines (Ref. NACMCF) and our HACCP regulation for juice (§ 120.3(p)) define validation as that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food

hazards. The Codex HACCP Annex defines validation as obtaining evidence that the elements of the HACCP plan are effective (Ref. Codex 2003). Another Codex document (i.e., "Guidelines for the Validation of Food Safety Control Measures" (Codex validation guidelines)) defines validation more broadly than in the realm of HACCP systems as obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome (Ref. Codex 2008). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry, do not define the term "validation." We discuss our proposed requirements for validation (proposed § 110.150(a)), and their relationship to HACCP systems, in section XII.G.2.a of this document.

FDA is proposing to define the term "verification" to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex and validation guidelines, and our HACCP regulation for juice. The NACMCF guidelines (Ref. NACMCF), and our HACCP regulation for juice (§ 120.3(q)) define verification as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The Codex HACCP Annex defines verification as the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (Ref. Codex 2003). The Codex validation guidelines define verification as the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a control measure is or has been operating as intended (Ref. Codex 2008). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry, do not define the term "verification."

FDA is proposing to define the term "very small business" to mean, for the purposes of part 110, a business that has less than $250,000 in total annual sales of foods, adjusted for inflation. We are proposing to define very small business using a dollar amount that is, for practical purposes, the same as the dollar amount of sales by a qualified facility to end users other than those that would satisfy the definition of "qualified end users." The proposed definition is consistent with the findings of a study that we conducted as required by section 418(l)(5) of the FD&C Act. Based on the study this definition of very small business adds approximately 28,000 facilities to the number of qualified facilities beyond the approximately 9,000 facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act. As a group businesses with less than $250,000 in total annual sales of foods produce less than one-half of one percent of all food produced in the United States when measured by dollar value. That study is available in the docket established for this proposed rule (Ref. to the study). We request comment on that study. After considering comments and determining whether to revise the study in light of the comments, and consistent with the requirements of the Information Quality Act (Pub. L. 106–554, section 515(a)) and the Final Information Quality Bulletin for Peer Review issued by the Office of Management and Budget (70 FR 2664, January 14, 2005), we will subject the document to peer review. We will consider comments regarding the study, as well as comments regarding our proposed definition for very small business, in any final rule based on this proposed rule.

D. Proposed § 110. 5--Applicability of Part 110 to a Facility Solely Engaged in the Storage of Packaged Food That is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Section 418(m) of the FD&C Act provides, in relevant part, that "[t]he Secretary may, by regulation, exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in ... the storage of packaged foods that are not exposed to the environment."

2. Petition Relevant to Section 418(m) of the FD&C Act

In a letter dated July 22, 2011, an industry coalition of the American Bakers Association, the American Frozen Food Institute, the Grocery Manufacturers Association, the International Bottled Water Association, the International Dairy Foods Association, the International Warehouse Logistics Association, the Peanut and Tree Nut Processors Association, and the Snack Food Association (the section 418(m) petitioners) submitted a citizen petition (Docket No. FDA-2011-P-0561). The petition requests that FDA promulgate regulations under section 418(m) of the FD&C Act "to exempt from compliance or modify the requirements for compliance under section 418 [of the FD&C Act] for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment, by allowing such facilities to satisfy the requirements of that section through compliance with the [CGMPs] mandated for such facilities by [current] § 110.93." The section 418(m) petitioners assert that the food safety issues presented by facilities used only to store packaged foods that are not exposed to the environment are essentially the same, regardless of the type of food. As such, trade associations representing a variety of product sectors are signatories to the petition and are supportive of the request to exempt such facilities from the provisions of section 418 of the FD&C Act. In the remainder of

this document, we refer to packaged food not exposed to the environment as "unexposed packaged food." We consider "not exposed to the environment" and "unexposed" to mean that the food is in a form that prevents any direct human contact with the food.

The section 418(m) petitioners state that most of the potential hazards and preventive controls noted in section 418 of the FD&C Act are not relevant to facilities solely engaged in the storage of unexposed packaged foods and that the foods handled in these facilities would have already been subjected to hazard analyses and preventive controls (including CGMPs) throughout the process of their manufacture and packaging for delivery to retailers and end-users. They further state that most of the preventive control activities carried out in food production settings (such as sanitation of food-contact surfaces and utensils) offer no benefit for a facility storing unexposed packaged foods and that controls such as supplier verification and recall plans would be addressed by the manufacturing facility from which the foods originated.

The section 418(m) petitioners state that the "few hazards" that may arise in facilities solely engaged in the storage of unexposed packaged foods, "including those relating to environmental, climate, and pest controls, are already addressed under FDA's existing CGMPs governing warehousing and distribution [in current § 110.93]." They state that storage facilities themselves pose "a very limited, if any, food-safety risk" and that they are not aware of any significant foodborne illness outbreaks attributable to storage at such facilities.

The section 418(m) petitioners note that many packaged food warehouses contain a variety of foods that can come from many different manufacturing facilities or even different companies. According to the petitioners, warehouse operators work closely with the food manufacturers to understand the conditions and controls that need to be utilized to ensure the

quality of the foods they store and distribute and, in many cases, those conditions and controls are formalized in written contracts.

The section 418(m) petitioners assert that the warehouse operators themselves do not have access to product formulations and other relevant information that would be necessary for them to conduct a hazard analysis, develop preventive controls, and monitor them. They state that the food manufacturer, on the other hand, does understand the products it produces and factors in the storage and distribution parameters and considerations into the hazard analysis and appropriately instructs the warehouses to ensure unexposed packaged foods are being properly stored. The section 418(m) petitioners thus assert that responsibility for hazard analysis and risk-based preventive controls under section 418 of the FD&C Act is properly and best shouldered by the food manufacturer.

The section 418(m) petitioners propose that FDA use the following language as part of its regulations implementing section 418 of the FD&C Act: "A facility that is engaged solely in the storage, holding, warehousing, or distribution of packaged foods that are not exposed to the environment shall be exempt from the requirements of section 418 of the Federal Food, Drug, and Cosmetic Act if the facility complies with the requirements set forth at 21 C.F.R. § 110.93."

FDA notes that petitioners also make arguments for their position relevant to "hazards that may be intentionally introduced, including by acts of terrorism," as described in § 418(b)(2). As discussed in sections II.B.2.f and XII.B.1, those hazards will be addressed in a future rulemaking so FDA is not addressing that aspect of the petition in this proposal.

3. FDA's Tentative Response to the Petition

We tentatively agree in part, and disagree in part, with the section 418(m) petitioners. As discussed more fully below, we agree it is appropriate for facilities solely engaged in the storage

of unexposed packaged food to be exempt from the requirements that would be established in proposed subpart C, provided that the food does not require time/temperature control for safety. For unexposed packaged food that requires time/temperature control for safety, we disagree that such an exemption is warranted, but tentatively conclude that unexposed packaged food that requires time/temperature control for safety could be subject to modified requirements rather than to the full requirements that would be established in proposed subpart C.

We disagree that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls. The principal hazard that would be identified in any hazard analysis for unexposed packaged food is the potential for the growth of, or toxin formation by, microorganisms of public health significance when an unexposed refrigerated packaged food requires time/temperature control for safety. Information about this hazard and appropriate preventive controls for this hazard is widely available (Ref. Food Code Chapter 1 and Annex 3, Chapter 1; IFT report on PHF). For example, the 2009 Edition of FDA's Food Code defines "Potentially Hazardous Food (Time/Temperature Control for Safety Food)" as a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation (Ref. Food Code Chapter 1). Earlier editions (e.g., the 2001 Food Code) included a similar definition for "potentially hazardous food"; since 2005, the definition jointly refers to "potentially hazardous food" and "time/temperature control for safety food" (commonly referred to as TCS food) to emphasize the importance of temperature control in keeping food safe. Although we disagree that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls, we agree that it is not necessary for each facility solely engaged in the storage of unexposed packaged food to conduct its own hazard analysis to

identify this hazard for unexposed refrigerated packaged food as reasonably likely to occur and for each such facility to determine that time/temperature control is the appropriate preventive control.

We also disagree that § 110.93 alone is adequate for addressing environmental problems such as a flood in the facility and pest control problems, even though the food in question is not exposed to the environment and pest control problems with the container would likely be visible to the warehouse operator. However, we tentatively conclude that § 110.93, along with other applicable provisions of subpart B, such as pest control in § 110.35, do adequately address most safety-related issues that may arise in facilities solely engaged in the storage of unexposed packaged food. We disagree that existing § 110.93 or other provisions in subpart B justifies the exemption from all preventive control requirements sought by the petitioners in the specific case of unexposed refrigerated packaged food that requires time/temperature control for safety (hereinafter unexposed refrigerated packaged TCS food). As discussed more fully in section XIII.B of this document, such food requires the implementation of an appropriate preventive control (temperature), monitoring that control, taking corrective actions when there is a problem with that control, verifying that the control is consistently implemented, and establishing and maintaining records documenting the monitoring, corrective actions, and verification. FDA tentatively concludes that it is appropriate for our response to the petition to distinguish between packaged food that requires such time/temperature control and packaged food that does not.

We also disagree that an exemption provided under section 418(m) of the FD&C Act should be established in a manner that has the potential to be interpreted more broadly than section 418(m) provides. The section 418(m) petitioners request that we establish a provision that "A facility that is engaged solely in the storage, holding, warehousing, or distribution of

packaged foods that are not exposed to the environment shall be exempt from the requirements of section 418 [of the FD&C Act]", whereas section 418(m) provides discretion for an exemption "with respect to facilities that are solely engaged in ... the storage of packaged foods that are not exposed to the environment." Under proposed § 110.3, "holding" would mean storage of food and holding facilities would include, relevant to unexposed packaged food, warehouses and cold storage facilities. To the extent that a facility that is engaged solely in "warehousing" or "distribution" of unexposed packaged food is merely "storing" or "holding" the food, an exemption established using the language provided by section 418(m) would apply to that facility. However, to the extent that a facility that is engaged solely in "warehousing" or "distribution" of unexposed packaged food is not merely "storing" or "holding" the food, an exemption established using the language provided by section 418(m) would not apply to that facility.

In response to the petition, FDA is proposing to establish an exemption from subpart C for facilities solely engaged in the storage of unexposed packaged food (proposed § 110.5). FDA also is proposing to establish modified requirements at such facilities to require that the owner, operator, or agent in charge of such a facility comply with modified requirements for any unexposed refrigerated packaged TCS food (proposed § 110.206). See the discussion of proposed § 110.5 in the next section of this document and the discussion of proposed § 110.206 in section XIII.B of this document.

4. Proposed § 110.5--Applicability of Part 110 to a Facility Solely Engaged in the Storage of Packaged Food that is Not Exposed to the Environment

Proposed § 110.5(a) would provide that subpart C does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment. Proposed §

110.5(b) would establish that unexposed packaged food at such facilities is subject to modified requirements that would be established in proposed § 110.206. As discussed more fully in section XIII.B of this document, the modified requirements would mandate that such a facility establish and implement appropriate temperature controls, monitor the temperature controls, take corrective actions, verify that the temperature controls are consistently implemented, and establish and maintain records documenting the monitoring, corrective actions, and verification activities for unexposed refrigerated packaged TCS food. These modified requirements would be a subset of the proposed requirements that would be established in subpart C.

There are limited routes of contamination for unexposed packaged food in a facility that solely stores unexposed packaged food (e.g., packaged food in containers in a warehouse). Contamination can occur, for example, if rodents gnaw through packages or if human waste from an improperly maintained toilet facility spills and seeps into paper-based packaging. However, with one exception, the CGMP requirements in proposed subpart B (e.g., proposed §§ 110.20, 110.35, 110.37, and 110.93) would apply to the storage of unexposed packaged food and be adequate to prevent such contamination so that it would not be necessary for the owner, operator, or agent in charge of a facility to address these routes of contamination by applying the hazard analysis and risk-based preventive controls that would be established in proposed subpart C. The exception would be for the rare circumstance in which RACs are packaged in a manner in which the RACs are not exposed to the environment. Under current § 110.19(a), an establishment solely engaged in storing RACs is exempt from CGMPs in current part 110; under proposed § 110.2(k), such an establishment would continue to be exempt from CGMPs. Such an establishment is now, and would continue to be, subject to section 402(a)(4) of the FD&C Act. An establishment that is solely engaged in the storage of packaged RACs that are not exposed to

the environment may find the provisions of proposed subpart B helpful in ensuring compliance with section 402(a)(4) of the FD&C Act.

Many of the requirements that would be established in proposed subpart C would be directed to manufacturing, processing, and packing food and would not apply to the storage of unexposed packaged food that does not require time/temperature control for safety. This is the case for:

- Process controls (proposed § 110.135(d)(1));
- Food allergen controls (proposed § 110.135(d)(2));
- Sanitation controls (proposed § 110.135(d)(3));
- Monitoring of process controls, food allergen controls, and sanitation controls (proposed § 110.140);
- Corrective actions (proposed § 110.145);
- Verification (including initial validation) of process controls (proposed § 110.150);
- A supplier approval and verification program (proposed § 110.152); and
- A recall plan (proposed § 110.137) (recalls generally are initiated by the manufacturer, processor, or packer of the food).

FDA tentatively concludes that the outcome of a hazard analysis for storage of unexposed packaged food that does not require time/temperature control for safety is that there are no hazards reasonably likely to occur. We also tentatively conclude that there would be little public health benefit to requiring the owner, operator, or agent in charge of each facility solely engaged in the storage of such food to conduct its own hazard analysis and document that outcome in its own food safety plan. Likewise, we tentatively conclude that there would be no need for the

facility to establish and implement preventive controls, with corresponding monitoring, corrective actions, or verification (including validation), because there would be no hazards reasonably likely to occur to trigger such activities. We also tentatively conclude that there would be no need for a qualified individual to conduct activities such as preparing the food safety plan (proposed § 110.126(c)); developing the hazard analysis (proposed § 110.130(a)(3)); validating the preventive controls (proposed § 110.150(a)(1)); reviewing records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (proposed § 110.150(d)(5)); or performing reanalysis of the food safety plan (proposed § 110.150(e)(1)(iv)), because the facility would not need to conduct these activities. Thus, with the exception of the unexposed refrigerated packaged TCS food, we tentatively conclude that the food safety system that would be established in proposed subpart C is not needed to significantly minimize or prevent the occurrence of hazards that could affect unexposed packaged food at a facility solely engaged in the storage of such food.

The purpose of proposed § 110.5(b) is to make clear that although a facility solely engaged in the storage of unexposed packaged food is exempt from subpart C, such a facility is subject to modified requirements that would be established in proposed § 110.206. These requirements would apply to the storage of unexposed refrigerated packaged TCS food. We explain the basis for those proposed requirements in section XIII.B of this document.

XI. Proposed Subpart B--Current Good Manufacturing Practice

A. Proposed Revisions to Address Cross-Contact

As discussed in section XI.A of this document, FDA is proposing a number of revisions to address cross-contact. Some of these proposed revisions would clarify that an existing provision that requires protection against contamination also requires protection against cross-

contact. Other proposed revisions would establish new requirements to protect against both contamination and cross-contact (e.g., by proposing to require, rather than recommend, a measure to protect against contamination). This proposed revision is part of FDA's broader effort to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." The clarification or new requirement would reduce the potential that the regulated industry would interpret "contamination" more narrowly than in the past and would ensure that CGMPs continue to address health concerns related to allergens.

B. Proposed Editorial Changes to Subpart B

As discussed in section XI.B of this document, FDA is proposing to revise current part 110 to make several changes that are editorial in nature. These editorial changes have no substantive effect on the current requirements of part 110 and, thus, we do not list every instance where these proposed editorial changes would apply.

C. Proposed Revisions to Current § 110.10--Personnel

1. Proposed Revisions to Current § 110.10(b)--Cleanliness

FDA is proposing to revise current § 110.10(b) (Cleanliness), (b)(1) and (b)(9) to make clear that certain provisions involving hygienic practices protect against cross-contact (i.e., inadvertent inclusion of an allergen) in addition to the contamination of food. This proposed revision is part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document regarding the changes to current part 110 to address cross-contact, to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." Poor hygiene may result in the transfer of food allergens from persons working in direct contact with food,

food-contact surfaces, and food-packaging materials to food. Appropriate use of outer garments protects against the transfer of food allergens from food to person to food. Proposed § 110.10(b) would require that all persons working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food (emphasis added). Proposed § 110.10(b)(1) would require that the methods for maintaining cleanliness include wearing outer garments suitable to the operation in a manner that protects against the cross-contact and contamination of food, food-contact surfaces, or food-packaging materials (emphasis added). Proposed § 110.10(b)(9) would require taking any other necessary precautions to protect against the contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against the cross-contact of food (emphasis added).

FDA is proposing to revise current § 110.10(b)(5) to remove the recommendation that gloves be of an impermeable material. In evaluating the recommendation in current § 110.10(b)(5) regarding use of impermeable material in gloves, we considered the diversity of food that is manufactured, processed, packed or held and is subject to the requirements of part 110. The use of an impermeable material may be important for handling a ready-to-eat food but may not be required for handling a food that will receive a validated heat treatment. Thus, we tentatively conclude that it would not be appropriate to require that gloves used for the handling of all foods be made of an impermeable material and that a discussion of gloves would be more appropriate in a guidance document, which could describe factors to consider in selecting and using gloves in the production of food. Proposed § 110.10(b)(5) would require that the methods

for maintaining cleanliness include maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

2. Proposed Revisions to Current § 110.10(c)--Education and Training

Current § 110.10(c) provides guidance that personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Current § 110.10(c) further recommends that food handlers and supervisors receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

As discussed in section II.A.1 of this document, the CGMP Working Group Report identified specific areas that presented an opportunity to modernize the regulation. One recommendation was to "require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products. This training must be delivered in a manner that can be easily understood by the worker. Food processors must maintain a record of this training for each worker" (Ref. CGMP Modernization Working Group Report 2005). Our analysis of recalls also indicates that ineffective employee training was a root cause of 32 percent of CGMP-related recalls in the 1999-2003 analysis; deficiencies in training were identified as a contributing factor in 24 percent of CGMP-related primary recalls in the 2008-2009 analysis. In addition, as discussed in section XII.C.4 of this document, section 418(o)(3) of the FD&C Act recognizes the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls, which identifies supervisor, manager, and employee

hygiene training (§ 418(o)(3)(B)) and CGMPs under part 110 (§ 418(o)(3)(F)) as some of the procedures, practices, and processes that may be included as preventive controls.

FDA is acting consistent with the recommendation in the CGMP Working Group Report regarding training by proposing to replace the current recommendations for personnel education and experience with requirements. Proposed § 110.10(c)(1) would require that each person engaged in food manufacturing, processing, packing, or holding (including temporary and seasonal personnel) or the supervision thereof, receive training as appropriate to the person's duties, upon hiring and periodically thereafter. Proposed § 110.10(c)(1) also would require training to include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene , as applied at the facility. Because ensuring that food is not contaminated is highly dependent on personnel following proper food hygiene practices, all personnel – including supervisors - must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, upon hiring so that they are aware of these principles before they participate in the production of food. Refresher training must be provided to ensure that all personnel remain aware of all procedures necessary to maintain the safety of food. Managers and supervisors must have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies. Persons who may have relevant experience – e.g., at another facility – nonetheless need to know the specific food safety and food hygiene practices applied at the facility so that all personnel at the facility approach food safety in a coordinated way.

Proposed § 110(c)(1) would be consistent with another recommendation of the CGMP Working Group report – i.e., that processing and supervisory personnel receive training in food

allergen control. Food safety includes allergen control, and procedures for allergen control, including label control and prevention of cross-contact, should be part of the food safety training in any facility that uses allergens. Although the CGMP Working Group considered that such training would be included in a food allergen control plan, we tentatively conclude that such training would be captured within proposed § 110.10(c)(1) and need not be repeated – e.g., as a preventive control within the food allergen control plan that would be required in proposed § 110.135(d)(2) (see discussion of proposed 110.135(d)(2) in section XII.C.6 of this document). The proposed requirements for training are consistent with recommendations in the Codex GPFH that those engaged in food operations that come directly or indirectly into contact with food be trained in food hygiene to a level appropriate to the operations they are to perform (Ref. Codex GPFH 2003).

Proposed § 110.10(c)(2) would require that each person engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or the supervision thereof, have the training, in combination with education or experience, to perform the person's assigned duties. Unlike proposed § 110(c)(1) (which would require training in the general topic areas of the principles of food hygiene and food safety), proposed § 110.10(c)(2) would require training (in combination with education or experience) that would be specific to a person's tasks and responsibilities. It is essential that all personnel be trained to carry out (and, when applicable, supervise) the functions involved in that person's assigned duties, especially when those duties involve an activity related to production of safe, unadulterated food.

Proposed § 110.10(c)(2) would provide flexibility for how personnel become qualified to perform their assigned functions by recognizing multiple pathways to obtaining the necessary qualifications: training (whether training provided on-the-job at a plant or training at a location

outside a plant), in combination with education (such as the basic ability to read work instructions and training materials, write to the extent necessary to establish required records, and understand training concepts such as the importance of hygiene), or experience (e.g., work experience related to an employee's current assigned duties, whether the experience is at the current plant or is associated with previous employment). Personnel delivering the training should have the education, training, or experience to conduct such training, irrespective of whether the training is conducted in-house, at a location outside the plant, or through distance learning (such as an Internet training course).

Proposed § 110.10(c)(3) would require that plant management establish and maintain records that document required training of personnel, including the date of the training, the type of training, and the person(s) trained. Such records would document that a person has, as would be required under proposed § 110.10(a) and (b), successfully completed training as appropriate to the person's duties, upon hiring and periodically thereafter, including the principles of food hygiene and food safety and also the training that would be specific to a person's tasks and responsibilities.

3. Proposed Revisions to Current § 110.10(d)--Supervision

Current § 110.10(d) requires that responsibility for "assuring" compliance by all personnel with all requirements of part 110 be clearly assigned to competent supervisory personnel. FDA is proposing to revise current § 110.10(d) to replace the term "assuring" with "ensuring" to clarify FDA's expectation that supervisory personnel make certain that all personnel comply with the CGMP requirements of proposed subpart B. As a grammatical matter, the word "ensure" more accurately communicates this expectation than the word "assure." FDA also is proposing to narrow the requirement for supervisory personnel to ensure

compliance with proposed subpart B rather than with all of part 110. Current § 110.10(d) is directed at the requirements already established in part 110 and does not apply to the proposed requirements that would be established in proposed subpart C. Proposed § 110.10(d) would now state that responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel (emphasis added).

D. Proposed Revisions to Current § 110.20--Plant and Grounds

FDA is proposing to revise current § 110.20(b) (Plant Construction and Design) to make two changes for consistency with terminology used in section 418 of the FD&C Act and with definitions that would be established in proposed § 110.3. (See the general discussion of such proposed changes in section XI.D of this document). First, FDA is proposing to replace the phrase "food-manufacturing purposes" with the phrase "food-production purposes (i.e., manufacturing, processing, packing, and holding)." This revision is part of a broader effort, discussed in section IX.C.1 of this document, to consistently use the same group of terms to broadly identify activities that take place in food establishments. Second, FDA is proposing to replace the phrase "plant and facilities" with the single term "plant" as defined in proposed § 110.3. The requirement would be clear using the single term "plant" and, thus, the term "facilities" is unnecessary. In addition, under proposed 110.3 (Definitions) the term "facilities" would be based on the definition in section 418(o)(2) of the FD&C Act, which is not how the term is used in current § 110.20(b). Proposed § 110.20(b) would require that the plant buildings and structures be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing packing, and holding) and would establish specific construction and design requirements that would apply to the "plant" rather than the "plant and facilities" (emphasis added).

FDA also is proposing to revise current §§ 110.20(b)(2) and (b)(6) to clarify that plants must be constructed and designed to protect against cross-contact in addition to protecting against the contamination of food. This proposed revision is part of FDA's effort, as discussed in sections IX.D and XI.A of this document regarding the changes to current part 110 to address cross-contact, to revise several provisions of part 110 to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." Inadequate construction and design of a plant can result in the transfer of food allergens to food. Proposed § 110.20(b)(2) would require that the plant take proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to reduce the potential for cross-contact (emphasis added). The potential for cross-contact and contamination must be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means (emphasis added). Separation of operations is a key means of preventing cross-contact. Proposed § 110.20(b)(6) would require that a plant provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for cross-contact (emphasis added). Proper ventilation, e.g., over powder dumping operations, and proper operation of fans and other air-blowing equipment are essential to prevent the transfer of allergens via dust in air currents.

In addition, FDA is proposing to broaden current § 110.20(b)(3) by removing the term "fermentation" so that the construction and design requirements to permit the taking of proper precautions to protect food would apply to all outdoor bulk vessels (e.g., fermentation vessels, silos, vessels, and bins) rather than be limited to outdoor bulk fermentation vessels. Outdoor bulk vessels containing food lack the basic protection from environmental factors provided by a building, irrespective of whether the purpose of the outdoor bulk vessel is fermentation or storage. Proposed § 110.20(b)(3) would require that the construction and design of a plant permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means. A conforming editorial change to current § 110.20(b)(3)(iv) would revise "skimming the fermentation vessels" (emphasis added) to "skimming fermentation vessels" to make clear that fermentation vessels would now be only one kind of vessel subject to proposed § 110.20(b)(3).

E. Proposed Revisions to Current § 110.35--Sanitary Operations

1. Proposed Revisions to Current § 110.35(a)--General Maintenance

FDA is proposing to revise current § 110.35(a) (General maintenance) to clarify that cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact of food, food-contact surfaces, or food packaging materials in addition to protecting these items against contamination. This proposed revision is part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document regarding the changes to current part 110 to address cross-contact, to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." Improper cleaning and sanitizing that leaves food residues on utensils or equipment may result in the transfer of food allergens from utensils or equipment to food, food-contact surfaces, or food packaging materials that come in

contact with the improperly cleaned and sanitized surfaces. Proposed § 110.35(a) would require that cleaning and sanitizing of utensils and equipment be conducted in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials (emphasis added).

2. Proposed Revisions to Current § 110.35(b)--Substances Used in Cleaning and Sanitizing; Storage of Toxic Materials

FDA is proposing to revise current § 110.35(b)(1) to emphasize that mechanisms to comply with provisions related to cleaning compounds and sanitizing agents must be safe and effective rather than to emphasize that there are multiple ways to achieve such compliance. With this shift in emphasis, proposed § 110.35(b)(1) would require that cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination (emphasis added). FDA considered whether to delete the examples of mechanisms to achieve compliance as nonbinding recommendations, but tentatively concludes that the examples provide useful information that is suitable in the context in which it remains in the provision.

FDA is proposing to revise current § 110.35(b)(2) to remove the recommendation for following all relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of toxic cleaning compounds, sanitizing agents, and pesticide chemicals. FDA tentatively concludes that although such a recommendation may be helpful, it is more properly addressed by the applicable Federal, State, and local government agencies and is outside the scope of part 110.

3. Proposed Revisions to Current § 110.35(c)--Pest Control

FDA is proposing to revise current § 110.35(c) (Pest control) to make a change for internal consistency and clarity as well as to harmonize with terminology used in section 418 of the FD&C Act. (See the general discussion of this type of proposed change in section IX.C of this document.) In relevant part, current § 110.35(c) both requires that "no pests shall be allowed in any area of a food plant" and requires that "[e]ffective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests." We are proposing to replace the phrase "processing area" with the phrase "manufacturing, processing, packing and holding areas." This revision is part of a broader effort, discussed in section IX.C.1 of this document, to consistently use the same group of terms to broadly identify activities that take place in food establishments and also would provide for internal consistency between the requirement to not allow pests in "any area of a food plant" and the requirement to take effective measures to exclude pests from the plant. Pests do not belong in any areas where manufacturing, processing, packing or holding of food occurs. We also are proposing a grammatical change to say that "[p]ests must not be allowed in any area of the plant. We are not proposing any changes to a provision in current § 110.35(c) that provides flexibility for the use of guard or guide dogs in the plant and requirements directed to the use of insecticides and rodenticides. Proposed § 110.35(c) would require "Pests must not be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the <u>manufacturing,</u> processing, <u>packing and holding</u> areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions

and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials" (emphasis added).

4. Proposed Revisions to Current § 110.35(d)--Sanitation of Food-Contact Surfaces

FDA is proposing several revisions to current § 110.35(d) (Sanitation of food-contact surfaces). First, FDA is proposing to redesignate current § 110.35(d)(3) as proposed § 110.35(e) (Sanitation of non-food-contact surfaces). Current § 110.35(d)(3) addresses sanitation of non-food-contact surfaces and, thus, does not belong in § 110.35(d), which addresses sanitation of food-contact surfaces. As a conforming editorial change, current § 110.35(e) would become proposed § 110.35(f).

Second, FDA is proposing to revise current § 110.35(d)(1) to be more explicit that food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean condition at the time of use. Current § 110.35(d)(1) requires that food-contact surfaces used for manufacturing or holding low-moisture food be in a dry, sanitary condition at the time of use; to be sanitary, a food-contact surface must be clean. The proposed revision would apply to "manufacturing/processing" rather than only to "manufacturing" in light of our proposed definition of manufacturing/processing (see discussion of the definition of manufacturing/processing in section X.C of this document). Proposed § 110.35(d)(1) would require that food-contact surfaces used for manufacturing/processing or holding low-moisture food be in a <u>clean,</u> dry, sanitary condition at the time of use (emphasis added).

Third, FDA is proposing to revise current §§ 110.35(d) and (d)(2) to address cross-contact and clarify that sanitation of food-contact surfaces must protect against cross-contact of food. These proposed revisions to § 110.35(d) and (d)(2) are part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document, to make clear that CGMPs require

protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." Inadequate sanitation of food contact surfaces may leave residues of food containing allergens on the surfaces and result in the transfer of food allergens from food-contact surfaces to food. Proposed § 110.35(d) would require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food (emphasis added). Proposed § 110.35(d)(2) would require in wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated (emphasis added).

Fourth, FDA also is proposing to revise current § 110.35(d)(4) (proposed § 110.35(d)(3)) to require, rather than recommend, that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) be stored in appropriate containers to prevent contamination of food or food-contact surfaces and, as part of the broader effort discussed immediately above to address cross-contact, to require protection against cross-contact in addition to protection against cross-contamination. Failure to properly store such articles could lead to contamination of the articles and then to contamination of food if the articles come in contact with food. Similarly, failure to properly store such articles could lead to cross-contact. Proposed § 110.35(d)(3) would require that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food or food-contact surfaces (emphasis added).

Fifth, FDA is proposing to delete current § 110.35(d)(5), which requires that sanitizing agents be adequate and safe under conditions of use and recommends that cleaning agents be adequate and safe under conditions of use. Current § 110.35(d)(5) is redundant with proposed § 110.35(b)(1), which requires that both cleaning compounds and sanitizing agents be safe and adequate under the conditions of use.

5. Proposed Revisions to Current § 110.35(d)(3)--Sanitation of Non-Food-Contact Surfaces

FDA is proposing to revise current § 110.35(d)(3) (proposed § 110.35(e); sanitation of non-food-contact surfaces) to require, rather than recommend, that non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against contamination of food and food-contact surfaces. Failure to clean non-food-contact surfaces could lead to contamination of food contact surfaces of the equipment and utensils and then to contamination of food if the contaminated equipment and utensils come in contact with food. For example, as discussed in section II.E.7 of this document, cleaning non-food-contact surfaces is essential to prevent contamination of food from environmental pathogens such as L. monocytogenes and Salmonella spp. Proposed § 110.35(e) would require that non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food and food-contact surfaces.

6. Proposed Revisions to Current § 110.35(e)--Storage and Handling of Cleaned Portable Equipment and Utensils

FDA is proposing to revise current § 110.35(e) (proposed § 110.35(f); storage and handling of cleaned portable equipment and utensils) to require, rather than recommend, storing cleaned and sanitized portable equipment with food-contact surfaces and utensils in a location

and manner that protects food contact surfaces from contamination. Failure to properly store and handle such equipment and utensils could lead to contamination of the equipment and utensils and then to contamination of food if the equipment and utensils come in contact with food. FDA also is proposing to require storing cleaned and sanitized portable equipment with food-contact surfaces and utensils in a location and manner that protects food contact surfaces from cross-contact, for the same reasons as described above for sanitation of food-contact surfaces (proposed § 110.35(d)) and for sanitation of non-food-contact surfaces (proposed § 110.35(e)). Proposed § 110.35(f) would require that cleaned and sanitized portable equipment with food-contact surfaces and utensils be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination.

F. Proposed Revisions to Current § 110.37--Sanitary Facilities and Controls

1. Proposed Revisions to Current § 110.37(d)--Toilet Facilities

Current § 110.37(d) requires that each plant provide its employees with adequate, readily accessible toilet facilities and provides recommendations for how compliance with the requirements may be accomplished. These recommendations address issues such as the sanitary and overall physical condition of the toilet facilities, as well as the type and location of toilet facilities' doors.

We considered whether to revise current § 110.37(d) to require, rather than recommend, specific provisions for achieving compliance with the requirements for toilet facilities. In doing so, we considered comments received in response to proposed bathroom requirements contained in the proposed rule to establish CGMP requirements for dietary supplements (the dietary supplement proposed rule; 68 FR 12157 at 12254). The dietary supplement proposed rule would have established - as requirements - provisions similar to the recommendations in current §

110.37(d). Comments on these proposed bathroom requirements stated that firms should be given flexibility in designing their bathrooms (72 FR 34752 at 34817). FDA agreed that it is unnecessary to require specific bathroom features because firms may be able to achieve compliance through means better suited to their operations. The final rule replaced requirements for specific bathroom features with more general requirements for providing employees with adequate, readily accessible bathrooms, and for bathrooms to be kept clean and not be a potential source of contamination to components, dietary supplements, or contact surfaces (§ 111.15(h)).

We tentatively conclude that revising current § 110.37(d) to establish a performance standard for toilet facilities similar to the one found in § 111.15(h) is a better approach than mandating the recommendations in current § 110.37(d). Therefore, proposed § 110.37(d) would maintain the current requirement that each plant provide its employees with adequate, readily accessible toilet facilities. In addition, proposed § 110.37(d) would require that toilet facilities be kept clean and not be a potential source of contamination of food or food contact surfaces.

2. Proposed Revisions to Current § 110.37(e)--Hand-washing Facilities

Current § 110.37(e) requires that hand-washing facilities be adequate and convenient and be furnished with running water at a suitable temperature and provides recommendations for how compliance with the requirements may be accomplished. These recommendations address issues such as providing hand-washing and hand-sanitizing facilities, hand-cleaning and sanitizing preparations, towel service or suitable drying devices, water control valves, appropriate signs and refuse receptacles that are properly constructed and maintained.

We considered whether to revise current § 110.37(e) to require, rather than recommend, mechanisms for achieving compliance with the requirements for hand-washing facilities. In doing so, we considered comments received in response to proposed hand-washing facility

requirements contained in the dietary supplement proposed rule (68 FR 12157 at 12254). The dietary supplement proposed rule would have established - as requirements - provisions similar to the recommendations in current § 110.37(e). Comments on these proposed hand-washing facility requirements stated that firms should be given flexibility to design their hand-washing facilities and that an overall sanitation requirement should be sufficient (72 FR 34752 at 34818). FDA agreed that it is unnecessary to require specific hand-washing mechanisms because firms may be able to achieve compliance through other means better suited for their operations; however, we disagreed that an overall sanitation requirement would be sufficient because such a requirement would not clearly state the purpose of the requirement, which is to ensure that an employee's hands are not a source of contamination. The final rule replaced requirements for specific hand-washing facility features with more general requirements for providing hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature (§ 111.15(i)).

We tentatively conclude that establishing a performance standard for hand-washing facilities similar to the one found in § 111.15(i) is a better approach than mandating the current recommendations in § 110.37(e). Therefore, proposed § 110.37(e) would require that each plant provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food or food contact surfaces by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

G. Proposed Revisions to Current § 110.40--Equipment and Utensils

FDA is proposing to reorganize the provisions found in current § 110.40(a) by creating paragraph designations (1) through (6) with associated editorial changes. This is a non-

substantive revision to make it easier to see the distinct requirements. FDA also is proposing to revise current § 110.40(a) to require, rather than recommend, that all equipment be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces (proposed § 110.40(a)(3)). Failure to properly clean equipment and adjacent spaces due to improper installation and maintenance could lead to contamination of the equipment and then contamination of food if the equipment comes in contact with the food.

FDA is proposing to revise current § 110.40(a) (in proposed § 110.40(a)(5)) to clarify that all plant equipment and utensils must protect against cross-contact in addition to the contamination of food. This proposed revision is part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document regarding the changes to current part 110 to address cross-contact, to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." Equipment and utensils that are improperly designed, cleaned and maintained may result in the transfer of food allergens from equipment and utensils to food. Proposed § 110.40(a)(5) would require food-contact surfaces be maintained to protect food from cross-contact and from being contaminated by any source, including unlawful indirect food additives (emphasis added). Proposed § 110.40(b) would require seams on food-contact surfaces be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and cross-contact (emphasis added).

FDA also is proposing to delete the recommendation in current § 110.40(e) that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms should be fitted with an automatic control for regulating temperature or with

an automatic alarm system to indicate a significant temperature change in a manual operation (emphasis added). In evaluating the recommendation in current § 110.40(e), we considered that it is now very common for freezer and cold storage compartments to be fitted with an automatic control for regulating temperature, even though there are other options (e.g., manually monitoring thermometers, temperature-measuring devices, or temperature-recording devices for freezers and cold storage compartments). Thus, we tentatively conclude that it is not necessary to revise current § 110.40(e) to require, rather than recommend, use of an automatic control for regulating temperature or an automatic alarm system, because the design of modern freezer and cold storage compartments has established this approach without the need for a Federal requirement. With this recommendation deleted, proposed § 110.40 would require that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

FDA is proposing to revise current § 110.40(f) to require that instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food be precise as well as accurate. By using the word "precise" we mean that individual measurements must be close to each other when made under the same conditions so that the variation in measurements is not statistically significant. An instrument that gives widely varying readings from one use to the next cannot be consistently accurate and therefore cannot ensure product safety over time. The proposed requirement for such instruments and controls to be precise as well as accurate would be consistent with the requirements in the dietary supplement GMPs (§ 111.27(a)(6)(i)),

which were established after the requirements in current § 110.40(f). Proposed § 110.40(f) would require that instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food be accurate and precise and adequately maintained, and adequate in number for their designated uses (emphasis added).

H. Proposed Revisions to Current § 110.80--Processes and Controls.

1. Proposed Revisions to Current § 110.80

FDA is proposing to reorganize the provisions found in six sentences that precede current § 110.80(a) by creating paragraph designations (a)(1) through (6) with associated editorial changes, including the title "General" for new paragraph (a). This is a non-substantive revision to make it easier to see the distinct requirements and to clearly identify each requirement with a paragraph citation. As corresponding changes, current § 110.80(a) would be come proposed § 110.80(b) and current § 110.80(b) would become proposed § 110.80(c).

FDA is proposing to revise current § 110.80 to clarify that certain practices involving processes and controls must protect against cross-contact. This proposed revision is part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document, to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." Inadequate processes and controls practices may result in the transfer of food allergens to food. Proposed § 110.80(a)(4), in relevant part, would require that reasonable precautions be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source (emphasis added). Proposed § 110.80(a)(5) would require that chemical, microbial, or

extraneous-material testing procedures be used where necessary to identify sanitation failures or possible cross-contact and food contamination (emphasis added).

2. Proposed Revisions to Current § 110.80(a) - Raw Materials and Other Ingredients

As discussed in section IX of this document, FDA is proposing to change the title of current § 110.80 to "Raw materials and ingredients." As a companion to this change in title, we are proposing to substitute "ingredients" for "other ingredients" throughout provisions in § 110.80 that refer to both raw materials and ingredients. We do not list every instance where this proposed revision would apply.

FDA is proposing a number of revisions to current § 110.80(a) (i.e., to current §§ 110.80(a)(1), (a)(5), and (a)(7)) to clarify that certain practices involving raw materials and ingredients must protect against cross-contact. These proposed revisions are part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document, to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." We discuss each of these proposed revisions, and others not related to allergens, immediately below.

FDA is proposing to revise current § 110.80(a)(1) to require, rather than recommend, that containers and carriers of raw materials be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food. Containers and carriers of raw materials not properly maintained can lead to contamination or deterioration of food. FDA also is proposing to require protection against cross-contact in three of the five separate statements within current § 110.80(a)(1) because raw materials and ingredients subject to cross contact due to improper segregation prior to receipt or during storage may result in undeclared allergens in food. The revisions to proposed § 110.80(b)(1) would require, in relevant part, that raw

materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and be stored under conditions that will protect against cross-contact and contamination, and minimize deterioration. ... Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross-contact. Containers and carriers of raw materials must be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food (emphasis added).

Current § 110.80(a)(2) requires that raw materials and other ingredients either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. FDA is proposing to revise current § 110.80(a)(2) by replacing the phrase "may produce food poisoning or other disease in humans" with "may render the food injurious to the health of humans." The proposed revision would align the provision with the adulteration provision in section 402(a)(4) of the FD&C Act. Current § 110.80(a)(2) also provides that compliance with the requirements may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification. We considered whether to revise current § 110.80(a)(2) to require, rather than recommend, mechanisms for achieving compliance with the requirements for the safety of raw materials and ingredients. We tentatively conclude that there are more mechanisms for achieving compliance than purchasing raw materials and ingredients under a supplier's guarantee or certification – e.g., in some cases, compliance could be achieved by testing raw materials and ingredients. Rather than propose to require a subset of mechanisms to achieve compliance, FDA tentatively concludes that these recommendations

would be more appropriate in a guidance document and is proposing to delete the recommendations in current § 110.80(a). Proposed § 110.80(b)(2) would require that raw materials and ingredients either not contain levels of microorganisms that may render the food injurious to the health of humans, or they be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated (emphasis added).

Current § 110.80(a)(3) requires that raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins comply with current FDA regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. An action level for an added poisonous or deleterious substance may be established to define a level of contamination at which a food may be regarded as adulterated (§ 109.4) (21 CFR 109.4). In 1990, we issued a final rule to revise part 109 to clarify that action levels constitute prosecutorial guidance rather than substantive rules (55 FR 20782, May 21, 1990). Because action levels themselves constitute guidance, revising § 110.80(a)(3) to reflect that action levels are nonbinding would be duplicative and unnecessary and FDA is proposing to delete the current requirement for compliance with action levels from current § 110.80(a)(3). Importantly, the proposed deletion merely reflects an administrative practice to limit the number of recommendations we include in our regulations; we continue to regard action levels as an important approach to food safety.

Current § 110.80(a)(3) also provides that compliance with the requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins. We considered whether to revise current § 110.80(a)(3) to require, rather

than recommend, mechanisms for achieving compliance with the requirements for the safety of raw materials and ingredients. Consistent with our approach to a similar provision in current § 110.80(a)(2), we tentatively conclude that there may be more mechanisms for achieving compliance than those identified in current § 110.80(a)(3). Rather than propose to require a subset of mechanisms to achieve compliance, FDA tentatively concludes that these recommendations would be more appropriate in a guidance document and is proposing to delete the recommendations in current § 110.80(a)(3). Proposed § 110.80(b)(3) would require that raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins comply with current Food and Drug Administration regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food (emphasis added).

Current § 110.80(a)(4) requires that raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material comply with applicable FDA regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Defect action levels are guidance for natural or unavoidable defects in food for human use that present no health hazard (Ref. Defect Levels Handbook). FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action (Ref. Defect Levels Handbook). As discussed above in this section, in 1990, we issued a final rule to revise part 109 to clarify that action levels are prosecutorial guidance rather than substantive rules (55 FR 20782). Because defect action levels themselves constitute guidance, revising current § 110.80(a)(4) to reflect that action levels are

nonbinding would be duplicative and unnecessary. Therefore, FDA is proposing to delete the current requirement for compliance with defect action levels in current § 110.80(a)(4).

Current § 110.80(a)(4) also provides that compliance with the requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination. Consistent with our approach to a similar provision in current § 110.80(a)(2), we tentatively conclude that there may be more mechanisms for achieving compliance than those identified in current § 110.80(a)(4). Rather than propose to require a subset of mechanisms to achieve compliance, FDA is proposing to delete the recommendations in current § 110.80(a)(4). FDA tentatively concludes that these recommendations would be more appropriate in a guidance document. Proposed § 110.80(b)(4) would require raw materials, ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material comply with applicable Food and Drug Administration regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

FDA is proposing to require protection against cross-contact in current § 110.80(a)(5) because improper handling of raw materials and ingredients may result in the transfer of food allergens to food. Proposed § 110.80(b)(5) would require in relevant part that raw materials, ingredients, and rework be held in bulk, or in containers designed and constructed so as to protect against cross-contact and contamination and be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated (emphasis added).

FDA is proposing to require protection against cross-contact in current § 110.80(a)(7) because improper handling of raw materials and ingredients may result in the transfer of food

allergens to food. Proposed § 110.80(b)(7) would require liquid or dry raw materials and ingredients received and stored in bulk form be held in a manner that protects against cross-contact and contamination (emphasis added).

FDA is proposing to establish a new requirement in current § 110.80(a) regarding cross-contact. Cross-contact may be associated with improper identification and holding of raw materials and ingredients that are food allergens, and rework that contains food allergens. Improper identification of an allergen-containing raw material, such as a seasoning mix that is not identified as containing soy protein, can result in the unintended incorporation of an allergen into a food (i.e., cross-contact). Improper holding, e.g., storing open-containers of raw materials or ingredients, including those containing allergens, in the same location can result in cross-contact. Therefore, FDA is proposing to address the potential for cross-contact associated with the identification and storage of raw materials and ingredients that are food allergens, and rework that contains food allergens. Proposed § 110.80(b)(8) would require that raw materials and ingredients that are food allergens, and rework that contains food allergens, be identified and held in a manner that prevents cross-contact.

3. Proposed Revisions to Current § 110.80(b)--Manufacturing Operations

FDA is proposing several revisions to current § 110.80(b) (i.e., current §§ 110.80(b)(5), (b)(6), (b)(7), (b)(10), (b)(12), and (b)(13)) to clarify that certain practices involving manufacturing operations must protect against cross-contact. This proposed revision is part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document, to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." We discuss each of these proposed revisions, and others not related to allergens, immediately below.

FDA is proposing to revise current § 110.80(b)(2) by replacing the phrase "manufacturing, including packaging and storage" with "manufacturing, processing, packing and holding." This revision is part of a broader effort, discussed in section IX.C.1 of this document, to consistently use the same group of terms to broadly identify activities that take place in food establishments. As discussed in section IX.C.1 of this document, we tentatively conclude there is no meaningful distinction between the terms "manufacturing" and "processing" with respect to CGMPs that would apply to these operations. Current § 110.80(b)(2) also provides that one way to comply with the requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food. In evaluating these recommendations, we considered the diversity of food that is manufactured, processed, packed or held and is subject to the requirements of part 110 and the physical factors and manufacturing operations that could be monitored to minimize the growth of microorganisms. FDA tentatively concludes that this diversity does not make it appropriate to propose establishing these specific recommendations as requirements and that these recommendations would be more appropriate in a guidance document; we are thus proposing to delete this recommendation. Proposed § 110.80(c)(2) would require that all food manufacturing, <u>processing, packing</u> and <u>holding,</u> be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food (emphasis added).

Current § 110.80(b)(3) requires that food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, be held in a manner that

prevents the food from becoming adulterated within the meaning of the act. Current § 110.80(b)(3) also provides that compliance with the requirements may be accomplished by any effective means, including maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved (current § 110.80(b)(3)(i)), maintaining frozen foods in a frozen state (current § 110.80(b)(3)(ii)), maintaining hot foods at 140°F (60°C) or above (current § 110.80(b)(3)(iii)), and heat treating acid or acidified foods(current § 110.80(b)(3)(iv)). FDA is proposing a series of revisions to current § 110.80(b)(3). Specifically, FDA is proposing to:

- Replace the phrase "in a manner" with "at temperatures" to identify a specific manner in which food that supports the rapid growth of microorganisms must be held – i.e., through temperature control. Temperature control is generally recognized as essential to food safety for foods that can support the rapid growth of microorganisms (Refs. Food Code Chapter 1 and Annex 3, Chapter 1; and the IFT report on PHF).
- Include the phrase "during manufacturing, processing, packing and holding" to emphasize that temperature controls do not end with the manufacturing/processing phase, but extend through packing and holding.
- Delete the recommendations in current § 110.80(b)(3)(i) through (iv). In evaluating these recommendations, we considered the diversity of food that is manufactured, processed, packed or held and is subject to the requirements of part 110, as well as the temperatures that are needed for the safe holding of foods. FDA tentatively concludes that this diversity does not make it appropriate to propose to establish these specific recommendations as requirements and that these recommendations would be more appropriate in a guidance document. In addition, we note that current § 110.80(b)(3)(iv) provides for heat treating acid or

acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures. However, current § 110.80(b)(4) addresses measures, including heat treating, taken to destroy or prevent the growth of undesirable microorganisms. We tentatively conclude that proposing to revise current § 110.80(b)(3)(iv) would create a redundancy with current § 110.80(b)(4).

Proposed § 110.80(c)(3) would require that food that can support the rapid growth of undesirable microorganisms be held at temperatures that will prevent the food from becoming adulterated, during manufacturing, processing, packing and holding.

Current § 110.80(b)(4) requires that measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act. FDA is proposing to include "cooking" as an additional such measure. Cooking, if done adequately, is well accepted as a mechanism of destroying microorganisms (Ref. FDA. Safe Food Handling: What You Need to Know). FDA also is proposing to delete the phrase "particularly those of public health significance" because it is redundant with the proposed definition for the term "microorganisms" (proposed § 110.3), which identifies microorganisms of public health significance as a type of undesirable microorganism, and therefore is unnecessary. Proposed § 110.80(c)(4) would require measures such as sterilizing, irradiating, pasteurizing, <u>cooking,</u> freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated (emphasis added).

Current § 110.80(b)(5) requires that work-in-process be handled in a manner that protects against contamination. FDA is proposing to revise current § 110.80(b)(5) to require handling in a manner to protect against the growth of undesirable microorganisms. The growth of any undesirable microorganisms already present in a food, such as pathogenic sporeformers, must be controlled, as well as protecting the food against the introduction of contaminants. FDA also is proposing to clarify that work-in-process must be handled in a manner to protect against "cross-contact" because manufacturing operations may result in the transfer of food allergens to food. In addition we are proposing to revise current § 110.80(b)(5) to broaden the provision to include "rework." The term would be defined in proposed § 110.3 to mean clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. As with work-in-process, improper handling of rework could result in cross-contact, contamination, or growth of undesirable microorganisms. Proposed § 110.80(c)(5) would require that work-in-process and rework be handled in a manner that protects against cross-contact, contamination, and growth of undesirable microorganisms (emphasis added).

Current § 110.80(b)(6) requires that effective measures be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. It requires that when raw materials, other ingredients, or refuse are unprotected, they not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Section 110.80(b)(6) further requires that food transported by conveyor be protected against contamination as necessary. The three sentences in current § 110.80(b)(6) address distinct situations in which cross-contact, as well as contamination, could occur. FDA is proposing to clarify that effective measures must be taken to protect finished food from cross-contact, as well

as from contamination, because manufacturing operations may result in the transfer of food allergens to food. FDA also is proposing to clarify that when raw materials, ingredients, or refuse are unprotected they must not be handled simultaneously in a receiving, loading or shipping area if that handling could result in cross-contact, because allergens may be transferred from one food to another when raw materials or ingredients are unprotected and because allergens in unprotected refuse could contaminate food. In addition, we are proposing to clarify that food transported by conveyor must be protected against cross-contact, as well as contamination, because cross-contact can occur when food is conveyed unprotected. Proposed § 110.80(c)(6) would require that effective measures be taken to protect finished food from cross-contact and contamination by raw materials, ingredients, or refuse (emphasis added). When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in cross-contact or contaminated food (emphasis added). Food transported by conveyor must be protected against cross-contact and contamination as necessary (emphasis added).

Current § 110.80(b)(7) requires that equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination. FDA is proposing to clarify that the provision requires protection against cross-contact because manufacturing operations may result in the transfer of food allergens to food. FDA also is proposing to replace the term "storage" with the term "holding" for consistency with use of the term "holding" throughout part 110. FDA also is proposing to add processing and packing as activities where protection is needed against contamination and cross-contact because contamination and cross-contact can occur during any activities subject to part 110 and to make

clear that the requirements for protection against cross-contact and contamination apply to all activities at a plant by inserting an "and," rather than an "or," between the cited activities. Proposed § 110.80(c)(7) would require that equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food be constructed, handled, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination (emphasis added).

Current § 110.80(b)(8) requires that effective measures be taken to protect against the inclusion of metal or other extraneous material in food and provides recommendations that compliance with this requirement be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means. In evaluating these recommendations, we considered the diversity of food that is manufactured, processed, packed or held and is subject to the requirements of part 110 and the methods that could be used to protect against the inclusion of metal or other extraneous material in food. FDA tentatively concludes that it would not be appropriate to establish such specific recommendations as requirements and that such recommendations would be more appropriate in a guidance document; we are thus proposing to delete the recommendations in current § 110.80(b)(8). Proposed § 110.80(c)(8) would require that effective measures be taken to protect against the inclusion of metal or other extraneous material in food.

Current § 110.80(b)(9) requires that food, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food. It further requires that if the adulterated food is capable of being reconditioned, it be reconditioned using a method that has been proven to be effective or it be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

FDA is proposing to delete the option for reexamination so that adulterated food can only be disposed of or reconditioned if the food is capable of being reconditioned. FDA is proposing this deletion because a food may test positive for a contaminant in one test and negative in one or more additional tests although the food continues to be contaminated. For example, the distribution of a pathogen in a food may not be homogeneous. Therefore, a food found to be adulterated must be reconditioned before it is reexamined. FDA also is proposing to combine the two sentences in current § 110.80(b)(9) with an "or" to make clear that reconditioning, rather than disposal, is an option. Proposed § 110.80(c)(9) would require food, raw materials, and ingredients that are adulterated be disposed of in a manner that protects against the contamination of other food or, if the adulterated food is capable of being reconditioned, it be reconditioned using a method that has been proven to be effective (emphasis added).

Current § 110.80(b)(10) requires that mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step. FDA is proposing to revise current § 110.80(b)(10) to replace the phrase "mechanical manufacturing steps" with the single term "steps" because "mechanical manufacturing" does not accurately describe all steps listed in the current provision. Current § 110.80(b)(10) also includes two recommendations. In evaluating the recommendation regarding physical protection of food, we tentatively conclude that there are no circumstances where it would not be necessary

to provide adequate physical protection of food from contaminants that may drip, drain, or be drawn into food and, thus, we are proposing to establish this recommendation as a requirement. In evaluating the recommendation regarding adequate cleaning and sanitizing of all food-contact surfaces, we considered that the cleaning and sanitizing of food-contact surfaces would already be addressed in proposed §§ 110.35(d), which requires that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food, and 110.80(b)(1), which requires, in relevant part, that equipment and utensils be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary, and, thus, we are proposing to delete this recommendation. In evaluating the recommendation regarding the use of time and temperature controls, we considered the diversity of food that is manufactured, processed, packed or held and is subject to the requirements of part 110 and that use of time and temperature controls at and between each manufacturing step may not be required for all foods. For example, the use of time and temperature controls would not be necessary for shelf-stable foods used as ingredients in another product. FDA tentatively concludes that this recommendation would be more appropriate in a guidance document. FDA also is proposing to require that steps identified in current § 110.80(b)(10) require protection against cross-contact because manufacturing operations may result in the transfer of food allergens to food. Proposed § 110.80(c)(10) would require that steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming be performed so as to protect food against cross-contact and contamination and would require that food must be protected from contaminants that may drip, drain, or be drawn into the food (emphasis added).

Current § 110.80(b)(11) states that heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. It also provides that thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. In addition, section 110.80(b)(11) requires that where the blanched food is washed prior to filling, water used be safe and of adequate sanitary quality. As written, current § 110.80(b)(11) includes two recommendation regarding blanching and one requirement regarding water quality. In evaluating the first recommendation for heat blanching, we considered that properly heating and cooling food during blanching is necessary to protect food from contamination and would apply in all cases for food when heat blanching is required in the preparation. Therefore, FDA tentatively concludes that it would be appropriate to establish this recommendation as a requirement. In evaluating the second recommendation regarding blanching, we considered that adequate operating temperatures and proper cleaning are necessary for controlling growth of thermophilic bacteria and contamination and would apply in all cases for food when heat blanching is required in the preparation. Therefore, FDA also tentatively concludes that it would be appropriate to establish this recommendation as a requirement. In evaluating the requirement regarding water quality, we considered that water quality would already be addressed in proposed § 110.37(a) and would be redundant in proposed § 110.80(c)(11) and therefore we are proposing to delete this specific requirement for water quality when the blanched food is washed prior to filling. Proposed § 110.80(c)(11) would require that heat blanching, when required in the preparation of food, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either

rapidly cooling the food or passing it to subsequent manufacturing without delay (emphasis added). Proposed § 110.80(c)(11) also would require that thermophilic growth and contamination in blanchers must be minimized by use of adequate operating temperatures and by periodic cleaning (emphasis added).

Current § 110.80(b)(12) requires that batters, breading, sauces, gravies, dressings, and other similar preparations be treated or maintained in such a manner that they are protected against contamination. Current § 110.80(b)(12) also provides several recommendations for how to comply with this requirement, including using ingredients free of contamination, employing adequate heat processes where applicable, using adequate time and temperature controls, providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them, cooling to an adequate temperature during manufacturing, and disposing of batters at appropriate intervals to protect against the growth of microorganisms. The recommendations regarding use of ingredients, employing adequate heat processes, and providing adequate physical protection would already be addressed in proposed §§ 110.80(b)(2), 110.80(c)(2), 110.80(c)(4) and 110.80(c)(10), respectively. As discussed regarding our proposed revisions to current § 110.80(b)(10) earlier in this section, FDA tentatively concludes that establishing requirements for time and temperature controls is not appropriate in light of the diversity of food operations. The remaining recommendations regarding cooling batters to an adequate temperature and disposing of batters at appropriate intervals are better addressed in guidance. Therefore, FDA is proposing to provide flexibility to industry by retaining the performance standard in current § 110.80(b)(12) (i.e., protection against contamination) but deleting the examples of mechanisms to achieve compliance rather than proposing to establish these recommendations as requirements. FDA also is proposing to require protection against

cross-contact because manufacturing operations may result in the transfer of food allergens to food. Proposed § 110.80(c)(12) would require that batters, breading, sauces, gravies, dressings, and other similar preparations be treated or maintained in such a manner that they are protected against cross-contact and contamination (emphasis added).

Current § 110.80(b)(13) requires that filling, assembling, packaging, and other operations be performed in such a way that the food is protected against contamination. It provides that compliance with this requirement may be accomplished by any effective means, including (i) use of a quality control operation in which the critical control points are identified and controlled during manufacturing; (ii) adequate cleaning and sanitizing of all food-contact surfaces and food containers; (iii) using materials for food containers and food- packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter; (iv) providing physical protection from contamination, particularly airborne contamination; and (v) using sanitary handling procedures. FDA is proposing to revise current § 110.80(b)(13) to require that filling, assembling, packaging, and other operations be performed in such a way that the food is protected against the growth of undesirable microorganisms as well as against contamination. The growth of any undesirable microorganisms already present in a food must be controlled, in addition to the introduction of contaminants. Current § 110.80(b)(13) also includes several recommendations for achieving compliance. FDA is proposing to provide flexibility to industry by retaining the performance standard in current § 110.80(b)(12) (i.e., protection against contamination) but deleting the examples of mechanisms to achieve compliance. FDA tentatively concludes that such examples would be more appropriate in a guidance document. Proposed § 110.80(c)(13) would require that filling, assembling, packaging, and other operations be performed in such a way that the

food is protected against cross-contact, contamination, and growth of undesirable microorganisms (emphasis added).

Current § 110.80(b)(14) requires that food, such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms be processed to and maintained at a safe moisture level. Current § 110.80(b)(14) also provides that compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices: monitoring the a_w of food, controlling the soluble solids-water ratio in finished food, and protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level. In evaluating the recommendations for mechanisms to achieve compliance, FDA considered that the listed mechanisms are not the only possible mechanisms for achieving compliance and that it would not be appropriate to establish these recommendations as requirements;, thus, we are proposing to delete these recommendations. Proposed § 110.80(c)(14) would require that food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms be processed to and maintained at a safe moisture level (emphasis added).

Current § 110.80(b)(15) requires that food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms be monitored and maintained at a pH of 4.6 or below. Current § 110.80(b)(15) also includes two recommendations for how to comply with the requirement. These recommendations are monitoring the pH of raw materials, food in process, and finished food and controlling the amount of acid or acidified food added to low-acid food. FDA considered that

the listed mechanisms may not be the only possible mechanisms for achieving compliance and that it would not be appropriate to establish these recommendations as requirements and, thus, is proposing to delete these recommendations. Proposed § 110.80(c)(15) would require food, including acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms be monitored and maintained at a pH of 4.6 or below.

Current § 110.80(b)(17) includes no requirements but instead recommends that food-manufacturing areas and equipment used for manufacturing human food not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food. FDA is proposing to establish this recommendation as a requirement. Certain nonhuman food-grade animal feed or inedible products can result in contamination of food and it is inappropriate to conduct manufacturing operations for human food in the same area that is used to manufacture nonhuman food-grade animal feed or inedible products. FDA also is proposing to require that the exception when there is no reasonable possibility for the contamination of human food also address cross-contact, because manufacturing operations may result in the transfer of food allergens to food. Proposed § 110.80(c)(1) would require that food-manufacturing areas and equipment used for manufacturing human food must not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for cross-contact or contamination of the human food (emphasis added).

I. Proposed Revisions to Current § 110.93--Warehousing and Distribution

Current § 110.93 requires that storage and transportation of finished food be under conditions that will protect food against physical, chemical, and microbial contamination as well

as against deterioration of the food and the container. FDA is proposing a series of revisions to current § 110.93.

FDA is proposing to delete the term "finished" before "food" because the requirements in this provision must apply to all food being held for distribution regardless of whether it is a raw material or ingredient or in its finished state. To ensure food safety throughout the food chain, food, whether a raw material or finished product, must be protected against contamination.

FDA also is proposing to revise § 110.93 to clarify that storage and transportation of food must be under conditions that will protect against cross-contact of food in addition to protecting against contamination of food. This proposed revision is part of FDA's broader effort, as discussed in sections IX.D and XI.A of this document, to make clear that CGMPs require protection against cross-contact, as well as contamination, of food in light of a recent shift in terminology that now distinguishes "cross-contact" from "contamination." Inadequate storage and transportation conditions may result in the transfer of food allergens to food.

FDA also is proposing to add radiological hazards as an additional category of contaminants to the list of contaminants which may be encountered in warehousing and distribution because food may be subject to contamination with radiological hazards. As discussed in section XII.B, FDA now recognizes four types of hazards: biological, chemical, physical and radiological. Our CGMP regulation for bottled water in part 129 requires plants to analyze product samples for bacteriological, chemical, physical and radiological purposes (§ 129.80(g)). Therefore, the proposed addition of radiological contaminants to the list of contaminants would be consistent with part 129. FDA tentatively concludes that there is no basis for requiring a facility to protect against some types of hazards but not others, and thus is proposing to include radiological hazards among those from which food must be protected.

FDA also is proposing to require protection against "biological," rather than "microbial" contamination of food so that, when a provision specifies all four types of hazards that must be addressed, the list is presented consistently throughout part 110. In section XII.B.3 of this document, we discuss a requirement, which would be established in proposed § 110.130(b), for a hazard analysis to address biological, chemical, radiological, and physical hazards. FDA also is proposing to present the list of types of hazards in the same order as the list would be presented in proposed § 110.130(b).

Proposed §110.93 would require that storage and transportation of food be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food as well as against deterioration of the food and the container.

J. Proposed Revisions to Current § 110.110--Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard

FDA is proposing to revise current § 110.110(b) to replace the word "whenever" in the current text with "when" for grammatical simplicity.

FDA is proposing to revise current § 110.110(c) to change the designated persons who must "observe good manufacturing practices" and "at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible" from the currently identified persons, (i.e., manufacturers, distributors and holders of food) to manufacturers, processors, packers and holders of food. We are proposing this change for consistency with terminology used in section 418 of the FD&C Act and throughout this proposed rule to describe responsible persons. FDA also is proposing to update the reference in current § 110.110(c) to section 402(a)(4) of the FD&C Act to make it more complete by specifying that the insanitary conditions are those whereby food may have become contaminated with filth, or

whereby food may have been rendered injurious to health. Proposed § 110.110(c) would specify that compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food not be prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. or the requirements in this part that food manufacturers, processors, packers, and holders must observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

FDA is proposing to revise current § 110.110(d) to replace the clause "The mixing of a food containing defects above the current defect action level…" with "The mixing of a food containing defects at levels that render the food adulterated…" We are proposing this change to clarify that food containing defects above the current defect action level is not automatically adulterated under the FD&C Act. A defect action level is nonbinding and is directed to a natural or unavoidable defect in food that presents no health hazards for humans (Ref. FDA's Defect Levels Handbook). Whether food containing defects above the current defect action levels adulterate the food is a case-by-case determination that depends on the circumstances. Proposed § 110.110(d) would specify that the mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

FDA is proposing to delete current § 110.110(e), which provides that a compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS–565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. The organizational entity identified in current § 110.110(e) (i.e., HFS-565) no longer exists. A compilation of such current defect action levels is available on the internet (Ref. Defect Levels Handbook).

K. Proposed Addition of § 110.120--Records Required for Subpart B

Proposed § 110.120(a) requires that plant management establish and maintain records that document required training of personnel, as would be required by proposed § 110.10(c)(3). Proposed § 110.120(a) would not establish any new requirements but merely make it obvious at a glance what records would be required under subpart B. This listing of records is consistent with our approach in proposed subpart C (see discussion of proposed § 110.175 in section XII.J of this document).

Proposed § 110.120(b) would require that the records that plant management must establish and maintain under subpart B be subject to the requirements of subpart F of part 110. As discussed in section XV of this document, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by part 110.

XII. Proposed Subpart C--Hazard Analysis and Risk-based Preventive Controls

A. Proposed § 110.126--Requirement for a Food Safety Plan

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act requires that:

- "The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of [section 418 of the FD&C Act], including analyzing the hazards under [section 418(b) of the FD&C Act] and identifying the preventive controls adopted under [section 418(c) of the FD&C Act] to address those hazards" and

- "Such written plan, together with the documentation described in [section 418(g) of the FD&C Act], shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request."

2. Proposed § 110.126(a)--Requirement for a Food Safety Plan

Proposed § 110.126(a) would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, and implement a written food safety plan. We use the term "written food safety plan" in proposed § 110.126(a) to mean the "written plan" referred to in section 418(h) of the FD&C Act. To make clear that the written plan is related to food safety rather than to other plans a facility may have (such as quality control plans or food defense plans), we have designated the "written plan" to be a "food safety plan."

Proposed § 110.126(a) would require that the plan be written as is expressly required by section 418(h). A written food safety plan is essential for the facility to implement the plan consistently, train its employees, and periodically reanalyze and update the plan. It is also essential to a facility's food safety team, to auditors, and to inspectors. Proposed § 110.126(a) would implement section 418(h) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The recordkeeping provisions of the NACMCF HACCP guidelines recommend that the HACCP plan include a list of the HACCP team and assigned

responsibilities; a description of the food, its distribution, intended use, and consumer; a verified flow diagram; a HACCP Plan Summary Table that includes information for steps in the process that are CCPs, the hazard(s) of concern, critical limits, monitoring, corrective actions, verification procedures and schedule, and record-keeping procedures (Ref. NACMCF, 1998). The Codex HACCP Annex recommends that HACCP procedures be documented, including the hazard analysis, and determinations of CCPs and critical limits (Ref. Codex 2003). Federal HACCP regulations for seafood, juice, and meat and poultry require a written plan (§§ 123.6(b)) and 120.8(a) and 9 CFR 417.2(b), respectively).

Proposed § 110.126(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf. This flexibility is consistent with the NACMCF HACCP guidelines (Ref. NACMCF, 1998), which advise that a HACCP team may need assistance from outside experts who are knowledgeable in the hazards associated with the product and the process. This flexibility also is consistent with the Codex HACCP Annex, which acknowledges that small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan and recommends that expert advice be obtained when necessary from other sources, such as trade and industry associations, independent experts and regulatory authorities. In addition, proposed § 110.126 would provide flexibility for facilities in the development of their food safety plans by allowing facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical.

Proposed § 110.126(a) would require that the owner, operator, or agent in charge of a facility implement the written food safety plan. Although section 418(h) of the FD&C Act is

silent with respect to implementation of the required written plan, other provisions of section 418 address implementation. For example, section 418(c) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility both establish and implement preventive controls (emphasis added). In addition, other provisions of section 418 (e.g., section 418(d) regarding monitoring, section 418(e) regarding corrective actions, and section 418(f) regarding verification) all establish requirements related to the preventive controls required under section 418(c). As discussed immediately below, the written food safety plan would include the hazard analysis required under section 418(b) of the FD&C Act, the preventive controls required under section 418(c) of the FD&C Act, the monitoring procedures required under section 418(d) of the FD&C Act, the corrective action procedures required under section 418(e) of the FD&C Act, the verification procedures required under section 418(f) of the FD&C Act, the recall plan as authorized by section 418(o)(3)(E) of the FD&C Act, and the procedures for supplier approval and verification as authorized by section 418(o)(3)(G). Specific provisions for implementing these sections of the statute would be established throughout proposed subpart C.

3. Proposed § 110.126(b)--Contents of a Food Safety Plan

Proposed § 110.126(b)(1) through (7) would require that the contents of a food safety plan include:

- The written hazard analysis as required by proposed § 110.130(a)(2);
- The written preventive controls as required by proposed § 110.135(b);
- The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by proposed § 110.140(a);
- The written corrective action procedures as required by proposed § 110.145(a)(1);

- The written verification procedures, and the frequency with which they are to be performed as required by proposed § 110.150(a);
- The written recall plan as required by § 110.137(a); and
- The written list of approved suppliers and the written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient as required by § 110.152(a)(3)(i) and (ii).

Section 418(h) requires that the written plan document and describe the procedures used by the facility to comply with the requirements of section 418, "including analyzing the hazards under [section 418(b) of the FD&C Act] and identifying the preventive controls adopted under [section 418(c) of the FD&C Act] to address those hazards" (emphasis added). Although section 418(h) of the FD&C Act explicitly references sections 418(b) and (c), the term "including," indicates that the contents of a food safety plan need not be limited to the provisions of sections 418(b) and (c) of the FD&C Act.

FDA interprets the requirement in section 418(h) of the FD&C Act that the written plan document and describe the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act to mean that the written food safety plan would include all procedures required under section 418 of the FD&C Act. As discussed in sections XII.E.6.a, XII.F.2, XII.G.6, XII.D.2, and XII.H of this document, the proposed rule would require written procedures for monitoring the implementation of the preventive controls (proposed § 110.140(a)); written corrective action procedures (proposed § 110.145(a)(1)); written procedures for some verification activities (proposed § 110.150(e)); a written recall plan (proposed § 110.137(a)); and a written list of approved suppliers and a written determination of which

designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient (proposed § 110.152(a)(3)(i) and (ii)).

FDA interprets the requirement in section 418(h) that the written plan describe the procedures used by the facility to comply with the requirements of section 418, including analyzing the hazards and identifying the preventive controls adopted to address those hazards, to mean that the contents of the food safety plan must include the hazard analysis conducted by the facility and the preventive controls that a facility must establish for hazards that its hazard analysis identifies as reasonably likely to occur, rather than procedures for analyzing the hazards and procedures for identifying the preventive controls. The general requirement in section 418(a) of the act is directed, in relevant part, to evaluating the hazards that could affect food manufactured, processed, packed, or held by a facility, and identifying and implementing preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Review of the evaluation of hazards in the hazard analysis is sufficient to determine the adequacy of the hazard analysis. Written procedures for conducting the hazard analysis are not necessary. Similarly, the preventive controls identified by the facility can be reviewed fully for adequacy without having a separate procedures document.

Under our interpretation of section 418(h) of the FD&C Act, proposed § 110.126(b)(1) and (2) are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that a HACCP plan include the hazards of concern (which are the end product of the hazard analysis), the CCPs (which are the steps at which control can be applied

and which are essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level), and critical limits (which are the maximum or minimum values established at a CCP to control a hazard) (Ref. NACMCF, 1998). The Codex HACCP Annex (Ref. Codex 2003) recommends that the HACCP plan include documentation of the hazard analysis and determinations of CCPs and critical limits. Federal HACCP regulations for seafood, juice, and meat and poultry all require that the HACCP plan list the food [safety] hazards that are reasonably likely to occur (§§ 123.6(c)(1) and 120.8(b)(1) and 9 CFR 417.2(c)(1), respectively), the CCPs (§§ 123.6(c)(2) and 120.8(b)(2) and 9 CFR 417.2(c)(2), respectively), and critical limits (§§ 123.6(c)(3) and 120.8(b)(3) and 9 CFR 417.2(c)(3), respectively). The FSIS HACCP regulation for meat and poultry further requires that the written hazard analysis be maintained as part of the documentation for the establishment's HACCP plan (9 CFR 417.5(a)(1)). None of these documents recommends or requires that the HACCP plan include the procedures for analyzing the hazards or procedures for identifying the CCPs and critical limits. Rather, these documents are clear that it is the outcomes rather than the procedures for conducting the hazard analysis and identifying the preventive controls that are part of the plan.

4. Proposed § 110.126(c)--Preparation of the Food Safety Plan by a Qualified Individual

Proposed § 110.126(c) would require that the food safety plan be prepared by a qualified individual. (See the discussion in section XII.I of this document regarding the qualifications of a qualified individual as would be established in proposed § 110.155(b)). Section 418 of the FD&C Act requires that firms identify and implement preventive controls and that facilities monitor and verify the effectiveness of the preventive controls. A qualified individual must develop the food safety plan in order to ensure the preventive controls are effective. The plan must be designed to identify and to significantly minimize or prevent hazards in order to prevent

illness or injury. Designing a plan requires an individual who is knowledgeable in the concepts of preventive controls, the hazards associated with a product and process, the appropriate preventive controls, with associated monitoring and corrective actions for those hazards, and appropriate verification activities for the applicable preventive controls. Such knowledge requires scientific and technical expertise developed through training, experience, or both.

Section 418 of the FD&C Act does not address the qualifications of the individual who would prepare the food safety plan. However, proposed § 110.126(c) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that, because of the technical nature required for the hazard analysis, experts who are knowledgeable in the food process either participate in or verify the hazard analysis and the HACCP plan (Ref. NACMCF, 1998). Our HACCP regulations for seafood and juice require that the individual developing the HACCP plan complete training in the application of HACCP principles to juice or seafood processing under a standardized curriculum or be qualified through job experience that provides knowledge at least equivalent to that provided through the standardized curriculum (§§ 123.10 and 120.13, respectively). The FSIS HACCP regulation for meat and poultry requires that the individual developing the HACCP plan complete training in the application of HACCP principles to meat or poultry product processing (9 CFR 417.7).

One way to comply with proposed § 110.126(c) could be for a team of individuals (for example, a "HACCP team" or a "food safety team") to develop the food safety plan under the oversight of a qualified individual. Each member of a HACCP or food safety team generally brings specific expertise important in developing the plan. For example, a microbiologist could provide knowledge of microbial hazards, an engineer could establish the critical parameters for

delivery of heat treatments, and a maintenance supervisor could identify sources of metal contamination. Proposed § 110.126 would not require that all such members of a food safety team satisfy the requirements in proposed § 110.126(c) for a qualified individual. However, under proposed § 110.126(c), a qualified individual must be responsible for ensuring that all components the food safety plan have been developed, including reviewing all information contained in the food safety plan, thereby verifying the hazard analysis and food safety plan developed by the food safety team.

5. Facility-Based Nature of the Written Food Safety Plan

The overall framework of section 418 of the FD&C Act is directed to a facility rather than, for example, a corporate entity that may have multiple facilities. For example, under section 418(b) of the FD&C Act the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility (emphasis added). Thus, proposed § 110.126 establishes a requirement for every facility to have its own written food safety plan. The facility-based nature of the written food safety plan that would be required by proposed § 110.126 is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines emphasize that it is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan (Ref. NACMCF, 1998). The Codex HACCP Annex states that HACCP should be applied to each specific operation separately (Ref. Codex 2003). Federal HACCP regulations for seafood, juice, and meat and poultry require that HACCP plans be specific to each location where the product is processed (§§ 123.6(b)(1) and 120.8(a)(1) for seafood and juice, respectively) or to "every official establishment" (9 CFR 417.2(a)) for meat and poultry).

Federal HACCP regulations for seafood, juice, and meat and poultry allow the HACCP plan to group food types or production method types if the hazards, critical control points, critical limits and required procedures such as monitoring are essentially identical, provided that any required features of the plan that are unique to a specific product or production method are clearly delineated in the plan and are observed in practice (§§ 123.6(b)(2) and 120.8(a)(2) and 9 CFR 417.2(b)(2) for seafood, juice, and meat and poultry, respectively). This type of grouping would be allowed under proposed § 110.126 and, thus, would provide flexibility for facilities in the development of their HACCP plans.

B. Proposed § 110.130--Hazard Analysis

1. Requirements of section 418 of the FD&C Act

Section 418(b) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall:

- "(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including"
    - "(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and"
    - "(B) hazards that occur naturally, or may be unintentionally introduced"
- "(3) develop a written analysis of the hazards."

As discussed in section II.B.2.f of this document, this rulemaking is not intended to address "hazards that may be intentionally introduced, including by acts of terrorism." Therefore, we are not implementing section 418(b)(2) of the FD&C Act in this proposed rule.

Section 418(c) of the FD&C Act specifies that "[t]he owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances" that:

- "(1) hazards identified in the hazard analysis conducted under [section 418(b)(1) of the FD&C Act] will be significantly minimized or prevented;" and
- "(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under [section 402 of the FD&C Act] or misbranded under [section 403(w) of the FD&C Act]."

Sections 418(c)(1) and (c)(3) of the FD&C Act, which we will address more fully in section XII.C.6 of this document, are relevant to our discussion of proposed § 110.130(a) regarding the purpose of the hazard analysis required by section 418(b) of the FD&C Act.

2. Proposed § 110.130(a) –Hazard Analysis

a. Proposed § 110.130(a)(1)--Requirement to identify and evaluate hazards. Proposed § 110.130(a)(1) would require that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards, for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. As discussed more fully in the remainder of this section, proposed § 110.130(a)(1) would implement section 418(b)(1) of the FD&C Act.

Proposed § 110.130(a)(1) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines describe a two-stage process for conducting a hazard analysis (Ref. NACMCF, 1998), i.e., hazard identification and hazard evaluation. Hazard identification has been described as a brainstorming session designed to facilitate the

development of a list of potential hazards, including those known to be associated with a type of food or process and those known to have occurred in a particular facility, for consideration during the hazard evaluation step (Ref. Bernard et al, GMA HACCP Ch 8). Hazard evaluation is conducted after development of the list of potential hazards associated with each step in the product's process. The Codex HACCP Annex recommends that the HACCP team list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption and then conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. Our HACCP regulation for juice requires that a hazard analysis both identify hazards and evaluate whether they are reasonably likely to occur (§§ 120.7(a)(1) and (2)). Federal HACCP regulations for seafood and meat and poultry require that a processor or establishment conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur (§ 123.6(a) and 9 CFR 417.2(a)).

In considering the proposed requirement for a hazard analysis, we considered the language of section 418(b)(1) of the FD&C Act describing the hazards that a facility would identify and evaluate – i.e., "known or reasonably foreseeable hazards that may be associated with the facility." We consider that the "known or reasonably foreseeable hazards" in section 418(b) of the FD&C Act are analogous to the "potential hazards" discussed in the NACMCF HACCP guidelines, and the hazards that are required to be identified to determine if they are "hazards that may be reasonably expected to occur at each step" in the Codex HACCP Annex, or "reasonably likely to occur" in Federal HACCP regulations for seafood, juice, and meat and poultry.

Proposed § 110.130(a)(1) would establish the requirement to identify and evaluate hazards by conducting a hazard analysis; we propose specific requirements for the hazard identification in proposed § 110.130(b) (see section XII.B.3 of this document) and specific requirements for the hazard evaluation in proposed § 110.130(c) (see section XII.B.4 of this document).

Proposed § 110.130(a)(1) would require that the identification and evaluation of hazards be done "for each type of food manufactured, processed, packed, or held at the facility." In considering the proposed requirement for a hazard analysis, we considered the language of section 418(b)(1) of the FD&C Act. The purpose of sections 418(b)(1) appears clear – i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards that may be associated with the food produced by the facility. The known or reasonably foreseeable hazards associated with the facility's food may differ based on the type of food and, thus, the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry all approach a hazard analysis for each type of food manufactured, processed, packed, or held at the facility. Proposed § 110.130(a) would do likewise.

The NACMCF HACCP guidelines (Ref NACMCF, 1998) and Codex HACCP Annex (Ref. Codex 2003) describe several preliminary tasks that need to be accomplished before application of the HACCP principles to a specific product and process, including describing the food and its distribution, describing the intended use and consumers of the food, and developing a flow diagram for the process. Our HACCP regulations for seafood and juice require that the hazard analysis be conducted for each kind of fish or fishery product (or for each type of juice product) processed by the processor (§§ 123.6(a) and 120.7(a)) but do not mandate any particular

process for the hazard analysis. The FSIS HACCP regulation for meat and poultry requires that a flow chart be prepared describing the steps for each process and product flow in the establishment (9 CFR § 417.2(a)(2)) and also requires a HACCP plan for each product produced by the establishment whenever the hazard analysis reveals one or more hazards that are reasonably likely to occur (9 CFR § 417.2(b)(1)).

The process of identifying and evaluating the hazards that may occur for specific types of food handled in a facility provides an efficient means for keeping track of multiple hazards that may occur in a facility that handles several types of foods. Such a process also provides an efficient means for ensuring that preventive controls are applied to specific foods when required. Thus, a facility may need to conduct multiple hazard analyses. For example, a facility that produces tea-based beverages may package its products in both glass and plastic bottles at the same facility. Although these two products might contain similar ingredients, we would consider them to be different types of food under proposed § 110.130(a)(1) because the two types of packaging entail significant differences in the handling of these products during processing. The hazard of glass particles resulting from glass container breakage during plant operations is a known hazard associated with glass-packaged products and, thus, should be identified and evaluated for the product packaged in glass but not for the product packaged in plastic.

Proposed § 110.130(a)(1) would identify the purpose of the hazard analysis - i.e., to determine whether there are hazards that are reasonably likely to occur. Although section 418(b)(1) of the FD&C Act does not explicitly identify the purpose of the hazard analysis, we interpret the combined requirements of sections 418(b), (c)(1) and (c)(3) of the FD&C Act to reflect a purpose, i.e., to enable the facility to identify and, where necessary, implement preventive controls to provide assurances that hazards identified in the hazard analysis will be

significantly minimized or prevented and that the food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. If, for example, the facility concludes during the hazard analysis that one or more (or even all) known or reasonably foreseeable hazards are not reasonably likely to occur in the facility for a certain type of food, the facility could conclude that there is no need to identify and implement preventive controls for those hazards. The purpose of the hazard analysis identified in proposed § 110.130(a)(1) is consistent with the purpose identified in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines identify the purpose of the hazard analysis as the development of a list of hazards that are of such significance that they are reasonably likely to cause illness or injury if not effectively controlled (Ref. NACMCF 1998). The Codex HACCP Annex recommends that the HACCP team identify for the HACCP plan hazards that are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food (Ref. Codex 2003). The stated purpose of the hazard analysis in Federal HACCP regulations for seafood, juice and meat and poultry is, in relevant part, to determine whether there are food safety hazards that are reasonably likely to occur for each kind of product (§§ 123.6(a) and 120.7(a), respectively, for seafood and juice) or in the production process for meat and poultry (9 CFR § 417.2(a)).

b. Proposed § 110.130(a)(2)--Requirement for the hazard analysis to be written.

Proposed § 110.130(a)(2) would require that the hazard analysis be written, as required by section 418(b)(3) of the FD&C Act. A written hazard analysis can help the facility organize the scientific basis for the hazard analysis and would be essential to the facility's food safety team, to auditors, and to inspectors. The facility's food safety team needs to fully understand the

nature of the hazards in order to produce a safe food. For example, although the facility's food safety plan would include corrective action procedures that address problems that can be anticipated, the food safety team will need to make decisions as to appropriate corrective actions when there is an unanticipated problem (see, e.g., the discussion of a proposed requirement (proposed § 110.145(b)) for corrective actions when there is an unanticipated problem in section XII.F.3 of this document). The written hazard analysis would be useful at these times. Having a written hazard analysis available for auditors and for inspectors is essential for them to assess the adequacy of the hazard analysis. A written hazard analysis also would be essential during reanalysis and updates of the hazard analysis, as would be required by proposed § 110.150(f) so that the person doing the reanalysis or update has a baseline from which to start. A written hazard analysis also would be useful for training purposes as a tool to make employees aware of food safety hazards that are reasonably likely to occur.

The written hazard analysis includes the justification for whatever conclusion the owner, operator, or agent in charge of a facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, proposed § 110.130(a)(2) would not limit the requirement for a written hazard analysis to those circumstances where the owner, operator, or agent in charge of a facility identifies one or more hazards that are reasonably likely to occur. Under proposed § 110.130(a)(2), a written hazard analysis would be required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur.

Proposed § 110.130(a)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry. The NACMCF HACCP guidelines and the Codex HACCP Annex each specify that the hazard analysis be documented in the HACCP plan (Refs. NACMCF and Codex). Our HACCP

regulation for juice requires a written hazard analysis (§ 120.7(a)). Our HACCP regulation for seafood requires that the list of food safety hazards that are reasonably likely to occur, identified in the hazard analysis, be included in the written HACCP plan (§ 123.6(c)). The FSIS HACCP regulation for meat and poultry requires a written hazard analysis, including all supporting documentation (9 CFR § 417.5(a)(1)).

3. Proposed § 110.130(b)--Hazard Identification

Proposed § 110.130(b) would require that the hazard analysis consider hazards that may occur naturally or may be unintentionally introduced, including:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance (proposed § 110.130(b)(1));
- Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, food or color additives, and food allergens (proposed § 110.130(b)(2));
- Physical hazards (proposed § 110.130(b)(3)); and
- Radiological hazards (proposed § 110.130(b)(4)); and

Proposed § 110.130(b) would implement section 418(b)(1) of the FD&C Act and would establish four groups of hazards (i.e., biological, chemical, physical, and radiological). Three of the proposed groups of hazards (i.e., biological, chemical, and physical) are the same as the groups of hazards in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry; the proposed group "radiological hazards" would be in addition to the groups of hazards in those HACCP systems. The additional group of "radiological hazards" is required by section 418(b)(1)(A) of the FD&C Act. The

NACMCF HACCP guidelines and Codex HACCP Annex identify biological, chemical, and physical hazards as types of hazards in the definition of hazard (Refs. NACMCF and Codex). Federal HACCP regulations for seafood, juice and meat and poultry identify biological, chemical, and physical hazards as types of hazards in the definition of "food safety hazard" (§ 123.3(f) and 9 CFR § 417.1 for seafood and meat and poultry, respectively) or food hazard (§ 120.3(g) for juice). Federal HACCP regulations for seafood, juice, and meat and poultry identify as hazards microbiological contamination, parasites, chemical contamination, unlawful pesticide residues, decomposition, natural toxins, unapproved use of food or color additives and physical hazards (§§123.6(c)(1), 120.7(c), and 9 CFR 417.2(a)(3), respectively). Federal HACCP regulations for seafood and meat and poultry also identify as hazards drug residues (§ 123.6(c)(1)(v) and 9 CFR 417.2(a)(3)(v) for seafood and meat and poultry, respectively) and undeclared ingredients that may be allergens (§ 120.7(c)(8) for juice). The FSIS HACCP regulation for meat and poultry also identifies zoonotic diseases as a hazard (9 CFR 417.2(a)(3)).

Microbiological hazards

Proposed § 110.130(b)(1) would include microbiological hazards within the category of biological hazards. Examples of microbiological hazards include:

- Parasites (which are required to be considered by section 418(b)(1)(A) of the FD&C Act). A parasite is an organism that lives on or in an organism of another species (often called the host organism) and feeds off that other species. Cryptosporidium spp., Giardia intestinalis, and Toxoplasma gondii are examples of parasites.
- Environmental pathogens (e.g., Listeria monocytogenes and Salmonella spp.); and
- Other microorganisms of public health significance, including bacteria (e.g., Campylobacter spp., Clostridium perfringens, Shiga toxin-producing Escherichia coli (STEC)

O157, STEC non-O157, Shigella spp., Staphylococcus aureus, Vibrio spp., and Yersinia enterocolitica) and viruses (e.g., hepatitis A virus and norovirus).

As discussed in section II.D.1 of this document, CDC has estimated that the total burden of foodborne illness is 48 million cases, 128,000 hospitalizations, and 3,000 deaths due to illnesses from both major pathogens and from unspecified agents (Refs. Scallan major pathogens; Scallan unspecified agents). Focusing only on the foodborne illnesses attributable to particular pathogens, a recent report estimated that 31 major pathogens (for which data for preparing national estimates are available, including those listed above) cause 9.4 million episodes of foodborne illness, 55,961 hospitalizations and 1351 deaths in the United States each year (Ref. Scallan major pathogens). In addition to contaminating raw materials, some of these pathogens (e.g., Listeria monocytogenes and Salmonella spp.) are common pathogens of concern with respect to contamination from the processing environment for specific types of facilities (Refs. Tompkin et al., 1999; Scott et al., 2009 FPT1). (See sections II.E.4 and II.E.5 of this document for a discussion of testing programs for environmental pathogens). Contamination of food with some pathogens (e.g., Staphylococcus aureus and norovius) is often due to poor employee hygiene or practices.

Chemical hazards

Proposed § 110.130(b)(2) would include substances such as pesticide and drug residues, natural toxins, decomposition, food or color additives, and food allergens (all of which are required to be considered by section 418(b)(1)(A) of the FD&C Act) within the category of chemical hazards. As discussed in section II.D.2.b of this document, pesticide residues may be present in food in the absence of or in excess of a tolerance established by the EPA. Residues of drugs (e.g., antibiotics administered to dairy cows) may be present in food derived from the

animal (such as milk) in the absence of or in excess of a tolerance or safe levels established and enforced by FDA (Ref. M-I-05-5). Natural toxins such as aflatoxin and patulin are well recognized as hazards in foods such as peanuts and apple juice products, respectively (Refs. CPG 570.375 and 510.150). Decomposition products such as histamine, produced from the amino acid histidine when certain bacteria grow, can pose a risk to health. An undeclared food allergen (such as a peanut) can cause a life-threatening reaction (such as anaphylactic shock) in susceptible individuals (Ref. Thresholds Food Allergens and for Gluten). Heavy metals (such as lead) can lead to impaired cognitive development in children (Ref. supporting document lead in candy).

Physical hazards

Proposed § 110.130(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. Physical hazards may be associated with raw materials, especially RACs. The facility and equipment can also be a source of physical hazards, e.g., container glass and metal fragments such as nuts and bolts.

Radiological hazards

Proposed § 110.130(b)(4) would require that the hazard analysis consider radiological hazards. As discussed in section II.D.2.e of this document, examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium, strontium-90 and iodine-131. The NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry do not identify radiological hazards as a type of hazard to be considered in the hazard analysis. However, section 418(b)(1)(A) of the FD&C Act

requires that radiological hazards be considered, and food may be subject to contamination with radiological hazards – e.g., if water used to manufacture a food contains a radionuclide. For example, radiological hazards may result from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. In addition, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium have been detected in private wells (Refs. USGS).

4. Proposed § 110.130(c)--Hazard Evaluation

a. Proposed § 110.130(c)(1)--Evaluation of whether a hazard is reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur. Proposed § 110.130(c)(1) would require that the hazard analysis include an evaluation of the hazards identified in § 110.130(b) to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur. As discussed in more detail later in this section, proposed § 110.130(c)(1) would implement sections 418(b)(1) and (c)(3) of the FD&C Act. Proposed § 110.130(c)(1) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines define severity as the seriousness of the effects of a hazard. The severity of the illness or injury includes the magnitude and duration of the illness and impact of any sequelae (chronic conditions resulting from an illness, such as reactive arthritis following a Salmonella infection). The NACMCF HACCP guidelines also recommend considering the likelihood of an illness or injury (usually based upon a combination of experience, epidemiological data, and information in the technical literature) and the potential effects associated with both short-term and long-term exposure (Ref. NACMCF). Likewise, the Codex HACCP Annex recommends that the hazard analysis consider

the severity of the adverse health effects associated with the hazards (Ref. Codex). Our juice HACCP regulation requires that the hazard evaluation include an assessment of the severity of the illness or injury if the hazard occurs (§ 120.7(a)(2)). The requirement for a hazard analysis in our seafood HACCP regulation does not specifically require an assessment of severity but addresses the potential for illness or injury in its definition of a food safety hazard, which refers to biological, chemical or physical properties that may cause a food to be unsafe for human consumption (§ 123.3(f)) and in the description of a food safety hazard that is reasonably likely to occur, which includes illness data as a basis for establishing controls (§ 123.6(a)). Similarly, the FSIS HACCP regulation for meat and poultry does not specifically require an assessment of severity in the hazard analysis (9 CFR § 417.2(a)), but its definition of a food safety hazard refers to biological, chemical or physical properties that may cause a food to be unsafe for human consumption (9 CFR 417.1(c)). In the final rule to establish our juice HACCP regulation, we agreed with the NACMCF approach to conducting the hazard analysis - i.e., that the process of evaluating food hazards to determine which potential hazards need to be addressed in the HACCP plan (i.e., those that are reasonably likely to occur) takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact of the potential hazards in question (66 FR 6138 at 6155).

As discussed in section II.D.2.a of this document, contamination of food with biological hazards often leads to immediate or near-term onset of illness or injury (e.g., gastrointestinal illness). Exposure to some biological hazards may have long-term consequences as well (e.g., infections with Salmonella may result in reactive arthritis). The effects of exposure to some biological hazards are severe (e.g., Hemolytic Uremic Syndrome (HUS) in individuals exposed to E. coli O157:H7 (63 FR 20450 at 20450) or invasive listeriosis in susceptible individuals

exposed to L. monocytogenes in ready-to-eat foods (Ref. FDA/FSIS 2003. Executive Summary, LmRA). Proposed § 110.130(c)(1) would require that such biological hazards be considered to determine whether they are reasonably likely to occur even if the biological hazard occurs infrequently.

As discussed in sections II.D.2.b and II.D.2.c of this document, contamination of food with chemical hazards may lead to immediate or near-term onset of illness – e.g., an allergic reaction to an undeclared peanut or to a residue in a milk product of penicillin used to treat the cow. In other instances the focus of the evaluation for chemical hazards is directed to their long term effects, such as impaired cognitive development in children exposed to lead in contaminated candy (Ref. Supporting document lead in candy) and liver cancer in persons exposed to the mycotoxin aflatoxin (Ref. Gordon S. Shephard, 2008). Proposed § 110.130(c)(1) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

Under the FD&C Act, certain products, such as food additives, color additives, new animal drugs, and pesticides require premarket approval before they may be legally used. (In the case of pesticides, EPA "registers" (i.e., approves) the use of pesticides and establishes tolerances (the maximum amounts of residues that are permitted in or on a food) if the use of a particular pesticide may result in residues in or on food. FDA enforces those tolerances, except for meat, poultry, and certain egg products, which are the responsibility of FSIS (Ref. FDA 2008 Pesticide Monitoring Report). Moreover, this approval can be limited so that the product may only be used legally on or with specific foods, or for specific purposes, for which approval has been obtained. This limitation reflects a longstanding understanding that the safety of these types of products is variable and must be established on a use-by-use basis. Whether an additive,

drug, or pesticide is safe for a particular use, in a particular food, at a particular level, depends on factors such as the amount of the food that is consumed and, if the additive, drug, or pesticide is ingested in a living animal before capture, how the product is metabolized in that animal. Therefore, an additive, drug, or pesticide that has been approved for use in some foods, but not other foods, is deemed by the FD&C Act to be unsafe for use with those other foods.

Natural toxins including aflatoxin in foods such as peanuts and tree nuts and patulin in apple juice products are well recognized as hazards (Refs. CPGs 570.375, 570.200, 570.500, and 510.150 for patulin in apple juice). In addition, decomposition products such as histamine, produced from the amino acid histidine when certain bacteria grow, can pose a risk to health. Further, biogenic amines other than histamine have been associated with illnesses, and these may also be formed when bacteria grow in some foods. Although certain fish species are the most common source of illness from histamine and other biogenic amines, illness from histamine has been reported from consumption of other foods, in particular cheese (Ref. Taylor, S. 1985). Heavy metals (such as lead) can lead to impaired cognitive development in children (Ref. supporting document lead in candy). Proposed § 110.130(c)(1) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

Physical hazards such as hard and sharp foreign objects that may be present in food can pose a health risk (Ref. CPG 555.425). Hard or sharp foreign objects in food may cause traumatic injury, including laceration and perforation of tissues of the mouth, tongue, throat, stomach and intestine as well as damage to the teeth and gums (Ref. CPG 555.425; Olsen, 1998). Thus, although physical hazards may occur infrequently, under proposed § 110.130(c)(1) the potential for severe consequences would require consideration of these physical hazards to

determine whether they are reasonably likely to occur. Factors relevant to an evaluation of the severity of a physical hazard include the potential size of the object, the nature of the food (e.g., ready to eat or required to undergo further processing), and whether intended consumers of the food include special risk groups (Ref. CPG 555.425).

Contamination of food with radiological hazards generally is evaluated for long-term effects such as the potential for cancer (Ref. 1998 document issued to states and local agencies). A significant radiation dose could be received as a result of consumption of food contaminated as a result of an accident at a nuclear power plant or other types of accidents (Ref. the 1998 document to states; see also (63 FR 43402, August 13, 1998)). Foods may contain unsafe levels of radionuclides (Ref. CPG 560.750). Thus, although radiological hazards occur infrequently, under proposed § 110.130(c)(1) the potential for severe consequences would require consideration of radiological hazards to determine whether they are reasonably likely to occur for a particular food or facility, especially when circumstances arise that could lead to contamination of food with radiological hazards.

The purpose of sections 418(b)(1) and 418(c)(3) of the FD&C Act seems clear – i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for the purpose of identifying and implementing preventive controls to provide assurances that identified hazards will be significantly minimized or prevented and that the food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. The process of evaluating food hazards to determine which potential hazards require preventive controls must take into account the consequences of exposure (i.e., severity) as well as the probability of occurrence (i.e., frequency) to provide assurances that the food manufactured,

processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Proposed § 110.130(c)(1) would implement this statutory direction.

b. Proposed § 110.130(c)(2)--Requirement to evaluate environmental pathogens. Proposed § 110.130(c)(2) would require that the hazard analysis include an evaluation of whether environmental pathogens are reasonably likely to occur whenever an RTE food is exposed to the environment prior to packaging. As noted in section II.D.2.a of this document, environmental pathogens can be a source of contamination of food. Examples of environmental pathogens that have contaminated foods (and, in particular, RTE foods) include Salmonella spp. and L. monocytogenes. Proposed § 110.130(b)(1) would include environmental pathogens as one of the biological hazards that must be considered in identifying hazards for evaluation. Under proposed § 110.130(c)(2), a facility that produces an RTE food that is exposed to the environment would be required to identify environmental pathogens as a known or reasonably foreseeable hazard under proposed § 110.130(b) and evaluate whether contamination of RTE food with the environmental pathogen is reasonably likely to occur in the facility.

c. Proposed § 110.130(c)(3)--Consideration of specific factors relevant to the hazard evaluation. Proposed § 110.130(c)(3) would require that, in conducting the hazard evaluation, consideration be given to the effect of several specific factors on the safety of the finished food for the intended consumer. We tentatively conclude that these are factors that a prudent person who manufactures, processes, packs, or holds foods would consider when evaluating identified hazards to determine whether they are reasonably likely to occur. As we indicated in proposing our HACCP regulation for juice, a prudent processor should consider factors such as these in doing a hazard analysis (63 FR 20450 at 20468).

Proposed § 110.130(c)(3)(i) would require that the hazard evaluation consider the formulation of the food. The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, since they may inhibit growth of, or even kill, microorganisms of public health significance. This could impact the evaluation of the hazard of pathogen growth at steps during production and storage. A multi-component food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or a_w) but when put together there may be an interface where the pH and a_w changes (e.g., pies, layered breads). Under proposed § 110.130(c)(3)(i), the interaction of the individual ingredients must be evaluated as part of the formulation of the food. Proposed § 110.130(c)(3)(i) also would require that the hazard evaluation consider whether or not the formulation contains an ingredient (such as a flavoring) that may contain an allergen.

Proposed § 110.130(c)(3)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment. The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling and conveying equipment) may be more difficult to clean (e.g., with close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments. Proposed § 110.130(c)(3)(ii) would require that facilities with such equipment consider the impact of the equipment on the potential for pathogens to be a hazard that is reasonably likely to occur; if so, a preventive control such as enhanced sanitation controls may be appropriate, particularly if the equipment is used in production of RTE food. Equipment designed such that there is metal-to-metal contact may generate metal fragments Proposed § 110.130(c)(3)(ii)

would require that facilities with such equipment consider the impact of the equipment on the potential for generation of such metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate. A facility that manufactures, processes, or packs soft, fresh cheese (such as queso fresco, which is consumed without cooking to adequately reduce pathogens) may have cold, moist conditions that are conducive to the development of a niche where the pathogen L. monocytogenes can become established and contaminate food-contact surfaces and, eventually, foods. Proposed § 110.130(c)(3)(ii) would require that facilities with such conditions consider the impact of the conditions on the potential for whether development of a niche where the pathogen L. monocytogenes can become established is a hazard that is reasonably likely to occur; if so, enhanced sanitation controls may be appropriate. A facility design that has closely spaced equipment would provide more opportunities for cross-contact of allergens (such as powdered milk or soy) from one line to another (e.g., through dust) than a facility that has more spacing between equipment. Proposed § 110.130(c)(3)(ii) would require that facilities with such closely spaced equipment consider the impact of the close spacing on the potential for cross-contact to be a hazard that is reasonably likely to occur; if so, targeted food allergen controls may be appropriate.

Proposed § 110.130(c)(3)(iii) would require that the hazard evaluation consider raw materials and ingredients. Current § 110.3 defines "food" to mean food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients, and that definition would be retained in this proposed rule. There is an overlap between raw materials and ingredients. Not all raw materials are ingredients. For example, under section 201(f) of the FD&C Act, a food additive is food and, thus, the manufacture of a food additive is subject to part 110. An example

of a food additive is sucrose fatty acid esters. Under § 172.859, sucrose fatty acid esters are the mono-, di-, and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or hydrogenated edible tallow or edible vegetable oils. The only solvents which may be used in the preparation of sucrose fatty acid esters are those generally recognized as safe in food or regulated for such use by an appropriate section in this part. Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters. The regulation for sucrose fatty acid esters identifies a number of raw materials used in the production of sucrose fatty acid esters. Because the production process transforms those raw materials into the substance "sucrose fatty acid esters," those raw materials generally would not be viewed as "ingredients" of the final chemical product. Likewise, if a facility adds the food additive "sucrose fatty acid esters" to a food product, the facility would view that food additive as an ingredient of its food product, but would not view the chemicals used to produce sucrose fatty acid esters as ingredients of its food product.

A food can become contaminated through the use of contaminated food ingredients. For example, in the past several years thousands of foods have been recalled as a result of contamination of food ingredients with pathogens such as Salmonella and E. coli O157:H7. The ingredients included peanut-derived ingredients (Ref. Peanut butter recall info), pistachio-derived ingredients (Ref. Pistachio recall info), hydrolyzed vegetable protein (Ref. "For Consumers; The HVP Recall"), instant nonfat dried milk, whey protein, and fruit stabilizers (Ref. 2 Plainview pieces on FDA web site), and bagged spinach (Ref. Pacific Coast Fruit). In some cases, the contamination was discovered only after the ingredient was associated with an outbreak of foodborne illness (Ref. FDA MajorProductRecalls/Peanut). In other cases, the

contamination was discovered in a food and associated with a particular ingredient without any known incidence of foodborne illness (Refs. to pistachio recall; Plainview press announcement and accessdata.fda.gov/scripts/HVPCP/; spinach archive recalls). Following some of these recalls, we issued guidance recommending that manufacturers of foods containing a particular type of ingredient either obtain the ingredients from suppliers with validated processes in place to adequately reduce the presence of the applicable pathogen, or ensure that their own manufacturing process would adequately reduce the presence of that pathogen (Refs. peanut guidance and pistachio guidance). Specific pathogens would be considered to be a hazard that is reasonably likely to occur for raw materials and ingredients that have been documented to be contaminated with such pathogens, as well as for ingredients with similar characteristics (because such contamination might be expected in ingredients that are produced in a similar manner).

A food also may become contaminated through the use of contaminated raw materials that are not food ingredients. In the example of the manufacture of the food additive sucrose fatty acid esters, § 172.859 establishes specifications for sucrose fatty acid esters, such as specifications that arsenic is not more than 3 parts per million, total heavy metal content (as lead) is not more than 50 parts per million, and lead is not more than 10 parts per million (§ 172.859(b)(6), (7), and (8)). The use of raw materials that are contaminated with arsenic, lead, or other heavy metals that would not be removed as part of the manufacturing process for sucrose fatty acid esters could lead to sucrose fatty acid esters that are contaminated with arsenic, lead, or other heavy metals such that they do not satisfy the specifications of the regulation.

As noted for formulation in the discussion of proposed § 110.130(c)(3)(i), ingredients must be evaluated for “hidden” allergens such as may be present in flavors. Production and

harvesting practices may impact whether raw materials and ingredients contain hazards. For example, machinery-harvested produce is more likely to be contaminated with physical hazards than hand-picked produce, because the machinery often picks up foreign material from the field.

Proposed § 110.130(c)(3)(iv) would require that the hazard evaluation consider transportation practices. A food may become unsafe as a result of poor transportation practices for incoming raw materials and ingredients or for outgoing finished product. For example, failure to adequately control temperature during transportation could make a food unsafe if the product requires time and temperature controls to ensure safety. Distributing a food in bulk of without adequate protective packaging makes the product susceptible to contamination during transportation – e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination (Ref. Wojtala 2007). (For additional examples of food safety problems that could occur during transportation, see 75 FR 22713, April 30, 2010).

The Sanitary Food Transportation Act of 2005 (SFTA) gives FDA authority to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. In 2010, we published an Advance Notice of Proposed Rulemaking to request data and information on the food transportation industry and its practices and we expect to issue a separate proposed rule to implement the SFTA (75 FR 22713, April 30, 2010). We do not expect a future rulemaking implementing the SFTA to eliminate the need for the owner, operator, or agent in charge of a facility to consider transportation practices when determining whether a hazard is reasonably likely to occur.

Proposed § 110.130(c)(3)(v) would require that the hazard evaluation consider manufacturing/processing procedures. For example, hazards may arise from manufacturing/processing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic spore forming bacteria such as Clostridium perfringens and Bacillus cereus (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing/processing processes such as acidification due to the potential for germination of spores of C. botulinum, with subsequent production of botulinum toxin, if the acidification is not done correctly. Toxins can be produced by the bacteria Staphylococcus aureus or Bacillus cereus in a product that has been heated and held at room temperature during the manufacturing process if the product formulation supports growth and toxin formation by the bacteria and S. aureus or B. cereus is present in the ingredients of the product or is introduced by poor employee hygiene (e.g. S. aureus). Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades or knives) is used to cut products during manufacturing.

Proposed § 110.130(c)(3)(vi) would require that the hazard evaluation consider packaging activities and labeling activities. For example, as discussed earlier in this section XII.4.c the hazards that are reasonably likely to occur would be different depending on whether a product is packaged in glass bottles or in plastic bottles. A label on a food may direct consumers to cook a product to a certain temperature; the likelihood of consumers following those cooking instructions may vary depending on the type of food. For example, it is well known that consumers will eat raw cookie dough, even though the cookie dough is clearly intended to be cooked, and there have been outbreaks of foodborne illness associated with the consumption of

uncooked cookie dough (Ref. to cookie dough outbreak/recall). Thus, although label information is a factor to consider, a hazard may be reasonably likely to occur even with label information such as cooking instructions.

Proposed § 110.130(c)(3)(vii) would require that the hazard evaluation consider storage and distribution. For example, biological hazards are more likely to be a hazard that is reasonably likely to occur during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods. Shelf-stable foods are designed such that biological hazards are controlled.

Proposed § 110.130(c)(3)(viii) would require that the hazard evaluation consider intended or reasonably foreseeable use. An example of intended or reasonably foreseeable use is whether the food would be cooked by the consumer. In some cases, the intended use of a product may include uses where it would be cooked by the consumer as well uses where it would not be cooked. For example, soup is generally cooked, but a dried soup mix is often used in RTE form as a component of a dip. Cookie dough is a product that is intended to be baked by the consumer, but it is well known that consumers eat raw cookie dough, and an outbreak of foodborne illness caused by E. coli O157:H7 has been linked to consumption of raw cookie dough (Ref. cookie dough recall notice). When it is known or reasonably foreseeable that a food would be consumed in RTE form, hazards such as Salmonella, L. monocytogenes, and E. coli O157:H7 would need to be considered to determine if they are hazards reasonably likely to occur.

Proposed § 110.130(c)(3)(ix) would require that the hazard evaluation consider sanitation, including employee hygiene. Sanitation measures and practices can impact the likelihood of a hazard being introduced into a food. For example, the frequency with which a

production line is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw produce that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as Salmonella, hepatitis A and norovirus.

Proposed § 110.130(c)(3)(x) would require that the hazard evaluation consider any other relevant factors that might potentially affect the safety of the finished food for the intended consumer. For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful microorganisms or chemical residues. Following a natural disaster, environmental contaminants that could be brought into the facility could be a hazard reasonably likely to occur. As another example, when local water authorities advise the public to boil tap water for drinking, a facility should consider whether bacterial, viral or parasitic (e.g., Cryptosporidium and Giardia) contamination presents a hazard reasonably likely to occur as a result of the events that triggered the advisory (Ref. FDA boil water advisory).

Proposed § 110.130(c)(3) is consistent with the NACMCF HACCP guidelines, the Hazards and Controls Guides we have issued regarding our HACCP regulations for juice and seafood, and the Hazards and Controls Guide FSIS has issued regarding the FSIS HACCP regulation for meat and poultry. The NACMCF HACCP guidelines note that hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product – e.g., due to differences in equipment and/or maintenance programs (Ref. NACMCF). Appendix C of the NACMCF HACCP guidelines provides examples of questions to be considered when conducting a hazard analysis and identifies factors to consider such as

ingredients, formulation, processing procedures, design of facility, design and use of equipment, packaging, sanitation, worker health and hygiene, storage, intended use, and intended consumer. Our Hazards and Controls Guide for juice provides recommendations related to factors such as shelf life of the product, location of the processing, and type of processing, e.g., thermal or non-thermal processing (Ref. juice guide). Our Hazards and Controls Guide for seafood provides recommendations related to factors such as storage conditions (time and temperature), the role of manufacturing conditions in minimizing the potential for formation of C. botulinum toxin, manufacturing procedures (cooking and pasteurization) to control pathogenic bacteria, manufacturing procedures (such as high hydrostatic pressure processing, individual quick freezing with extended frozen storage, mild heat processing, and irradiation) designed to retain raw product characteristics, and the introduction of pathogenic bacteria after pasteurization and specialized cooking processes. The FSIS Hazards and Controls Guide for meat and poultry provides recommendations related to factors such as receiving, thawing, formulation, manufacturing procedures, packaging, storage and shipping (Ref. FSIS Meat and Poultry Hazards and Controls Guide).

C. Proposed § 110.135--Preventive Controls for Hazards That Are Reasonably Likely to Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c) of the FD&C Act, in relevant part, specifies that the "owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that":

- "[H]azards identified in the hazard analysis conducted under [section 418(b)(1) of the FD&C Act] will be significantly minimized or prevented" (section 418(c)(1) of the FD&C Act); and

- "[T]he food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act]" (section 418(c)(3) of the FD&C Act).

As discussed in section X.C.4 of this document, section 418(o)(3) of the FD&C Act defines preventive controls and proposed § 110.3 would include the statutory definition in part 110. Under section 418(o)(3), the procedures, practices, and processes described in the definition of preventive controls may include the following:

- "Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment" (section 418(o)(3)(A) of the FD&C Act);
- "Supervisor, manager, and employee hygiene training" (section 418(o)(3)(B) of the FD&C Act);
- "An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment" (section 418(o)(3)(C) of the FD&C Act);
- "A food allergen control program" (section 418(o)(3)(D) of the FD&C Act);
- "A recall plan" (section 418(o)(3)(E) of the FD&C Act);
- "(CGMPs) under part 110 … (or any successor regulations)" (section 418(o)(3)(F) of the FD&C Act); and
- "Supplier verification activities that relate to the safety of food" (section 418(o)(3)(G) of the FD&C Act).

2. Proposed § 110.135(a)--Requirement to Identify and Implement Preventive Controls for Hazards that are Reasonably Likely to Occur

Proposed § 110.135(a) would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at CCPs, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

As discussed in section XII.B.2.a of this document, proposed § 110.130(a) would require that the owner, operator, or agent in charge of a facility conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are "reasonably likely to occur." Under proposed § 110.135(a), a facility that determines through its hazard analysis that there are hazards that are reasonably likely to occur would then be required to identify and implement preventive controls for those hazards. Preventive controls would be required when applicable hazards are identified as reasonably likely to occur. As discussed in sections XII.B.2 through XII.C.10 of this document, the types of preventive controls implemented would depend on the facility and the food it produces. Some hazards would be addressed through process controls, food allergen controls, and sanitation controls. In some cases hazards may be addressed through other programs such as a supplier approval and verification program. For any type of preventive control, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes

available to it that would provide the assurances that would be required by proposed § 110.135(a).

Proposed § 110.135(a) would implement section 418(c) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry, although there are some differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. The NACMCF HACCP guidelines (Ref. NACMCF, 1998), the Codex HACCP Annex (Ref. Codex HACCP 2003), and Federal HACCP regulations for seafood, juice , and meat and poultry (§§ 123.6 and § 120.7 and 9 CFR § 417.2, respectively) direct a processor to address potential hazards that are reasonably likely to cause illness or injury in the absence of their control by determining CCPs and establishing critical limits for those CCPs. As discussed in section II.C.2 of this document, the approach in section 418 of the FD&C Act is broader than the approach in HACCP systems, in that section 418 of the FD&C Act clearly contemplates that CCPs are only one place to apply a preventive control, and that there may in fact not be any CCPs. Under proposed § 110.135(a), a processor could address hazards that are reasonably likely to occur through preventive controls that would be applied at CCPs, but doing so would not be the only option available to the facility in all circumstances. In some cases adequate assurances could be achieved via preventive controls implemented through other procedures and practices of a facility, such as its supplier approval and verification program or food allergen control program, which may not have specific CCPs. (For discussion of the supplier approval and verification program that would be required by proposed § 110.152, see section XII.H of this document. For discussion of the food allergen control program that would be required by proposed § 110.135(d)(2), see section XII.C.6 of this document.)

For example, potential biological hazards in raw materials such as spices include microorganisms of public health significance. When a facility identifies microorganisms of public health significance as reasonably likely to occur (e.g., when it uses spices as an ingredient in dehydrated soup mixes), control of that biological hazard could be achieved by treating the spices to adequately reduce that biological hazard in the spices. Such treatment could be conducted either by the supplier, which may be a component of a supplier approval and verification program, or by the receiving facility at a CCP within the manufacturing process for its product.

Whatever types of preventive controls a facility chooses to apply in its operations, the requirement in proposed § 110.135(a) would be risk based. Establishing risk-based preventive controls involves consideration of the available scientific data and information related to food safety risks. Typically, the hazard evaluation will enable the facility to determine appropriate risk-based preventive controls for the hazard based on the severity of the hazard and the likelihood of its occurrence.

For example, as discussed in section II.E.4.f of this document, L. monocytogenes is an environmental pathogen that can establish a harborage in the environment such as on a production line used in wet manufacturing. Once established, L. monocytogenes can intermittently contaminate products on the production line. When a hazard analysis identifies L. monocytogenes as a hazard that is reasonably likely to occur in a food, the facility would establish sanitation controls to prevent L. monocytogenes from establishing itself in a harborage site. In addition to such sanitation controls, a facility may consider applying a listericidal process step (i.e., a process control applied to adequately reduce levels of L. monocytogenes) in RTE foods. As discussed in section II.D.2.a of this document, some RTE foods (like soft

cheese) support the growth of L. monocytogenes, while others (like hard cheese) do not. The FAO/WHO Listeria risk assessment demonstrated that the risk of serious illness from consumption of RTE products contaminated with L. monocytogenes increases with the number of L. monocytogenes in an RTE food (Ref. Chapter 5 of the FAO/WHO Listeria risk assessment). Thus, as a risk-based approach to the control of the biological hazard L. monocytogenes, the facility may elect to apply a listericidal process step to those RTE foods that support growth of L. monocytogenes in addition to its sanitation controls, but not apply such a process to those RTE foods that do not support growth of L. monocytogenes.

3. Proposed § 110.135(b)--Requirement for Written Preventive Controls

Proposed § 110.135(b) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur be written. Proposed § 110.135(b) would implement section 418(h) of the FD&C Act which, as discussed in section XII.A.2 of this document, requires that the owner, operator, or agent in charge of a facility prepare a written food safety plan that, among other things, identifies the preventive controls within the plan. Written preventive controls are essential for the facility to implement the preventive controls consistently and essential for the facility's food safety team, auditors, and to inspectors. Written preventive controls also would be essential for training purposes and during reanalysis and updates of the preventive controls. Proposed § 110.135(b) is consistent with our HACCP regulation for juice, which requires that the written hazard analysis identify control measures that the processor can apply to control the food hazards identified as reasonably likely to occur (§ 120.7(a)).

4. Proposed § 110.135(c)--Requirement for Parameters Associated with the Control of Hazards That Are Reasonably Likely to Occur

Proposed § 110.135(c)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the food, parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, dehydrating, and refrigerating foods. Proposed § 110.135(c)(1) would include examples of several measures identified in § 110.80(b)(4) (Manufacturing Operations) that if used as a preventive control must be adequate when used to prevent adulteration, but would not establish an exhaustive list of such processes, just as § 110.80(b)(4) does not establish an exhaustive list of measures that must be adequate. Examples of other processes that would require the identification of parameters if used as a preventive control are brining, chilling, high pressure processing, treating with ultraviolet light, and washing with antimicrobial agents. The parameters are those factors that must be controlled to ensure the hazard will be significantly minimized or prevented. The specific parameters required, and how they would be controlled, would depend on the facility and the food. For example, for a heat process, parameters such as temperature and time must be controlled. Temperature may be controlled through controls on product temperature (as when treating a fluid product in a heat exchanger) or through controls on oven temperature (as when heating product in an oven). Foods such as beverages lend themselves to a heat exchanger; foods such as baked goods lend themselves to an oven. Heating time may be controlled automatically by a pump setting that controls flow of the fluid through the heat exchanger and hold tube or manually by an operator recording the time a product is put in the oven and the time it is removed. Heating time may also

be controlled by the belt speed for the conveyor on a continuous oven. A facility would have flexibility to establish controls on heating time through these or other mechanisms.

Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal contamination. Sanitation procedures may include scrubbing certain pieces of equipment by hand; this may not require the identification of specific parameters. Similarly, label controls for food allergens do not involve identification of specific parameters.

Proposed § 110.135(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the food, the maximum or minimum value, or combination of values, to which any biological, chemical, radiological, or physical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. Some of the preventive controls a facility may implement may be based upon scientific studies or other information that demonstrate the effectiveness of the control measure at specific values of a physical, biological, radiological or chemical parameter, e.g., the application of heat to food at a specific time/temperature combination to adequately reduce pathogens. Proposed § 110.135(c)(2) would require that a facility that establishes such a preventive control specify values of the essential parameters to be applied in implementing the control. Specifying these values would enable the facility to implement them consistently, would facilitate validation of the preventive controls as would be required by proposed § 110.150(a), and would facilitate audits and inspection.

Proposed § 110.135(c)(1) and (2) would implement section 418(c) of the FD&C Act and are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry, although there are some differences related to the differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. The NACMCF HACCP guidelines and the Codex HACCP Annex (Refs. NACMCF and Codex) each specify that the critical limits be documented in the HACCP plan. Federal HACCP regulations for seafood, juice, and meat and poultry each require that HACCP plan list the critical limits that must be met at each of the CCPs (§§ 123.6(c)(3) and 120.8(b)(3), and 9 CFR 417.2(c)(3), respectively). The NACMCF HACCP guidelines define "critical limit" to mean a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The definition of "critical limit" in Federal HACCP regulations for seafood, juice, and meat and poultry are, for practical purposes, identical to the definition in the NACMCF HACCP guidelines (§§ 123.3(c) and 120.3(e) and 9 CFR 417.1(b), respectively). The Codex HACCP Annex defines "critical limit" to mean a criterion which separates acceptability from unacceptability (Ref. Codex HACCP 2003).

FSMA does not use the term "critical limit." As discussed in section II.C.2 of this document, the approach in section 418(c) of the FD&C Act is broader than the approach in HACCP systems, in that section 418(c) of the FD&C Act is less prescriptive than HACCP systems in terms of mechanisms to control hazards. As also discussed in section XII.C.2 of this document, section 418 of the FD&C Act clearly contemplates that CCPs are only one place to apply a preventive control, and that there may in fact not be any CCPs. Critical limits may not be appropriate for preventive controls that are not CCPs. Thus, proposed § 110.135(c)(1) and (2)

use a broader term – i.e., parameter – to encompass preventive controls that may or may not apply to CCPs. Consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry, proposed § 110.135(c)(2) would require the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. This is similar to requiring critical limits at CCPs but would apply to values set for parameters that apply to preventive controls, whether these apply at a CCP or not.

5. Proposed § 110.135(d)(1)--Process Controls

Proposed § 110.135(d)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include process controls that include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Process controls do not include those procedures, practices, and processes that are not applied to the food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards that are reasonably likely to occur but are not applied to the food itself. Specifying that process controls are employed during manufacturing/processing to significantly minimize or prevent hazards that are reasonably likely to occur would distinguish those controls applied in manufacturing/processing that significantly minimize or prevent hazards (e.g., cooking, cooling, irradiating, refrigerating, and reducing water activity) from other types of controls that may be applied in manufacturing/processing to provide the desired product (e.g., controls for product size and shape). Many process controls, such as the application of heat to a food to adequately reduce pathogens, are applied in the same manner and for the same

purpose as control measures established within HACCP plans and applied at CCPs as recommended by the NACMCF HACCP guidelines (Ref. NACMCF 1998) and the Codex HACCP Annex (Ref. Codex 2003) and as required by Federal regulations for seafood, juice, and meat and poultry (§§ 123.6(c)(3) and 120.8(b)(3)) and 9 CFR 417.2(c)(3), respectively).

As discussed in section XII.C.4 of this document, proposed § 110.135(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, when applicable, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled. For process controls in particular, the term "parameter" used in proposed § 110.135(c)(1), and the value associated with the parameter in proposed § 110.135(c)(2), are associated with the term "critical limit" used in HACCP systems. We described the use of the term "critical limit" in other contexts in the previous section of this document. Collectively, proposed §§ 110.135(b), (c) and (d)(1) would require that a facility include in its written process controls information equivalent to that provided when listing critical limits that must be met at each of the CCPs, such as is required in our HACCP regulations for seafood and juice (§§ 123.6(c)(3) and 120.8((b)(3), respectively). However, the process controls may or may not apply at CCPs.

For example, a facility that holds in-shell pistachios in bulk storage units for an extended time period until they are shelled and packaged may identify the potential for growth of aflatoxin-producing molds on the nuts as a hazard reasonably likely to occur. As a process control to prevent such molds from growing on the nuts during storage, the facility may elect to dry (dehydrate) the nuts to a specific moisture content (e.g., no more than seven percent) prior to placing them in storage. The process control would be "drying" and the associated parameter would be moisture level, with its maximum value, or limit, being seven percent.

As another example, a facility that manufactures refrigerated deli salads may identify the potential for growth of L, monocytogenes in the salads as a hazard reasonably likely to occur. As a process control to prevent such growth, the facility may elect to add an acidifying agent during its process to ensure that the pH of the product does not exceed 4.4. The process control would be "acidifying" and the associated parameter would be pH, with its maximum value, or limit, being 4.4.

A facility that manufactures a deli salad product may establish refrigeration as a process control to prevent growth of pathogenic sporeformers such as B. cereus, if it determines this organism is a hazard reasonably likely to occur in the deli salads being produced. (A facility may conclude that refrigeration is not necessary to prevent the growth of pathogenic sporeformers if, for example, it controls this potential hazard through product formulation, such as pH.) The facility may also establish process controls addressing the amount of time that in-process materials are held above 4 °C (40 °F) during manufacturing and addressing their temperatures during this time period. If so, the process control would be "manufacturing time" and the associated parameters would be time and temperature, with the maximum time that in-process materials are held above 4 °C (40 °F) being specified.

6. Proposed § 110.135(d)(2)--Food Allergen Controls

Proposed § 110.135(d)(2)(i) would require that food allergen controls include those procedures, processes, and practices employed for ensuring protection of food from cross-contact, including during storage and use. Examples of such controls include procedures for separating ingredients and finished product that contain allergens from those that do not contain allergens, and procedures for separating foods that contain different allergens. Such controls are essential to prevent the inadvertent incorporation of an allergen into a product for which it is not

an ingredient. Examples of such procedures for controlling food allergens include procedures that:

- Provide physical barriers;
- Eliminate or minimize the formation of dust, aerosols, or splashes;
- Conduct manufacturing/processing of foods in different parts of a facility;
- Emphasize separation in time, such as by production sequencing or by cleaning equipment between production runs;
- Emphasize storage and handling appropriate to reduce the potential for cross-contact; and
- Control the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods that do not, or when the same production lines are used for foods that contain different allergens.

Proposed § 110.135(d)(2)(ii) would require that food allergen controls include those procedures, practices, and processes employed for labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the act. Such controls can prevent application of the wrong label to a food, use of the wrong packaging, and use of packaging with an incorrect allergen declaration. Examples of such procedures for controlling food allergens include procedures that:

- Ensure that the food label correctly declares all of the food allergens present (including those contained in flavors);
- Ensure that the correct food label is applied to a food;
- Ensure that the correct food is in the correct package (e.g., by checking that the correct packaging is used for each food);

- Review formulations and compare them to the labels (especially when new batches of labels are received); and

Proposed § 110.135(d)(2) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3) of the FD&C Act. Proposed § 110.135(d)(2) is consistent with our HACCP regulation for juice, which requires processors to consider whether the presence of undeclared ingredients that may be allergens is a hazard that is reasonably likely to occur (§ 120.7(c)(8)). Proposed § 110.135(d)(2) also is consistent with the recommendations in the CGMP Working Group Report (Ref. CGMP workgroup report) that food processing establishments that produce foods containing a major food allergen be required to have a food allergen control plan that addresses segregation of food allergens during storage and handling, prevention of cross-contact during processing, product label review and label usage and control, and a supplier control program for ingredients and labels.

7. Proposed § 110.135(d)(3)--Sanitation Controls

Proposed § 110.135(d)(3)(i)(A) and (B) would establish two requirements for sanitation controls where necessary to significantly minimize or prevent hazards that are reasonably likely to occur, (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard). Proposed § 110.135(d)(3)(i)(A) would require that sanitation controls include procedures for the cleanliness of food contact surfaces, including food contact surfaces of utensils and equipment. Such hazards would include any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging and any food allergen hazard. (We would generally not expect

that microorganisms of public health significance contaminating an RTE food due to employee handling would be a hazard relevant to procedures for cleaning food contact surfaces.) Examples of sanitation controls related to the cleanliness of food contact surfaces include cleaning and sanitizing procedures (including appropriate frequencies for these procedures, concentrations of cleaning and sanitizing compounds, method of application, and contact time). Such controls can prevent contamination of food with microorganisms of public health significance, including environmental pathogens, that result from inadequate cleaning of food-contact surfaces. Such controls also can prevent cross-contact that results from inadequate cleaning of food-contact surfaces or surfaces that transfer material to food-contact surfaces.

Proposed § 110.135(d)(3)(i)(B) would require that sanitation controls include procedures for the prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. Such hazards would include any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to contaminate food if employees are handling RTE food, and any food allergen hazard. Examples of sanitation controls to prevent cross-contact include procedures for ensuring that production utensils and maintenance tools do not transfer an allergen from one product to another (e.g., by proper cleaning of utensils and maintenance tools between uses if it is not practical to dedicate utensils and tools to specific processing lines); procedures for ensuring that personnel practices do not result in transfer of allergens from one production line to another (e.g., by ensuring employees do not handle food containing an allergen and one that does not without washing

hands and changing outer garments); and procedures for minimizing the transfer of dust containing allergens (e.g., by cleaning powder spills around dumping stations as they occur).

Examples of sanitation controls to prevent cross-contamination include procedures for ensuring that personnel do not touch insanitary objects (e.g., waste, trash cans, the floor, and rest room fixtures or surfaces) and then food, food contact surfaces, or food packaging material without first washing and sanitizing their hands; procedures for protecting food packaging material from environmental contamination; procedures for protecting exposed food products from contamination from the environment; and procedures for controlling traffic (including traffic of people and traffic of equipment such as forklifts) between the raw and finished sides of the operation.

To make clear that sanitation controls are required when an environmental pathogen is a hazard that is reasonably likely to occur in an RTE food that is exposed to the environment prior to packaging, proposed § 110.135(d)(3)(i) includes this circumstance as an example where sanitation controls would be required. Recent outbreaks of foodborne illness caused by environmental pathogens (e.g., Salmonella spp. and L. monocytogenes), as well as the scientific literature, emphasize the critical need for sanitation controls to minimize the potential for food, particularly RTE food, to become contaminated with environmental pathogens. (See sections II.E.4 and II.E.5 of this document for a discussion of the importance of controlling environmental pathogens.) Any time a food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated. Appropriate sanitation controls can minimize the presence and transfer of contaminants, including environmental pathogens, to food. The need for sanitation controls

related to food workers has long been recognized; however, appreciation of the importance of sanitation controls in preventing contamination due to environmental pathogens is more recent.

To make clear that sanitation controls are required when a microorganism of public health significance is a hazard reasonably likely to occur in an RTE food due to employee handling, proposed § 110.135(d)(3)(i) includes this circumstance as an example where sanitation controls would be required. Sanitation controls have long been used to prevent cross-contamination with pathogens (such as Staphylococcus aureus or enteric pathogens such as Salmonella) that may be introduced by workers. People are common carriers of S. aureus – at any time up to 50% of humans will be carriers of this organism (e.g., in the nose and on the skin) (Ref. ICMSF 5, Chapter 17). People are also a source of enteric pathogens, including both symptomatic and asymptomatic infected workers (Ref. Grieg et al. 2007). Workers can contaminate RTE foods during handling, which can result in foodborne illness, in particular if the food is then held at temperatures that support growth and, in the case of S. aureus, production of enterotoxin (Ref. Todd et al. 2007; ICMSF 5, Chapter 17). Appropriate sanitation controls can minimize the transfer of microorganisms of public health significance from workers to food

To make clear that sanitation controls are required when an food allergen hazard is reasonably likely to occur, proposed § 110.135(d)(3)(i) and includes this circumstance as an example where sanitation controls would be required. As discussed in section IX.D of this document, cross-contact can occur in a facility that manufactures, processes, packs or holds a food that contains a major food allergen and other food that does not contain that allergen. Appropriate sanitation controls can minimize the transfer of food allergens that result in cross-contact.

Proposed § 110.135(d)(3)(i)(A) and (B) would implement section 418(c) of the FD&C Act. Proposed § 110.135(d)(3)(i)(A) also is consistent with the recommendation of the Food CGMP Working Group that food processors be required to develop and maintain, at a minimum, written sanitation procedures for all food contact equipment and food contact surfaces (Ref. CGMP Working Group Report). Under proposed § 110.135(b), the preventive controls for sanitation required by proposed § 110.135(d)(3)(i)(A) and (B) would have to be written.

HACCP plans, as described in the NACMCF HACCP guidelines (Ref. NACMCF 1998), the Codex HACCP Annex (Ref. CAC 2003), and Federal HACCP regulations for seafood, juice, and meat and poultry (§ 123.6, § 120.7, and 9 CFR 417, respectively) require that control measures be established at CCPs to address hazards that are reasonably likely to occur. Because sanitation covers the entire processing environment, not just at CCPs, and is not limited to hazards reasonably likely to occur, sanitation controls have been difficult to fit into HACCP plans and are often addressed using prerequisite programs (e.g., SSOPs). The NACMCF HACCP guidelines (Ref. NACMCF 1998) and the Codex HACCP Annex (Ref. CAC HACCP Annex 2003) address sanitation measures as prerequisite programs and are silent on their inclusion in HACCP plans to address identified hazards. FSIS addresses sanitation controls for meat and poultry products in a separate sanitation regulation (9 CFR 416), which is similar to our CGMPs in current part 110 except that it includes SSOP requirements that, unlike our SSOPs, require written sanitation procedures.

In our HACCP regulations for seafood and juice, FDA provides processors with an option to include sanitation controls in their HACCP plans (§§ 123.6(f) and 120.8(c), respectively). Our HACCP regulations require monitoring for eight specified sanitary conditions and practices (referred to as SSOPs) regardless of whether these conditions and practices are

related to hazards that are reasonably likely to occur (§ 123.11(b) and 120.6(a) and (b), respectively). The eight conditions and practices are:

- Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;
- Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
- Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;
- Maintenance of hand washing, hand sanitizing, and toilet facilities;
- Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
- Proper labeling, storage, and use of toxic compounds;
- Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
- Exclusion of pests from the food plant.

The PMO HACCP Appendix essentially includes the same requirements as described in the HACCP regulation for juice (part 120) with respect to the eight conditions and practices. However, in the PMO HACCP Appendix these conditions and practices are referred to as "required prerequisite programs (PPs)" rather than SSOPs.

The eight areas for which sanitation monitoring is required in our HACCP regulations for seafood and juice are those elements of sanitation in Part 110 that we identified as the most

likely to have an impact on the safety of food. FDA's HACCP regulations impose mandatory monitoring, corrective action and recordkeeping for these activities to provide a framework to help ensure that the provisions of Part 110 that relate to the eight specific elements of sanitation are addressed in a systematic way, resulting in greater compliance with those provisions.

The HACCP regulation for seafood recommends but does not require that processors develop written SSOPs for the eight areas of sanitation (§ 123.11(a)). The HACCP regulation for juice requires that an SSOP be developed for these areas but does not require that it be written (§ 120.6(a)). In contrast, proposed § 110.135(d) would require written procedures for identified areas of sanitation and, in addition to monitoring and corrective actions as required in seafood and juice HACCP for the eight areas of sanitation, proposed § 110.135(d) would require monitoring procedures and verification activities.

In considering the application of preventive controls to the eight sanitation controls and practices, we considered the different framework for sanitation controls under this regulation (e.g., the additional requirements) as compared to the juice and seafood HACCP regulations, the traditional role of SSOPs as part of prerequisite programs, and the broad diversity of the food industry covered by this regulation. We tentatively conclude that it is necessary to require that the two areas included in proposed § 110.135(d)(3) be addressed as preventive controls under subpart C and therefore be subject to requirements such as mandatory written procedures. Further, we tentatively conclude that for each of the other six areas, the current CGMPs are sufficient to address any hazards and further requirements in subpart C are not necessary. For these six areas, the value of mandating written procedures and other additional requirements (e.g., written monitoring procedures and verification) would not be significant because the relevant CGMP provisions in essence serve as the written procedures to which the facility must

adhere. Some facilities may find value in adding more detail to the material contained in subpart B, but FDA has tentatively concluded that that would not be necessary in order to ensure that the hazards that are reasonably likely to occur are significantly minimized or prevented.

For example, one of the six areas of sanitation is the safety of water used in food operations. In many facilities, the water is supplied by a municipal water authority that monitors the water and alerts its customers of any safety problems. Where facilities use well water, monitoring usually consists of an annual collection and analysis of the water for microbiological (and sometimes also chemical and radiological) safety. Another of the six areas contains provisions that ill workers must be excluded from operations where their presence could lead to contamination of food. A requirement in this regulation to develop written procedures for ensuring that this condition is met does not appear to be necessary, given the rather straightforward and universal nature of the controls (i.e., observe employees for signs of illness and redirect their activities accordingly). Similarly, procedures for ensuring the cleanliness of rest rooms or checking for the presence of pests appear to be unnecessary, given the rather straightforward and universal nature of the controls.

On the other hand, equipment cleaning procedures, as would be required by proposed § 110.135(d)(3)(i)(A) are very specific to the construction of the equipment, the nature of the food, the physical characteristics of the water used, the concentration of cleaning and sanitizing chemicals, the method of application, and the cleaning and sanitizing interval, among other things. For this reason, the procedures must be clearly stated to ensure that they are consistently followed. Often these procedures are performed by contract staff, often during night shifts where management is less likely to be present. In these circumstances, explicit cleaning procedures are essential.

Procedures to prevent cross-contact and cross-contamination, as required by proposed § 110.135(d)(3)(i)(B) are similarly complex and very situational. Identifying product and traffic flow within the facility, employee hand washing and sanitizing, and employee garbing requirements are critical to ensure that employees are trained on the correct procedures to ensure product safety.

Proposed § 110.135(d)(3)(ii) would require that the owner, operator, or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures that would be established in proposed § 110.135(d)(3)(i)(A) or (B). Proposed § 110.135(d)(3)(ii) is consistent with our HACCP regulations for seafood and juice, which each require that the processor correct, in a timely manner, those sanitation conditions and practices that are not met (§§ 123.11(b) and 120.6(b), respectively). Proposed § 110.135(d)(3)(ii) also is consistent with 9 CFR 416, which requires, in general, that each establishment take appropriate corrective action(s) when the establishment's SSOPs or the implementation or maintenance of the SSOPs, may have failed to prevent direct contamination or adulteration of product(s); corrective actions must include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the SSOPs or appropriate improvements in the execution of the SSOPs (9 CFR 416.15).

Proposed § 110.135(d)(3)(iii) would provide that the owner, operator, or agent in charge of a facility is not required to follow the corrective actions that would be established in proposed § 110.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with proposed § 110.135(d)(3)(ii), to correct conditions and practices that are not

consistent with the procedures in proposed § 110.135(d)(3)(i) (A) or (B). As discussed in sections X.II.F.2 and X.II.F.3 of this document, proposed § 110.145(a) would require that the owner, operator or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, and outlines specific components that must be included. Proposed § 110.145(b) would require specific actions in the event of an unanticipated problem when a preventive control is not properly implemented and a specific corrective action procedure has not been established or a preventive control is found to be ineffective. For sanitation controls, proposed § 110.135(d)(3)(ii) would require that the owner, operator or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the established sanitation control practices.

There are many different ways in which conditions and practices for sanitation can deviate from the established procedures. In many instances the actions taken will be the same, regardless of the deviation. The corrective actions will generally involve re-establishing sanitary conditions (e.g., re-cleaning a piece of equipment) and/or retraining personnel to carry out the procedures correctly. In many instances the procedural deviations are not reasonably likely to impact product (e.g., insanitary food contact surfaces are usually detected by a pre-production inspection of the equipment by plant personnel; deviations in cleaning solution strength rarely result in the production of unsafe product if other cleaning and sanitizing procedures were properly carried out). Thus, there is rarely a need to evaluate the impact of the sanitation failure on food and to prevent food from entering commerce, as would be required by proposed § 110.145(a)(2)(ii) and (iii). Because the corrective actions that will need to be taken for most sanitation controls are so general, we see little benefit in requiring a facility to develop written

corrective action procedures for the many sanitation deviations that could occur. We do expect the facility to take action to correct conditions and practices as appropriate to the situation as would be required by proposed § 110.135(d)(3)(ii). The requirement in proposed § 110.135(d)(3)(ii) to take action to correct, in a timely manner, sanitation conditions and practices that are not in accordance with procedures is consistent with proposed § 110.145(a)(2)(i), which would require that appropriate action be taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur.

Importantly, we are only proposing to limit the applicability of proposed § 110.145(a) and (b) when the owner, operator, or agent in charge of a facility takes corrective action in accordance with proposed § 110.135(d)(3)(ii). As discussed in section XII.F.4 of this document, proposed § 110.145(c) would establish a requirement for corrective actions – including increased efforts directed at sanitation - when the environmental monitoring conducted as a verification of sanitation controls in accordance with proposed § 110.150(d)(4) demonstrates a failure in sanitation controls as evidenced by the presence of an environmental pathogen or appropriate indicator organism.

Proposed § 110.135(d)(3)(iv) would require that all corrective actions taken in accordance with proposed § 110.135(d)(3)(ii) be documented in records that would be subject to verification in accordance with proposed § 110.150(c) and records review in accordance with proposed § 110.150(d)(5)(i). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

8. Proposed § 110.135(d)(4)--Recall Plan

Proposed § 110.135(d)(4) would require that preventive controls include, as appropriate, a recall plan as would be required by proposed § 110.137. Proposed § 110.135(d)(4) would incorporate the statutory definition of "preventive controls" from section 418(o)(3)(E) of the FD&C Act, which establishes that preventive controls may include a recall plan. We include the details of the recall plan in proposed § 110.137 and discuss it in section XII.D of this document.

9. Proposed § 110.135(d)(5)--Supplier Approval and Verification Program

Proposed § 110.135(d)(5) would require that preventive controls include, as appropriate, a supplier approval and verification program as would be required by proposed § 110.152. Proposed § 110.135(d)(5) would incorporate the statutory definition of "preventive controls" from section 418(o)(3)(G) of the FD&C Act, which establishes that preventive controls may include supplier verification activities that relate to the safety of food. We include the details of the supplier approval and verification program in proposed § 110.152 and discuss it in section XII.H of this document.

10. Proposed § 110.135(d)(6)--Other Controls

Proposed § 110.135(d)(6) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include any other controls necessary to satisfy the requirements of proposed § 110.135(a) – i.e., to significantly minimize or prevent hazards identified in the hazard analysis and to provide assurance that the food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. For example, if a facility produces a refrigerated product that could support the growth of pathogens if proper temperature is not maintained during transportation, the facility must consider the need to implement preventive

controls to minimize or prevent the potential for pathogen growth due to failure to control the temperature of the product during transportation. Most instances of failing to control temperature result primarily in quality issues such as product degradation or shortened shelf life, rendering the product unpalatable and thus precluding consumption. However, it is not common that products reach high enough temperatures for sufficient time to become hazardous due to growth of pathogens that may be present. For products that present a risk that pathogens would grow and present a health hazard, preventive controls could include temperature monitoring during transportation or other procedures that would ensure that product was not exposed to temperature/time intervals during transportation that would result in increased product temperatures for sufficient time to result in a potential safety issue. Often such procedures involve the shipper ensuring that product temperature is controlled during loading of the transportation vehicle, use of temperature recording devices that record the temperature of the transportation compartment during transportation, and the receiver verifying the temperature of product during transit as displayed by the temperature device.

FDA notes that some of the controls listed in section 418(o) of the FD&C Act are not explicitly identified in proposed § 110.135. We are addressing the environmental monitoring program provision of section 418(o)(3)(C) of the FD&C Act by establishing requirements for environmental monitoring within the verification requirements in proposed § 110.150 as discussed in section XII.G.3 of this document. Preventive controls for supervisor, manager, and employee hygiene training and Current Good Manufacturing Practices could be required as "other controls" in proposed § 110.135(d)(4). However, such controls differ from other controls in section 418(o)(3) of the FD&C Act in the extent to which they are addressed by requirements in proposed subpart B. Further, as discussed in section XII.C.7 of this document, such controls

are traditionally considered to be part of prerequisite programs, essential to effective preventive controls but often not part of them. FDA expects that compliance with those requirements in part 110 (proposed subpart B) will be sufficient.

11. Proposed § 110.135(e)--Applicability of Monitoring, Corrective Actions, and Verification

Proposed § 110.135(e)(1)(i) through (iii) would specify that, except as provided by proposed § 110.135(e)(2), the preventive controls required under this section would be subject to monitoring as would be required by proposed § 110.140; corrective actions as would be required by proposed § 110.145; and verification as would be required by proposed § 110.150. Proposed § 110.135(e)(1)(i) through (iii) would restate the requirements of proposed §§ 110.140, 110.145, and 110.150 to clearly communicate the applicability of proposed §§ 110.140, 110.145, and 110.150 to the preventive controls that would be required under proposed § 110.135 and would establish no new requirements.

Proposed § 110.135(e)(2) would provide that the recall plan that would be established in proposed § 110.137, and the supplier approval and verification program that would be established in proposed § 110.152, would not be subject to the requirements of proposed § 110.135(e)(1). A recall plan would address food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at food while it remains at the facility. Thus, as proposed, the requirements for monitoring, corrective actions, and verification have limited applicability to a recall plan. However, a "mock recall" (i.e., a simulated recall situation) is a verification activity that could identify problems with a recall plan, enable a facility to correct the problems, and provide reasonable assurance that the recall plan would be effective in removing products from commerce. FDA requests comments on whether to include a requirement for a mock recall as verification activity in the final rule.

Proposed § 110.135(e)(2) would provide that the supplier approval and verification program that would be established in proposed § 110.152 would not be subject to the requirements of proposed § 110.135(e)(1). As discussed in section XII.H of this document, proposed § 110.152 would be a tailored, self-contained program that addresses all applicable activities for a supplier approval and verification program.

D. Proposed § 110.137--Recall Plan for Food in Which There is a Hazard that is Reasonably Likely to Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c) of the FD&C Act specifies that the "owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that":

- "[H]azards identified in the hazard analysis conducted under [section 418(b)(1) of the FD&C Act] will be significantly minimized or prevented" (section 418(c)(1) of the FD&C Act); and
- "[T]he food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act]" (section 418(c)(3) of the FD&C Act).

Under section 418(o)(3)(D), the procedures, practices, and processes described in the definition of preventive controls may include, in relevant part, a recall plan.

2. Proposed § 110.137--Recall Plan for Food in Which There is a Hazard That is Reasonably Likely to Occur

Proposed § 110.137(a) would require that the owner, operator, or agent in charge of a facility establish a written recall plan for food in which there is a hazard that is reasonably likely

to occur. Although a recall is different from other preventive controls in that it is carried out after a product is distributed, it shares the purpose of significantly minimizing or preventing hazards, which is accomplished by limiting consumption of the affected food. Time is critical during a recall. A written recall plan is essential to minimizing the time needed to accomplish a recall; additional time during which the food is on the market can result in additional consumer exposure. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked.

Proposed § 110.137(a) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3)(E) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex general principles of food hygiene (GPFH). The NACMCF HACCP guidelines recommend that a recall system be in place (Ref. NACMCF 1998). The GPFH recommend that managers ensure effective procedures are in place to enable the complete, rapid recall of any implicated lot of the finished food from the market (Ref. Codex GPFH, 2003). Our HACCP regulations for seafood and juice do not include any requirements for a recall plan; recommendations for addressing a recall for food can be found in our general guidance on policy, procedures, and industry responsibilities regarding recalls in subpart C of part 7 (§§ 7.40 through 7.59). The guidance advises firms to prepare and maintain a current written contingency plan for use in initiating and effecting a recall (§ 7.59). Likewise, the FSIS HACCP regulation for meat and poultry does not require a recall plan; FSIS addresses recalls through guidance to industry.

Proposed § 110.137(b) would require that the recall plan include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

- Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected product (proposed § 110.137(b)(1));
- Notify the public about any hazard presented by the food when appropriate to protect public health (proposed § 110.137(b)(2));
- Conduct effectiveness checks to verify that the recall is carried out (proposed § 110.137(b)(3)); and
- Appropriately dispose of recalled product – e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the product (proposed § 110.137(b)(4)).

Procedures that describe the steps to be taken would enable a facility to act promptly by following its plan when the facility determines that a recall is warranted rather than developing a plan of action after the need for a recall is identified. Procedures that assign responsibility for taking those steps would save the time needed to make such determinations during a recall and enable the owner, operator, or agent in charge of a facility to clearly communicate such responsibilities to applicable managers or staff so that such managers or staff can take action as soon as the decision to conduct a recall is made.

Directly notifying direct consignees about the recall (proposed § 110.137(b)(1)) is the most effective mechanism to ensure direct consignees know that the product is being recalled and is consistent with our general guidance on recall communications in § 7.49(a). Further, instructing direct consignees how to return or dispose of an affected product minimizes the

chance the affected product will be disposed of improperly and allows direct consignees to act quickly. Further, it is consistent with our guidance on the content of recall communications in § 7.49(c)(4). We have provided guidance to industry on model recall letters (Ref. Recall Guidance). This guidance may be useful in developing procedures for directly notifying direct consignees about the recall and on how to return or dispose of an affected product.

Notification procedures could identify a variety of communication means, including email, telephone, fax, text messaging, and urgent mail delivery. Notification procedures that would establish only a general notification to the public (e.g., through a press release or through information posted on a facility's Web site), without procedures for concurrent contact directly with direct consignees about how to access the general notification, would not satisfy proposed § 110.137(b)(1); a general notification to the public would rely on the chance that the direct consignees would see the information and may not be effective.

Notifying the public about any hazard presented by the food when appropriate to protect public health is a common practice (e.g., see FDA's Web site that provides information gathered from press releases and other public notices about recalls of food (Ref. Recalls, Market Withdrawals, & Safety Alerts)). Notifying the public in such circumstances is consistent with our guidance on a recall strategy that the purpose of a public warning is to alert the public that a product being recalled presents a hazard to health (§ 7.42(b)). Notifying the public, in addition to direct consignees, may not be necessary to protect the public if, for example, the food being recalled was all distributed to food service operations (who were notified as a direct consignee) and not distributed for retail sale. Procedures in the recall plan for notifying the public could include model press releases and procedures for disseminating information to the public though press releases or other means, such as by information posted on the facility's Web site or

provided to consumers using social media. We have provided guidance to industry with examples of model press releases for the presence in food of undeclared food allergens and several foodborne pathogens, including Salmonella and L. monocytogenes (Ref. Recall Guidance).

An effectiveness check is a procedure designed to verify that all notified consignees have received notification about the recall and have taken appropriate action; procedures to conduct effectiveness checks would be consistent with our guidance on a recall strategy in § 7.42(c)(3). Procedures to conduct an effectiveness check could expand on the procedures used to directly contact consignees about the recall –e.g., to include forms for consignees to provide information about the amount of recalled product on hand, to include information on follow up contacts via phone or email, or to include personal visits to consignees by sales representatives. We have provided guidance to industry on conducting effectiveness checks (Ref. Recall Guidance); this guidance includes a model effectiveness check letter, a model effectiveness check response form that could be sent to a consignee, and a model questionnaire to be used during effectiveness checks conducted by telephone or by personal visit.

A facility that receives recalled product from their customers must appropriately dispose of the product – e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the product. These types of disposition actions are similar to the disposition actions that a facility would consider as a corrective action as a result of a problem that is discovered before the product leaves the facility (see, e.g., the discussion of corrective actions in the final rule to establish our HACCP regulation for seafood; 60 FR 65096 at 65127). Procedures for disposition of a product can help the facility ensure that disposition of recalled product will be appropriate and will not present a risk to consumers. Implementation of such

procedures is part of determining whether a recall can be considered terminated. Thus, having procedures in place can result in more efficient completion of a recall. Under § 7.55, appropriate disposition of recalled product is a consideration in determining whether a recall is terminated.

We request comment on whether the procedures to be included in the recall plan (i.e., to directly notify consignees, to notify the public, to conduct effectiveness checks and to appropriately dispose of recalled product) are appropriate for all types of facilities or if they should be modified for certain facilities.

We request comment on whether we should require a recall plan to include procedures and assignments of responsibility for notifying FDA of recalls subject to the plan. Notifying FDA could enhance the effectiveness of a recall by allowing FDA to take appropriate steps to minimize the risk of illness or injury related to recalled products. As discussed in section II.6 of this document, notifying FDA of a reportable food is required by section 417 of the FD&C Act. Reportable food reports include information about whether a reportable food is being recalled. Thus, in some cases, reporting a recall to FDA could be accomplished by submitting a reportable food report required under section 417. In other cases, facilities could notify the local FDA district office of the recall .

E. Proposed § 110.140--Monitoring

1. Requirements of Section 418 of the FD&C Act

Section 418(a) of the FD&C Act specifies that "[t]he owner, operator, or agent in charge of a facility shall . . . monitor the performance of [the preventive controls]." Section 418(d) of the FD&C Act specifies that "[t]he owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under [section 418(c) of the FD&C Act] to provide assurances that the outcomes described in [section 418(c)] shall be achieved."

The outcomes relevant to this proposal are those that provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that food manufactured, processed, packed or held by a facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Section 418(g) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act.

Section 418(h) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act.

2. Monitoring in HACCP Systems

Proposed § 110.3 would define "monitor" to mean "to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification." We discussed this definition, and how it is used in HACCP systems, including in guidelines developed by NACMCF and Codex, in section X.C.4 of this document. Examples of monitoring activities include: visual observation and measurement of temperature, time, pH, and moisture level (Ref. NACMCF, 1998). The NACMCF HACCP guidelines identify three purposes of monitoring (Ref. NACMCF, 1998). First, monitoring is essential to managing food safety because it facilitates tracking of the operation (i.e., the "process, point or procedure" that is being controlled). This provides ongoing information about whether the process, point or procedure is under control (i.e., operating according to plan), and can provide information about shifts away from control. If monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the

process back into control before a deviation from a critical limit occurs. For example, if the temperature needed to ensure safety of roasted nuts is 290ºF, and the procedure for roasting the nuts in an oil roaster calls for an operating temperature of 350ºF, monitoring would detect that the temperature in the oil roaster was dropping and enable the facility to identify and fix the problem with temperature before the temperature drops to 290ºF. Second, monitoring is used to determine when a deviation occurs at a critical control point (i.e., exceeding or not meeting a critical limit), indicating there is loss of control. In the previous example, there would be loss of control if the temperature drops to 289ºF. When a deviation occurs, an appropriate corrective action must be taken – e.g., stop the roasting process until the temperature in the oil roaster can be maintained above 290ºF and reprocess nuts that were not roasted at the appropriate temperature. Third, monitoring provides written documentation for use in verification. For example, if the facility monitors the temperature of the oil roaster continuously, using a temperature recording device, the output of the temperature recording device is available during the verification activity of review of records. Under this approach, monitoring is directed to evaluating implementation of the preventive controls, and the written documentation of the monitoring is then used in verification.

3. Verification in HACCP Systems

Proposed § 110.3 would define "verification" to mean "those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan." We discussed this definition, and how it is used in HACCP systems, in section X.C.4 of this document. The NACMCF HACCP guidelines identify several aspects of verification (Ref. NACMCF, 1998). One aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards

have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Another aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. Both of these aspects are directed at the effectiveness of a preventive control; they establish that the preventive control is scientifically valid for controlling the hazard and verify that the preventive control is accomplishing its intended purpose. The Codex HACCP Annex addresses verification as determining compliance with the HACCP plan and confirming that the HACCP system is working effectively (Ref. Codex 2003). Examples of verification activities include review of monitoring records and review of records for deviations and corrective actions. We discuss verification activities in more detail during our discussion of proposed § 110.150 (Verification) in section XII.G of this document.

4. Relationship Between Monitoring and Verification

Monitoring and verification are closely related; both address the performance of preventive controls, and verification relies in part on monitoring records to establish that preventive controls developed to significantly minimize or prevent hazards are being implemented according to plan. Three provisions of section 418(f) of the FD&C Act (Verification) are particularly relevant when considering the role of monitoring. First, section 418(f)(1) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the preventive controls implemented . . . are adequate to control the hazards identified. . . ." Second, section 418(f)(2) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the owner, operator, or agent is conducting monitoring. . . ." Third, section 418(f)(4) of the FD&C Act requires that the owner, operator, or agent in

charge of a facility verify that “the preventive controls implemented . . . are effectively and significantly minimizing or preventing the occurrence of identified hazards. . . .”

5. Monitoring the Performance of Preventive Controls

Section 418(a) requires monitoring the “performance” of preventive controls whereas section 418(d) requires monitoring their “effectiveness.” We tentatively conclude that the language of section 418 regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the performance of preventive controls. “Performance” means “the execution or accomplishment of an action, operation, or process undertaken or ordered" (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 2157) and is consistent with use of the term “monitoring” in traditional HACCP. Monitoring the performance of preventive controls would be undertaken to determine whether a facility is implementing its preventive controls and would generate records that would be used to verify implementation of the controls. For example, monitoring performance could include visual observations and measurements of temperature, time pH, and moisture level. In contrast, “effectiveness” refers to the quality of "having an effect or result" (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 794) and is not consistent with use of the term “monitoring” in traditional HACCP. The term “verification,” not “monitoring” is used to refer to effectiveness in traditional HACCP. Monitoring the effectiveness of preventive controls would evaluate whether the preventive controls were working.

Requiring monitoring of the effectiveness of the preventive controls would be redundant with required verification activities. Section 418(f) requires verification that the preventive controls “are effectively and significantly minimizing the occurrence of the identified hazards. . . .” The activities necessary for such verification are the same as would be required for

monitoring the effectiveness of the preventive controls. For example, because effectiveness addresses whether the hazard is controlled, monitoring the effectiveness could include testing for the presence of the hazard, such as testing for the presence of staphylococcal enterotoxin that can occur during cheese making if the pH does not drop to a low enough level in a short enough time. Further, requiring monitoring of effectiveness rather than performance of the preventive controls would create a significant gap in the preventive controls system if the factors that are critical to control of the hazard, e.g., pH of the cheese curd and time, are not monitored to ensure the process is implemented correctly. In contrast, monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately (e.g., pH of the cheese curd drops below 5.6 within 8 hours) and thereby are effectively and significantly minimizing or preventing the hazards (e.g., staphylococcal enterotoxin).

As discussed more fully in the next section of this document, this interpretation also is grounded in our existing HACCP regulations and guidance. Section 418(n)(5) of the FD&C Act directs the Secretary, in promulgating these regulations, to review hazard analysis and preventive control programs in existence to ensure that this regulation is consistent to the extent practicable with applicable domestic and internationally-recognized standards in existence. Requiring monitoring of the performance of preventive controls is consistent with applicable domestic and internationally recognized standards.

Therefore, we tentatively conclude that this interpretation is reasonable, and we propose to adopt it in the proposed requirements implementing section 418(d) of the FD&C Act. We request comment on this interpretation.

6. Proposed § 110.140--Monitoring

a. Proposed § 110.140(a)--Requirement for written procedures for monitoring. Proposed § 110.140(a) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. Proposed § 110.140(a) would implement sections 418(d) and (h) of the FD&C Act.

Proposed § 110.140(a) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. We discuss the purposes that the NACMCF HACCP guidelines identify for monitoring under a HACCP system in section II.C.4.d of this document. Each of these purposes applies to preventive controls as well, and we tentatively conclude that these purposes would be achieved by proposed § 110.140(a). Proposed § 110.140(a) would facilitate tracking the implementation of the preventive controls to provide assurance that they are consistently performed; if monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a preventive control is not properly implemented and potentially unsafe product is produced. Further, if monitoring is conducted with sufficient frequency to ensure preventive controls are consistently performed, it will detect if a preventive control is not properly implemented (e.g., if the temperature of an oven falls below the temperature needed to ensure safety), indicating loss of control and signaling the need for an appropriate corrective action. Finally, the proposed monitoring requirement would result in written documentation for use in verification.

The Codex HACCP Annex advises that monitoring procedures must be able to detect loss of control at the CCP and ideally should provide this information in time to make adjustments to

ensure control of the process to prevent violating the critical limits. The Codex HACCP Annex also recommends that, where possible, process adjustments be made when monitoring results indicate a trend towards loss of control at a CCP, before a deviation occurs (Ref. Codex 2003). Federal HACCP regulations for seafood, juice, and meat and poultry require in the written HACCP plan monitoring of control measures to determine whether physical, chemical, or biological parameters are being met (i.e., monitoring of critical control points to ensure compliance with the critical limits) (§ 123.6(b) and (c)(4)), § 120.8(a) and (b)(4), and 9 CFR 417.2(b)(1) and (c)(4), respectively). Like the Federal HACCP regulations for seafood, juice, and meat and poultry, the requirements for monitoring in proposed § 110.140(a) focus on evaluating performance of the preventive controls.

Proposed § 110.140(a) would require that the monitoring procedures be written. Under section 418(d) of the FD&C Act, the owner, operator, or agent in charge of a facility must monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act, and under section 418(h) of the FD&C Act the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act must be included in the written plan. The NACMCF HACCP guidelines note under record-keeping and documentation procedures that the procedures for monitoring should be provided (Ref. NACMCF 1998). The Codex HACCP Annex includes "Monitoring procedures" in its example of a HACCP worksheet (Ref. Codex 2003). Federal HACCP regulations for seafood, juice and meat and poultry require that the HACCP plan be written (§§ 123.6(b), 120.8(a), and 9 CFR 417.2(b)(1), respectively) and that procedures for monitoring be included in the written HACCP plan (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively).

Proposed § 110.140(a) would require that the monitoring procedures include the frequency with which they are to be performed. We discuss the frequency of monitoring in the next section of this document. Briefly, the frequency of monitoring must be sufficient to ensure that the preventive control is consistently performed in order to help ensure that the preventive control is effective. The NACMCF HACCP guidelines note that the frequency of monitoring should be provided in the HACCP Plan Summary Table (Ref. NACMCF 1998). Federal HACCP regulations for seafood, juice and meat and poultry require that the written HACCP plan include the procedures, and frequency thereof, that will be used for monitoring (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively).

b. Proposed § 110.140(b)--Frequency of monitoring. Proposed § 110.140(b) would require that the owner, operator, or agent in charge of a facility monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed. Proposed § 110.140(b) does not specify a single monitoring frequency applicable to all facilities and processes. Rather, it requires monitoring with "sufficient frequency" to assure that the preventive controls are consistently performed. Proposed § 110.140(b) would implement section 418(d) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex.

The NACMCF guidelines recommend continuous monitoring where possible (Ref. NACMCF 1998). Continuous monitoring is possible with many types of physical and chemical parameters. For example, the temperature and time for many thermal processes can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the affected product can be

retained and evaluated to determine the appropriate disposition. Examples of other parameters that can be monitored continuously include pressure, flow rate and pH.

However, the NACMCF guidelines acknowledge that continuous monitoring may not be possible, or even necessary, in all cases. For example, it may not be practical to continuously monitor the size of particles in a food to ensure they do not exceed the maximum dimensions that are required to ensure a process such as cooking, cooling, or acidification can be properly implemented. NACMCF states that if monitoring is not continuous it may be difficult to ensure that the preventive controls are consistently implemented and a problem has not occurred. Thus, according to NACMCF, the frequency of non-continuous monitoring must be sufficient to ensure that a critical control point (or, in the case of this proposed rule, a preventive control) is under control (Ref. NACMCF 1998). The Codex HACCP Annex also notes that, if monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control (Ref. Codex 2003). The frequency of non-continuous monitoring would depend on factors such as the proximity of operating conditions to the conditions needed to ensure safety and the variability of the process. For example, if the temperature needed to ensure safety of roasted nuts is 290ºF, non-continuous monitoring would need to be more frequent when an oil roaster for nuts is operated at 300ºF than when the oil roaster is operated at 350ºF. As another example, if temperatures vary by 10-15ºF during processing, monitoring would need to be more frequent than if the variation is only 1-2 degrees.

As discussed in the previous section of this document, Federal HACCP regulations for seafood, juice, and meat and poultry require that the written HACCP plan include the procedures, and frequency thereof, that will be used for monitoring (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively). Our Fish and Fishery Products Hazards and Controls

Guidance discusses the frequency of monitoring and notes that the frequency of monitoring depends upon the circumstances, with continuous monitoring being desirable; in some cases, continuous monitoring may be necessary, while in other cases, it may not be necessary or practical (Ref. Seafood HACCP edition 4). Our Juice HACCP Hazards and Controls Guidance provides examples of "Summary HACCP Plans," which show how the frequency of monitoring would depend on the circumstances (Ref. Juice HACCP guide).

c. Proposed § 110.140(c)--Requirement for records. Proposed § 110.140(c) would require that all monitoring of preventive controls in accordance with proposed § 110.140 be documented in records that are subject to verification in accordance with § 110.150(b) and records review in accordance with 110.150(d)(5)(i). Proposed § 110.140(c) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan (Ref. NACMCF 1998). The Codex HACCP Annex gives records of CCP monitoring activities as an example of records (Ref. Codex 2003). Our HACCP regulations for seafood and juice require that the HACCP plan provide for a recordkeeping system that documents the monitoring of the critical control points (§§123.6(c)(7) and 120.8(b)(7), respectively. The FSIS HACCP regulation for meat and poultry requires records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values.

The monitoring records would be used to verify that the preventive controls are adequate, as would be required by proposed § 110.150(a), and to verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to

occur, as would be required by proposed § 110.150(d). This is further discussed in section XII.G.5.f of this document. Together, proposed §§ 110.140(a), (b), and (c) and 110.150(a), (b), and (d) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

F. Proposed § 110.145--Corrective Actions

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act, in relevant part, specifies that "[t]he owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of [section 418 of the FD&C Act]…." Section 418(e) of the FD&C Act specifies that "[t]he owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under [section 418(c) of the FD&C Act] are not properly implemented or are found to be ineffective":

- "[A]ppropriate action is taken to reduce the likelihood of recurrence of the implementation failure" (section 418(e)(1) of the FD&C Act);
- "[A]ll affected food is evaluated for safety" (section 418(e)(2) of the FD&C Act); and
- "[A]ll affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated

under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act]" (section 418(e)(3) of the FD&C Act).

> Section 418(f)(4) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility verify that "the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards…."

2. Proposed § 110.145(a)--Corrective Action Procedures

Proposed § 110.145(a)(1) would require that the owner, operator, or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. Having written procedures in place would enable facilities to act quickly and appropriately when preventive controls are not properly implemented – e.g., when a parameter associated with heat processing exceeds a maximum value or falls below a minimum value. Proposed § 110.145(a)(1) would implement section 418(e) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

The NACMCF HACCP guidelines define a corrective action as procedures followed when a deviation occurs at a CCP and recommend that specific corrective actions be developed in advance for each CCP and included in the HACCP plan (Ref. NACMCF,1998). The Codex HACCP Annex advises that specific corrective actions be developed for each CCP in the HACCP system (Ref. CAC, 2003). Our HACCP regulations for seafood and juice require that processers take corrective action whenever a deviation from a critical limit occurs, either by following specific corrective action procedures specified in the regulation, or by following procedures in written corrective action plans that the processor develops (§§ 123.7 and 120.10,

respectively). If the processor of a seafood or juice product covered by the applicable HACCP regulation develops such plans, they must be included in the written HACCP plan (§§ 123.6(c)(5) and 123.7(b) and 120.8(b)(5), respectively). The FSIS HACCP regulation for meat and poultry requires that the written HACCP plan identify the corrective action to be followed in response to a deviation from a critical limit (9 CFR 417.3(a)).

As discussed in section XII.C.4 of this document, the proposed rule would establish requirements for preventive controls (which may be at critical control points), and proposed § 110.135(c)(2) would require that the preventive controls include, as appropriate to the facility and the food, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur (which reflects the NACMCF definition of a critical limit). As already noted earlier in this section, if a parameter associated with heat processing falls below a minimum value, corrective action would be triggered. Thus, the concept in the proposed rule of taking corrective action when a preventive control is not properly implemented is similar to the concept in HACCP systems of taking corrective action for a deviation from a critical limit at a critical control point.

The benefits from identifying corrective action procedures in advance of the need to actually take corrective action largely derive from having the procedures in written form. Written corrective action procedures would be essential to the facility's food safety team, to auditors, and to inspectors. The facility's food safety team will be responsible for ensuring that appropriate corrective actions are taken if preventive controls are not properly implemented. Having access to appropriate, written corrective action procedures determined in advance of the need for such action can ensure that correct and complete actions are taken in a timely fashion

without the need for the team to meet and decide on the appropriate action. Having written corrective action procedures available for auditors and for inspectors is essential for them to assess the adequacy of the food safety plan; the procedures a facility will use to address implementation failures are essential to the production of safe food, and without them a complete assessment cannot be made. Written corrective action procedures also would be useful for training purposes, so that employees who would need to implement the corrective action procedures will be prepared for what they would need to do.

Proposed § 110.145(a)(2) would implement section 418(e) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must establish corrective action procedures) and section 418(h) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must prepare a written plan). Proposed § 110.145(a)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and with Federal HACCP regulations for seafood, and juice, and meat and poultry. The NACMCF HACCP guidelines recommend that specific corrective actions be included in the HACCP plan (Ref. NACMCF, 1998). In its discussion of corrective actions, the Codex HACCP Annex advises that deviation and product disposition procedures be documented in the HACCP record keeping (Ref. Codex, 2003). Our HACCP regulations for seafood and juice both require that the written HACCP plan include any corrective action plans that have been developed by the processor (§§ 123.6(c)(5) and 123.7(b) and 120.8(b)(5)). The FSIS HACCP regulation for meat and poultry requires that the written HACCP plan identify the corrective action to be followed in response to a deviation from a critical limit (9 CFR 417.3(a)).

Proposed § 110.145(a)(2) would require that corrective action procedures describe the steps to be taken to ensure that:

- Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur (proposed § 110.145(a)(2)(i));
- All affected food is evaluated for safety (proposed § 110.145(a)(2)(ii)); and
- All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 110.145(a)(2)(iii)).

The hazard analysis and risk-based preventive controls in this proposed rule are designed to identify hazards that are reasonably likely to occur, and to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. However, a preventive controls system, similar to a HACCP system (Ref. NACMCF, 1998), accounts for the possibility of implementation and effectiveness problems and includes procedures for addressing those problems and any affected food.

Proposed § 110.145(a)(2) would implement sections 418(e)(1)-(3) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that corrective actions include elements to determine and correct the cause of non-compliance and to determine the disposition of non-compliant product (Ref. NACMCF, 1998). The Codex HACCP Annex advises that the specific corrective actions must ensure that the CCP has been brought under control and that actions taken must also include proper disposition of the affected product (Ref. CAC 2003). Our HACCP regulations for seafood and juice establish that a

corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation, and the cause of the deviation is corrected (§§ 123.7(b) and 120.10(a), respectively). The FSIS HACCP regulation for meat and poultry requires that the HACCP plan describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) the cause of the deviation is identified and eliminated; (2) the CCP will be under control after the corrective action is taken; (3) measures to prevent recurrence are established; and (4) no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce (9 CFR 417.3(a)).

Section 418(e)(1) of the FD&C Act and proposed § 110.145(a)(2)(i) explicitly require that action be taken to reduce the likelihood of recurrence of the implementation failure. Although not prescribed by proposed § 110.145(a)(2)(i), reducing the likelihood of recurrence of an implementation failure is best accomplished by identifying the root cause of failure and then taking action to address that root cause. If the root cause is not identified and corrected, it is more likely that the failure will recur. For example, if the temperature of a heat process cannot be maintained, a corrective action to raise the temperature using the controller may correct the problem short-term. However, if the root cause is a lack of boiler capacity to run multiple heating units at the same time, corrective action should address replacing the boiler to increase capacity. Similarly, if a facility cannot cool a food rapidly enough in a refrigerator to meet the cooling times and temperatures in its HACCP plan, the initial corrective action may be to move product into a freezer for cooling. If the root cause is determined to be that the product was filled too high in the cooling tray, the corrective action may be to include procedures to measure

the depth of product in the tray. If the root cause is determined to be insufficient cooling capacity to remove heat from the amount of product being cooled, the corrective action may involve using a cooling unit with greater cooling capacity or changing the method of cooling, e.g., to a blast freezer.

Proposed § 110.145(a)(2)(ii) and (iii), would require that corrective action procedures include an evaluation of all food affected by a problem and procedures for ensuring that affected food is prevented from entering into commerce if the owner, operator or agent in charge of the facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Such an evaluation is implicit in our HACCP regulations for seafood and juice (§§ 123.7(b) and 120.10(a)) in that these sections do not explicitly require that food affected by the problem be evaluated, but do require that steps be taken to ensure that product that is injurious to health or otherwise adulterated does not enter commerce. Although our HACCP regulations for seafood and juice do not specify the steps that must be described in a corrective action plan, the regulations require that specific steps be taken when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation (§§ 123.7(c) and 120.10(b), respectively). Under these regulations, required steps include segregating and holding effected product, performing or obtaining a review to determine the acceptability of the affected product for distribution and taking corrective action, when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. FDA notes that the corrective action procedures in the HACCP regulations do not reference misbranding under section 403(w) of the FD&C Act. Section 403(w) of the FD&C Act was added to the FD&C Act by the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title

II), which was enacted after issuance of both the seafood and juice HACCP regulations. However, our HACCP regulation for juice includes the presence of undeclared ingredients that may be allergens as a potential hazard that must be considered in the hazard analysis (§ 120.7(c)(8)), and our Fish and Fishery Products Hazards and Controls Guidance (Fourth Edition) (Ref. seafood hazards/controls guide) and Juice HACCP Hazards and Controls Guidance (Ref. juice guide) both include recommendations directed to hazards from undeclared food allergens.

3. Proposed § 110.145(b)--Corrective Action in the Event of an Unanticipated Problem

Proposed § 110.145(b)(1) would require that if a preventive control is not properly implemented and a specific corrective action has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility take corrective action to identify and correct the problem, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under proposed § 110.145(a)(2)(i)-(iii). However, a facility might not anticipate all of the problems that may occur, and a facility may experience an implementation failure for which a corrective action procedure has not been established. Regardless of whether a problem was anticipated and a corrective action procedure was developed in advance, corrective actions to accomplish the steps that would have been included in a corrective action procedure are necessary. Likewise, a facility might determine (e.g., as a verification activity in accordance with proposed § 110.150(d), discussed in section XII.G.5 of this document), that a preventive control is ineffective. For example, detecting a pathogen in an RTE food may signal that preventive controls for that pathogen are ineffective. As in the case of an unanticipated implementation failure of a preventive control, corrective actions would be necessary if a preventive control is found to be ineffective.

Proposed § 110.145(b)(1) is consistent with Federal HACCP regulations for seafood, juice, and meat and poultry. Our HACCP regulations for seafood and juice require that, when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor segregate and hold the affected product; perform or obtain a review to determine the acceptability of the affected product for distribution; take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and take corrective action, when necessary, to correct the cause of the deviation (§§ 123.7(c)(1)-(4) and 120.10(b)(1)-(4), respectively). The FSIS HACCP regulation for meat and poultry (9 CFR 417.3(b)) requires, in relevant part, that if a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must: (1) segregate and hold the affected product, at least until the requirements of 9 CFR 417.3(b)(2) and (3) are met; (2) perform a review to determine the acceptability of the affected product for distribution; and (3) take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce. The NACMCF HACCP guidelines and the Codex HACCP Annex are silent on the specific issue of taking corrective actions when a preventive control is not properly implemented and a specific corrective action has not been established or when a preventive control has been found to be ineffective. However, proposed § 110.145(b)(1) is consistent with HACCP principles, discussed earlier in this section, recommended in the NACMCF HACCP guidelines and Codex HACCP Annex regarding the importance of corrective actions whenever there is a deviation from a critical limit. In each of the situations described (following an established corrective action, taking corrective action in the absence of a plan, or taking

corrective action when the preventive control is found to be ineffective) the intent of taking corrective action is to restore control and to ensure that hazardous foods do not reach the consumer.

Proposed § 110.145(b)(2) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 110.150(f) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented and a specific corrective action has not been established, or if a preventive control is found to be ineffective. (We use the term "reanalyze" when we refer to a reassessment of the validity of a preventive control or the food safety plan to control a hazard.) Under proposed § 110.150(a), the verification required by section 418(f) of the FD&C Act would include validation of the food safety plan, referring to whether it is effectively controlling the hazards or "working correctly." See section XII.G of this document for a discussion of proposed requirements for verification (including validation and reanalysis) under section 418(f) of the FD&C Act. Proposed § 110.145(b)(2) would apply to unanticipated food safety problems, and the unanticipated nature of the problems is relevant to the reanalysis of the food safety plan. If the owner, operator, or agent in charge of a facility has assessed its procedures, practices, and processed and has not identified a specific failure as a foreseeable occurrence, the owner, operator, or agent in charge must assess whether the problem is simply an implementation failure that could be expected to occur in the normal course of manufacturing, processing, packing or holding the food, or the result of a system-wide problem that is not being properly addressed by the plan (e.g., ineffective preventive controls). If the problem is simply an implementation failure, and such a failure is now a foreseeable circumstance, reanalysis of the food safety plan would be necessary to determine whether a corrective action procedure should be established for

that foreseeable failure. Likewise, if the problem is the result of a system-wide problem that is not being properly addressed by the plan (or is otherwise a result of ineffective preventive controls), reanalysis of the food safety plan would be necessary to identify effective preventive controls. Either way, reanalyzing the food safety plan and modifying it as necessary would be necessary to reduce the risk of recurrence of the problem.

Proposed § 110.145(b)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines, in relevant part, recommend that validations (i.e., an assessment of the validity of the HACCP plan) be conducted when there is an unexplained system failure (e.g., an implementation failure or ineffective preventive controls) (Ref. NACMCF, 1998). The Codex HACCP Annex, in relevant part, advises that verification procedures be used to determine if the HACCP system is working correctly; such verification procedures would also be used if an unexpected implementation failure of a preventive control suggests that the system is not working correctly. Our HACCP regulations for seafood and juice, in relevant part, require that, when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor must perform or obtain timely reassessment or verification by a trained individual to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation and to modify the HACCP plan as necessary (§§ 123.7(c)(5) and 120.10(b)(5), respectively). The FSIS regulation for meat and poultry requires, in relevant part, that if a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must perform or obtain reassessment to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan (9 CFR 417.3(b)(4)). (The FSIS HACCP

regulation for meat and poultry uses the term “reassessment” much as this proposed rule would use the term “reanalysis.”)

4. Proposed § 110.145(c)--Corrective Actions for Environmental Monitoring

Proposed § 110.150(d)(4) would establish a requirement for monitoring of environmental pathogens as a verification of the implementation and effectiveness of the sanitation controls that under certain circumstances would be a required preventive control under proposed § 110.135(d)(3). (See the discussion of proposed § 110.150(d)(4) in section XII.G.5.d of this document and the discussion of proposed § 110.135(d)(3) in section XII.G.5.c of this document. As discussed in section II.E.4.d of this document, the primary purpose for monitoring of environmental pathogens in facilities where food is manufactured, processed, packed or held is to verify the implementation and effectiveness of sanitation controls and, in so doing, to find any sources of environmental pathogens that remain in the facility after routine cleaning and sanitizing (particularly strains that may have become established in the facility, i.e., resident strains) so that the environmental pathogens can be eliminated by appropriate corrective actions. Proposed § 110.145(c) would establish requirements for such corrective actions if environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism.

a. Proposed § 110.145(c)(1) through (3)--microbial testing, cleaning, and sanitizing. Proposed § 110.145(c)(1) through (3) would require that if environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the owner, operator, or agent in charge of a facility take corrective actions that would include:

- Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination (proposed § 110.145(c)(1));
- Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism (proposed § 110.145(c)(2)); and
- Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated (proposed § 110.145(c)(3)).

The adequacy of a corrective action in response to environmental monitoring depends in part on the following factors related to the risk presented in a particular situation:

- Whether the environmental contamination is on a food-contact surface or a non-food-contact surface;
- The proximity of a contaminated non- food-contact surface to one or more food-contact surfaces;
- Whether there have been previous positives on the specific food-contact surface or non- food-contact surface or in the same area; and
- The environmental monitoring strategy for the type of food, and whether the food supports growth of the environmental pathogen (see the discussion of the relevance of whether a food supports the growth of an environmental pathogen in section II.E.4..d of this document).

If an environmental pathogen or an appropriate indicator organism (the test organism) is detected in the environment, corrective actions must be taken to eliminate the organism, including finding a harborage site if one exists (Refs. Tompkin et al. 1999; Tompkin, 2002; Chen et al. 2009 FPT3). Otherwise, the presence of the environmental pathogen could result in contamination of food-contact surfaces or food. The presence of the indicator organism suggests

that conditions exist in which the environmental pathogen may be present and could result in contamination of food-contact surfaces or food. Corrective actions must be taken for every finding of an environmental pathogen or indicator organism in the environment to prevent contamination of food-contact surfaces or food.

Sampling and microbial testing from surfaces surrounding the area where the test organism was found (proposed § 110.145(c)(1)) are necessary to determine whether the test organism is more widely distributed than on the original surface where it was found and to help find the source of contamination if other sites are involved. Cleaning and sanitizing the contaminated surfaces and surrounding areas (proposed § 110.145(c)(2)) are necessary to eliminate the test organism that was found there. Additional sampling and microbial testing (proposed § 110.145(c)(3)) are necessary to determine the efficacy of cleaning and sanitizing. For example, detection of the test organism after cleaning and sanitizing indicates that the initial cleaning was not effective, and additional, more intensified cleaning and sanitizing, or other actions may be needed, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts (Ref. Tompkin et al. 1999). Examples of additional corrective actions that could be taken include reinforcing employee hygiene practices and traffic patterns; repairing damaged floors; eliminating damp insulation, water leaks, and sources of standing water; replacing equipment parts that can become harborage sites (e.g., hollow conveyor rollers and equipment framework), and repairing roof leaks (Ref. Tompkin, et al., 1999; Chen et al. FPT3, 2009). The types of corrective actions are dependent on the type of food, the facility and the environmental pathogen.

The finding of a test organism on a food-contact surface usually represents transient contamination rather than a harborage site (Ref. Tompkin, 2002). However, finding the test

organism on multiple surfaces in the same area, or continuing to find the test organism after cleaning and sanitizing the surfaces where it was found, suggests a harborage site for the test organism. Mapping the location of contamination sites, whether the harborage site is on equipment or in the environment, can help locate the source of the harborage site or identify additional locations to sample (Chen et al. 2009 FPT3).

Proposed § 110.145(c) would not specify how certain actions must be performed, such as the number of sites to test when the test organism is found in a facility, or how to clean and sanitize the surfaces on which the test organism was detected. The types of facilities that may conduct environmental monitoring and that would be required to implement corrective actions on finding the test organism in the facility are quite diverse, and include facilities producing low-moisture products such as cereals, chocolate and dried milk powders and facilities producing a variety of RTE refrigerated products such as deli salads, cheeses and bagged salads. The number of sites appropriate for testing and the applicable cleaning and sanitizing procedures will depend on the facility and the equipment. FDA tentatively concludes that, when microbial testing is conducted as part of a corrective action in light of the results of environmental monitoring, specifying such procedural requirements would not provide facilities with sufficient flexibility to develop and implement aggressive and appropriate corrective actions to find and eliminate the source of the contamination in the environment.

Corrective actions may involve investigative procedures when the initial corrective actions have not been successful in eliminating the environmental pathogen or indicator organism. One example of an investigative procedure is taking samples from food-contact surfaces and/or product from the processing line at multiple times during the day while the equipment is operating and producing product (Ref. Tompkin et al. 1999). Another example of

an investigative procedure is conducting molecular strain typing such as pulsed-field gel electrophoresis (PFGE), ribotyping, or polymerase chain reaction (PCR) analysis to determine if particular strains are persistent in the environment (Proudy et al. 2008; Mullane et al., 2007; Carpentier and Cerf, 2011; Blatter et al., 2010; Miettinen et al. 1999; Pourshaban et al. 2000). Molecular strain typing can indicate that strains isolated at different points in time have the same molecular "fingerprint," suggesting a common source, and perhaps a harborage site, that has not been detected based on the results of routine environmental monitoring (Ref. Miettinen et al., 1999; Pourshaban et al. 2000). Molecular strain typing can also be used when trying to determine if a specific ingredient is the source of contamination (Proudy et al., 2008).

b. Proposed § 110.145(c)(4)--product testing. Proposed § 110.145(c)(4) would require that if environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the owner, operator, or agent in charge of a facility conduct finished product testing, when appropriate. As discussed in section II.E.6 of this document, there are shortcomings for microbiological testing of food for process control purposes. Testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed. If an environmental pathogen is detected on a food-contact surface, finished product testing would be appropriate only to confirm actual contamination or assess the extent of contamination, because negative findings from product testing could not adequately assure that the environmental pathogen is not present in food exposed to the food-contact surface. If a facility detects an environmental pathogen on a food-contact surface, the facility should presume that the environmental pathogen is in the food.

Finished product testing could be appropriate if an environmental pathogen is detected on a non-food-contact surface, such as on the exterior of equipment, on a floor or in a drain. The

potential for food to be contaminated directly from contamination in or on a non-food-contact surface is generally low, but transfer from non-food-contact surfaces to food contact surfaces can occur. Finished product testing can provide useful information on the overall risk of a food when pathogens have been detected in the environment.

In general, finished product testing is most appropriate when an indicator organism, rather than an environmental pathogen, is detected on a food-contact surface. As discussed in section II.E.5.d of this document, FDA's current thinking is that there is no currently available indicator organism for Salmonella spp.. However, Listeria spp. is an appropriate indicator organism for L. monocytogenes. Therefore, the remainder of this discussion is directed to finding the indicator organism Listeria spp. during environmental monitoring.

The presence of Listeria spp. on a food-contact surface does not necessarily mean that L. monocytogenes is on that food-contact surface. The significance of finding Listeria spp. on a food-contact surface, and whether that finding makes product testing appropriate, depends on factors such as the location of the Listeria spp. and its potential to contaminate food, whether the food ordinarily would be treated to adequately reduce any L. monocytogenes (if the Listeria spp. was indeed L. monocytogenes) after the location in the processing line where the Listeria spp. was found, and the intended use of the food. For example, finished product testing could be appropriate if Listeria spp. is detected on a non-food-contact surface near food contact surfaces, because the potential for food contact surfaces or food to become contaminated directly from contamination on a non-food-contact surface is increased due to the proximity of the non-food-contact surface to a food contact surface. However, finished product testing would be of little value if the facility treats the food produced using that food-contact surface with a process to adequately reduce L. monocytogenes after the stage in processing where any contamination

likely occurred, because the treatment would correct the problem if indeed L. monocytogenes was in the food.

Finished product testing generally is appropriate if Listeria spp. is detected on a food-contact surface and food produced using that food-contact surface will not be treated to adequately reduce L. monocytogenes. As also discussed in section II.D.2.a of this document, the risk of serious illness or death from consumption of a food contaminated with L. monocytogenes increases with the number of L, monocytogenes in the food. L. monocytogenes can grow under refrigeration conditions and, thus, a small number of L, monocytogenes in a refrigerated food (such as soft cheese) that supports its growth could grow to a number sufficient to cause serious illness or death by the time the consumer eats the food. In contrast, a small number of L. monocytogenes in a refrigerated food (like hard cheese) that does not support its growth would remain a small number and would present a much lower risk of serious illness or death. Thus, where the intended use could involve extended storage under refrigeration, finished product testing is appropriate if Listeria spp. is detected on a food-contact surface, particularly if the food supports growth.

An example of a risk-based approach to finding Listeria spp. on a food-contact surface when the food will not be further processed to adequately reduce L. monocytogenes is to implement "hold and test" procedures for food based on whether it does or does not support the growth of L. monocytogenes. For example, for a food that does not support the growth of L. monocytogenes, "hold and test" procedures might be implemented after two, or even three, rounds of corrective actions to find and eliminate Listeria spp. detected on a food-contact surface are not successful in eliminating the contamination. However, if a food supports the growth of L. monocytogenes, a firm might implement "hold and test" procedures if a single round of

corrective action is not successful. Such an approach is described by FSIS in their guidance on the control of L. monocytogenes (Ref, FSIS Lm guidance 2006).

As discussed in section II.E.6 of this document, there are significant limitations to the ability of finished product testing to detect a contaminant that is present at a low level. However, appropriate sampling protocols and testing methods can provide a level of statistical confidence in the results. For example, as discussed in section II.E.6 of this document the International Commission on Microbiological Criteria for Foods has published information regarding the statistical significance of various sampling plans (e.g., the most stringent sampling plan, requiring no positives in 60 25-g samples (n=60), will reject, with a 95% probability, a lot of food if the mean concentration of the pathogen is at least 1.9 cfu/1000 g) (Ref. ICMSF Book 7, Chapter 8). This information can be used in combination with the results of environmental monitoring and corrective actions to help ensure that the food released into commerce is not adulterated. For example, if a facility with an aggressive environmental monitoring program detects an indicator organism on a food-contact surface, it may use information such as the following in determining whether to release product into commerce:

- The number and location of positive sample findings, including from the original sampling and from additional/follow-up testing of areas surrounding the site of the original finding;
- The root cause analysis of the source of the contamination;
- Information on the efficacy of the facility's corrective actions (including the results of additional follow-up sampling);
- Information obtained from any finished product testing, taking into consideration the statistical confidence associated with the results.

c. Proposed § 110.145(c)(5)--other corrective actions as necessary. Proposed § 110.145(c)(5) would require that if environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the owner, operator, or agent in charge of a facility perform any other steps necessary to prevent recurrence of the contamination. The corrective actions taken as a result of monitoring for an environmental pathogen or an indicator organism for such pathogen must ensure these requirements are met. The corrective actions for environmental monitoring specified in proposed § 110.145(c)(1) through (4) are not all inclusive. Considerations relevant to whether other corrective actions are necessary under proposed § 110.145(c)(5) include the nature of the facility, the products being produced, and the pathogen of concern. For example, the actions taken to address Salmonella spp. in a dry environment will be different from those taken for Listeria spp. in a wet environment. Examples of corrective actions that may be necessary include reinforcing employee hygiene practices and traffic patterns; repairing damaged floors; eliminating damp insulation, water leaks, and sources of standing water; replacing equipment parts that can become harborage sites (e.g., hollow conveyor rollers and equipment framework), and repairing roof leaks (Ref. Tompkin, et al., 1999; Chen et al. FPT3, 2009). Additional information on corrective actions for environmental monitoring can be found in the literature (Ref. Tompkin, 2002; Tompkin et al. 1999; Chen et al. 2009 FPT3).

d. Relation to HACCP guidelines, Codex Annex, and Federal HACCP regulations. The specific requirement in proposed § 110.145(c) – i.e., corrective actions for environmental monitoring – is not explicitly addressed in the NACMCF HACCP guidelines, the Codex HACCP Annex, or Federal HACCP regulations for seafood, juice and meat and poultry. However, proposed § 110.145(c) is consistent with the concept of corrective actions in all of these HACCP

systems (see section II.C.4.e of this document for a discussion of corrective actions in these HACCP systems).

Proposed § 110.145(c) also is consistent with the FSIS Listeria Guidelines (Ref. FSIS Listeria guidelines). As discussed in section II.E.5.c of this document, under 9 CFR 430.4(a), L. monocytogenes is a hazard that must be addressed by an FSIS-regulated establishment producing a RTE meat or poultry product that is exposed to the environment where it could be recontaminated after a treatment that is lethal to the organism. In general, as a verification procedure such establishments would test food contact surfaces in the post-lethality processing environment to ensure that the surfaces are free of L. monocytogenes or of an indicator organism for L. monocytogenes (9 CFR 430.4(b)(2)(iii)(A) and 9 CFR 430.4(b)(3)(i)(A)). The establishment would also be required to identify the conditions under which the establishment will implement "hold and test" procedures following a positive test of a food-contact surface for L. monocytogenes or an indicator organism (9 CFR 430.4(b)(2)(iii)(B) and 9 CFR 430.4(b)(3)(i)(B)). The FSIS Listeria guidelines describe corrective actions to be taken as a result of finding L. monocytogenes or Listeria spp. on food contact surfaces, and include guidance on implementing product "hold and test" procedures (Ref. FSIS Lm guidance). Depending on the specific characteristics of the RTE meat or poultry product and the process used to produce it, the "hold and test" procedures described in the FSIS Listeria guidelines would apply after either two or three consecutive tests for the presence of an indicator organism for L. monocytogenes on a food-contact surface.

Proposed § 110.145(c) also is consistent with the Codex guidelines on control of L. monocytogenes in foods and in the Code of Hygienic Practice for Powdered Infant Formulae for Infants and Young Children (Ref. CAC Lm 2007; CAC PIF 2008). Each of these guidelines

recommends environmental monitoring programs and the development of an action plan to respond to positive findings or when decision criteria are exceeded. Both guidelines emphasize the need to take action for each positive result.

5. Proposed § 110.145(d)--Documentation.

Proposed § 110.145(d) would require that all corrective actions taken in accordance with this section be documented in records that are subject to verification in accordance with § 110.150(c) and records review in accordance with § 110.150(d)(5)(i). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

G. Proposed § 110.150--Verification

1. Requirements of Section 418 of the FD&C Act

Section 418(f) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that:

- "[T]he preventive controls implemented under [section 418(c) of the FD&C Act] are adequate to control the hazards identified under [section 418(b) of the FD&C Act]" (section 418(f)(1) of the FD&C Act);
- "[T]he owner, operator, or agent is conducting monitoring in accordance with [section 418(d) of the FD&C Act]" (section 418(f)(2) of the FD&C Act);
- "[T]he owner, operator, or agent is making appropriate decisions about corrective actions taken under [section 418(e) of the FD&C Act]" (section 418(f)(3) of the FD&C Act);
- "[T]he preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards,

including through the use of environmental and product testing programs and other appropriate means" (section 418(f)(4) of the FD&C Act); and

- "[T]here is documented, periodic reanalysis of the plan under [section 418(i) of the FD&C Act] to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats" (section 418(f)(5) of the FD&C Act).

In addition, section 418(g) of the FD&C Act specifies, in relevant part, that "[t]he owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under [section 418(c) of the FD&C Act], instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under [section 418(f)(4) of the FD&C Act], instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions."

Further, section 418(i) of the FD&C Act specifies that "[t]he owner, operator, or agent in charge of a facility shall conduct a reanalysis under [section 418(b) of the FD&C Act (the requirement to identify and evaluate known or reasonably foreseeable hazards)] whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is operative. The owner, operator, or agent shall revise the written plan required under [section 418(h) of the FD&C Act] if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are

needed. The Secretary may require a reanalysis under [section 418(i) of the FD&C Act] to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment."

2. Proposed Requirements for Validation

a. Proposed § 110.150(a)--Validation that preventive controls are adequate to control the hazard. Proposed § 110.150(a) (Validation) would require that, except as provided by paragraph (a)(3), the owner, operator, or agent in charge of a facility validate that the preventive controls identified and implemented in accordance with § 110.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. Proposed § 110.150(a) would implement section 418(f)(1) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines describe verification as activities that, in relevant part, determine the validity of the HACCP plan (Ref. NACMCF, 1998). The NACMCF guidelines advise that an important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that, if the HACCP plan is properly implemented, these hazards will be effectively controlled (Ref. NACMCF, 1998). The Codex HACCP guidelines recommend that, where possible, validation activities include actions to confirm the efficacy of all elements of the HACCP system (Ref. CAC 2003). Our HACCP regulation for seafood does not specifically use the term "validation," but it reflects the concept in requiring that every processor verify that the HACCP plan is adequate to control the hazards (§ 123.8(a)). Our HACCP regulation for juice addresses both validation of the HACCP plan (§ 120.11(b)) and the

hazard analysis (§ 120.11(c)). The regulation requires each processor to validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur at least once within 12 months after implementation and at least annually thereafter. (This annual validation is the same as reanalysis proposed in § 110.150(e) and discussed in section XII.G.6 of this document. The requirement for validation of the hazard analysis in § 120.11(c) aligns more with a requirement for reanalysis and is discussed in section XII.G.2.a of this document). The FSIS HACCP regulation for meat and poultry (9 CFR 417.4(a)) requires that every establishment validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis. The regulations and guidelines described above reflect the widespread recognition of the importance of ensuring that preventive controls, if properly implemented, will adequately control the hazards.

b. Proposed § 110.150(a)(1)--Validation by a qualified individual prior to implementation and on reanalysis. Proposed § 110.150(a)(1) would require that the validation of the preventive controls be performed by a qualified individual. The preventive controls must be adequate to control the hazards identified in the hazard analysis as reasonably likely to occur. Determining whether specific preventive controls are adequate requires an individual who is knowledgeable in the hazards associated with a product and process and the appropriate preventive controls for those hazards. Such knowledge requires scientific and technical expertise developed through training, experience or both. Under proposed § 110.150(a)(1), the validation could be performed or overseen by a qualified individual.

Proposed § 110.150(a)(1)(i) would require that validation occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production. The validation of preventive controls includes collecting and evaluating scientific and technical

information (or, when such information is not available or is insufficient, conducting studies), as discussed in the next section of this document. The collected data or information, or the studies, would establish a scientific and technical basis for the preventive controls used, in particular those that involve critical control points. This scientific and technical basis largely must be established prior to producing a product to ensure that the food produced using those preventive controls will be safe. However, as a practical matter, the scientific and technical basis for some aspects of a preventive control may require production conditions and, thus, would be established by the collection of data or information during, rather than before, producing a product. For example, ensuring that limits for control parameters can be met during production would be done under production conditions. FDA tentatively concludes that preventive controls that require the collection of data or information, or studies, during production conditions are part of validation, and, thus proposed § 110.150(a)(1)(i) would require that the validation of preventive controls be performed, when necessary, during the first six weeks of production. We selected six weeks as a time interval that would be adequate to allow facilities to methodically collect data and information during production, yet would be close to implementation of a preventive control.

The NACMCF HACCP guidelines recommend that initial validation be conducted prior to and during initial implementation of the plan (Ref. NACMCF 1998). A Codex document entitled "Guidelines for the Validation of Food Safety Control Measures" (hereinafter the Codex validation guidelines) recommends that validation of control measures be performed, whenever possible, before their full implementation (Ref. Codex Val 2008). Codex also includes as a validation measure the collection of data, e.g., product and/or environmental sampling and testing, during operating conditions in the food operation for a specified period (e.g., 3-6 weeks)

(Ref. Codex Val. 2008). The HACCP regulation for juice requires that validation of HACCP plans be conducted once during the year after implementation and at least annually thereafter (§ 120.11(b)). The FSIS HACCP regulation for meat and poultry (9 CFR 417.4(a)) requires that initial validation be conducted upon completion of the hazard analysis and development of the HACCP plan to determine that the HACCP plan is functioning as intended (9 CFR 417.4(a)(1)). During the HACCP plan validation period, the meat or poultry establishment must repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan (9 CFR 417.4(a)(1)).

FDA requests comment on whether the proposed time frame for validation should be shorter or longer. Comments should provide the basis for an alternative time frame.

Proposed § 110.150(a)(1)(ii) would require that the validation of the preventive controls be performed whenever a reanalysis of the food safety plan reveals the need to do so. The circumstances under which a reanalysis would be required are addressed in proposed § 110.150(f). Proposed § 110.150(f)(1)(ii) would require that the owner, operator, or agent in charge of a facility complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative, or, when necessary, during the first six weeks of production. All preventive controls established to address a hazard identified as reasonably likely to occur must have a scientific and technical basis; establishing that scientific and technical basis is a validation activity regardless of whether the preventive control is established in the facility's initial food safety plan or as a result of reanalysis of the food safety plan.

c. Proposed § 110.150(a)(2)--Validation based on scientific and technical information. Proposed § 110.150(a)(2) would require that, except as provided by paragraph (a)(3) of this

section, the validation of preventive controls include collecting and evaluating scientific and technical information or, when such information is not available or is insufficient, conducting studies to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur. The NACMCF HACCP guidelines note that information needed to validate the HACCP plan often includes (1) expert advice and scientific studies and (2) in-plant observations, measurements and evaluations (Ref. NACMCF, 1998). The Codex validation guidelines address several approaches for validating control measures, including (1) reference to scientific or technical literature, previous validation studies or historical knowledge, (2) scientifically valid experimental data, (3) collection of data during operating conditions, (4) mathematical modeling, and (5) surveys, and note that these may be used individually or in combination (Ref. CAC Val 2008).

The scientific and technical information that would be evaluated to determine whether preventive controls effectively control the hazards that are reasonably likely to occur may include scientific publications, government documents, predictive mathematical models and other risk-based models, and technical information from equipment manufacturers, trade associations, and other sources. If the qualified individual conducting the validation relies on sources such as scientific publications, the qualified individual would need to ensure during validation that the conditions used by the facility are consistent with those described in the publication that is being used to support the adequacy of the preventive control measure to control the hazard. For example, if a study demonstrates adequate inactivation of Salmonella in peanuts using a roasting process, conditions such as roaster temperature, heating time, bed depth and humidity that were critical to achieving inactivation in the study must be the same when the facility roasts peanuts (or any change in the critical parameters must be such that lethality is

maintained). Documents published by FDA, such as the Food Code (Ref. FDA Food Code), the Pasteurized Milk Ordinance (Ref. FDA's PMO), and the Fish and Fisheries Products Hazards and Controls Guidance (Ref. FDA's 4th ed of the guidance) may provide scientific and technical information useful in establishing the validity of a preventive control measure, such as times and temperatures for cooling foods in which bacterial pathogen growth may occur or minimum water activities, minimum pH values, and minimum and maximum temperatures for growth of a variety of pathogens.

Predictive mathematical models that describe the growth, survival, or inactivation of microorganisms in foods may provide scientific and technical information useful in determining whether a process would be adequate to reduce microorganisms of public health concern (Ref. CAC Val 2008; NACMCF, 2010). Other risk-based models may examine the impact of a control measure on a hazard and may be useful if appropriately validated for a specific food. If the model is for a different food, it may still provide useful validation information that could be supplemented by additional data. For example, there are many mathematical models for thermal resistance of Salmonella. If a model for the thermal resistance of Salmonella is developed for the same type of food as the food being produced, and the food being produced has the same critical parameters such as pH and a_w that were used in developing the thermal resistance model, then heat processes based on the model would generally be considered validated. For example, if a model for the thermal resistance of Salmonella is developed in tomatoes with a pH of 4.3, the model would be considered valid for tomatoes with a pH of 4.3 or below, but not for tomatoes with a higher pH. If however, the model is for thermal resistance of Salmonella in a type of food that is only similar to the food being produced, or has different critical parameters than were used in developing the thermal resistance model, it would be necessary to conduct additional

thermal resistance studies in the food being produced to provide the data needed to show that a heat process adequately reduces Salmonella in that food and to establish the critical parameters for the process. For example, a model for thermal resistance of Salmonella on almonds may not apply to hazelnuts, even though the foods are similar in that both are tree nuts. The extent of such studies would, however, be less than the extent of such studies if there were no data on the heat resistance of Salmonella in a similar food. For example, if the thermal resistance of Salmonella in initial studies with hazelnuts is similar to that for almonds, then a thermal resistance study used to develop data for hazelnuts could investigate fewer times and temperatures, or use fewer replicates, than would be the case in the absence of the information about the thermal resistance of Salmonella in almonds.

A process validation study would establish the relationship between parameters such as process times and temperatures and other factors and the rate at which pathogens are reduced, and a prevalence study would determine the levels at which pathogens may occur in the raw material, ingredient, or food product to establish the cumulative amount of pathogen reduction that would be required to adequately reduce the risk of illness from that pathogen. Such studies are typically published or otherwise broadly disseminated within the scientific community and, when properly designed and carried out, are generally regarded by experts as scientifically definitive with respect to the matters addressed by the study. However, if scientific and technical information is not available or is insufficient to support the adequacy of a preventive control measure to control the hazard, the owner, operator or agent in charge of a facility would need to conduct controlled scientific studies to establish that a preventive control measure is adequate to control the hazard. As an example, a facility that wants to use propylene oxide (PPO) to inactivate enteric pathogens such as E. coli O157:H7 on shelled hazelnuts would need to conduct

studies to establish that PPO could significantly minimize the hazard because no such studies currently exist in the public domain. Such studies would also establish the critical parameters and limits (e.g., critical limits at a CCP) that the facility would need to use to effectively control the hazard. For the hazelnut example, the critical factors might include amount of PPO, temperature of the nuts to be treated, treatment time, chamber temperature, PPO vaporizer temperature, chamber vacuum, and post-treatment hold time and temperature. Studies on inactivation of Salmonella on almonds could provide information about appropriate parameters to investigate for the inactivation of E. coli O157:H7 on shelled hazelnuts, but additional studies would be needed to establish the specific values for those parameters in the inactivation of E. coli O157:H7 on shelled hazelnuts.

Information is available in the literature that can assist in the design of studies to support the adequacy of preventive control measures. For example, NACMCF has published information on "Parameters for Determining Inoculated Pack/Challenge Study Protocols" (Ref. NACMCF 2010) and "Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization" (Ref. NACMCF 2006). Studies to validate preventive control measures must be conducted by persons with experience and expertise relevant to the product, process and hazard to be controlled. Under proposed § 110.152(a)(1)), any studies needed to provide the scientific and technical information to establish the validity of the plan would either be conducted by a qualified individual (as would be defined in proposed § 110.3) or would be overseen by a qualified individual. In other words, the qualified individual need not have the experience and expertise to conduct validation studies, but must have sufficient expertise in risk-based preventive controls to understand the studies and how they support the validity of the preventive controls with respect to the hazard of concern.

d. Proposed § 110.150(a)(3)--Preventive controls for which validation is not required

Proposed § 110.150(a)(3)(i) through (iv) would provide that validation need not address:

- The food allergen controls that would be established in proposed § 110.135(d)(3);
- The sanitation controls that would be established in proposed § 110.135(d)(3);
- The recall plan that would be established in proposed § 110.137; and
- The supplier approval and verification program that would be established in proposed § 110.152.

According to NACMCF, verification involves activities to determine the validity of the HACCP plan and that the system is operating according to the plan (Ref. NACMCF, 1998). Thus, validation is a verification activity. The purpose of validation is to provide the scientific and technical basis for ensuring that the preventive controls implemented are adequate to control the hazards identified as reasonably likely to occur. FDA tentatively concludes that validation, i.e., the evaluation of scientific and technical information, is either not an essential activity, is not practical or is not relevant, for the controls identified in proposed § 110.150(a)(3).

Food allergen controls

As discussed in section XII.C.6 of this document, proposed § 110.135(d)(2)(i) would require that food allergen controls include those procedures, practices, and processes employed for ensuring protection of food from cross-contact, including during storage and use. Examples of such procedures, practices, and processes include providing physical barriers between sections of a facility, conducting manufacturing/processing of foods in different parts of a facility, and controlling the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods those that do not, or when the same production lines are used for foods that contain different allergens. These types

of controls generally are not evaluated through scientific studies or by the collection of technical information as would be required under proposed § 110.150(a)(2). Instead, monitoring (e.g., by visual observation) that these activities do not result in cross-contact provides sufficient assurance that the controls are functioning as intended to prevent the hazard of undeclared allergens in the food due to cross-contact. Examples of such visual observations include observations that bags of allergenic foods (such as soy flour) are stored in sealed containers, that spills of allergen powders are promptly cleaned, and that equipment is cleaned between manufacturing/processing of different foods. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the food allergen cross-contact controls that would be established in proposed § 110.135(d)(2)(i). We request comment on this approach.

As discussed in section XII.C.6 of this document, proposed § 110.135(d)(2)(ii) would require that food allergen controls include those procedures, practices, and processes employed for labeling the finished food, including, including ensuring that foods are not misbranded under section 403(w) of the FD&C Act. Examples of such procedures, processes, and practices include ensuring that the food label correctly declares all of the food allergens present (including those contained in flavors), ensuring that the correct food label is applied to a food, and ensuring that the correct food is in the correct package (e.g., by checking that the correct packaging is used for each food). These types of controls generally are not evaluated through scientific studies or by the collection of technical information as would be required under proposed § 110.150(a)(2). Instead, verifying that labels contain appropriate information and monitoring that the correct label is being applied to the product provide sufficient assurance that the controls are functioning as intended to prevent the hazard of undeclared allergens in the food due to incorrect labels.

Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the food allergen labeling controls that would be required by proposed § 110.135(d)(2)(ii). We request comment on this approach.

Sanitation controls

As discussed in section XII.C.7 of this document, proposed § 110.135(d)(3)(i)(A) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the cleanliness of food contact surfaces, including food contact surfaces of utensils and equipment. Traditionally, sanitarians employed by the facility or experts employed by companies that supply cleaning and sanitizing compounds will establish critical parameters and associated limits for cleaning and sanitation, including the choice and strength of the cleaning and sanitizing chemicals, contact time, and temperature requirements, based on studies conducted by the manufacturers of the products. Antimicrobial solutions applied to food processing equipment and utensils to sanitize such objects after they have been washed are included in the definition of "pesticide chemical" and therefore, are subject to regulation by EPA under section 408 of the FD&C Act (Ref. FDA guidance for industry on antimicrobial food additives). Chapter 4 (Additional Considerations for Antimicrobial Products) of EPA's "Pesticide Registration Manual" (Ref. http://www.epa.gov/pesticides/bluebook/chapter4.html) outlines EPA's requirements and recommendations for registration of antimicrobial substances, including testing against a validated protocol to be granted EPA-registered claims for pathogen reduction.. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the sanitation controls that would be required by proposed § 110.135(d)(3)(i)(A). Monitoring activities to ensure the procedures are followed will provide

assurance that the controls are functioning as intended to prevent hazards from insanitary food contact surfaces. We request comment on this approach.

As discussed in section XII.C.7 of this document, proposed § 110.135(d)(3)(i)(B) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the prevention of cross-contact and cross-contamination from insanitary objects and from employees to food, food packaging material, and other food-contact surfaces and from raw product to processed product. As already discussed with respect to proposed § 110.135(d)(3)(i)(A), sanitation controls to prevent cross-contamination can be established by sanitarians or by companies that supply cleaning and sanitizing compounds without the need for validation. Cleaning procedures established by sanitation experts should also be adequate to remove allergens from equipment and the environment in facilities where raw materials or ingredients containing allergens are used. Although it is prudent to validate the efficacy of cleaning with respect to allergens, appropriate allergen test methods may not be available at present for this purpose in all situations (Ref. Jackson et al. 2008. JFP). For example, when the same equipment is used to make milk-based and soy-based beverages, the availability of analytical methods that can detect milk protein and soy protein may make it practical to clean the equipment and then test a water rinse of the system to determine whether milk or soy proteins can be detected in the rinse water. However, this may not be the case when equipment used to make breaded shrimp is subsequently used to make breaded fish. We tentatively conclude that validation by the facility to demonstrate that sanitation controls adequately protect against cross-contact is not feasible for all situations at this time.

Regardless of whether this proposed rule would require the specific verification activity of validation to demonstrate that sanitation controls adequately protect against cross-contact,

proposed § 110.135(d)(3)(i)(A) would require that the owner, operator, or agent in charge of a facility establish appropriate allergen sanitation procedures to ensure that products do not contain undeclared allergens from other products. Cleaning procedures established to remove food residues and verification that food residues have been removed (e.g., by visual inspection) should significantly minimize or prevent the presence of undeclared food allergens. When appropriate tests are available, we recommend that facilities use testing as well as visual inspection to verify that procedures have been done adequately. We request comment on this approach. We also request comment on whether we should require validation of sanitation controls to protect against cross-contact in those situations where appropriate analytical methods for use in validation studies are currently available, even if such methods are not available for all major food allergens.

Recall plan

As discussed in section XII.C.8 of this document, a recall plan can significantly minimize or prevent hazards by limiting consumption of affected food during a recall. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked. The proposed requirement to validate a preventive control by collecting and evaluating scientific and technical information or by conducting studies simply does not apply to such a plan. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the recall plan that would be required by proposed § 110.137.

Supplier approval and verification program.

As discussed in section XII.C.9 of this document, proposed § 110.152 would establish a requirement for a supplier approval and verification program that would be self-contained in that

it would include targeted verification activities applicable to suppliers. The proposed requirement to validate a preventive control by collecting and evaluating scientific and technical information or by conducting studies does not apply to evaluation of suppliers.

3. Proposed § 110.150(b)--Verification of Monitoring

Proposed § 110.150(b) would require that the owner, operator, or agent in charge of a facility verify that monitoring is being conducted, as would be required by proposed § 110.140. One example of verification that monitoring is being conducted is a periodic observation of the monitoring activity, e.g., by a supervisor. Another example of such a verification activity is an independent test made by a person other than the person doing the monitoring. For example, if the line operator is verifying the operation of a metal detector by running test pieces through the metal detector every two hours to verify it rejects them, a quality assurance technician could periodically run a similar test - e.g., once per shift. Proposed § 110.150(b) does not address the review of monitoring records, which would be required under proposed § 110.150(d)(5)(i) (see the discussion in section XII.G.5.f of this document).

Proposed § 110.150(b) would implement section 418(f)(2) of the FD&C Act and is consistent with the FSIS HACCP regulation for meat and poultry, which requires direct observations of monitoring activities as an ongoing verification activity (9 CFR 417.4(a)(2)(ii)). Proposed § 110.150(b) would differ from the NACMCF HACCP guidelines (Ref. NACMCF 1998), the Codex HACCP guidelines (Ref. Codex 2003), and FDA's HACCP regulations for seafood and juice (§§ 123.8(a)(3)(i) and 120.11(a)(1)(iv)(A), respectively), which address verification of monitoring through the review of records (which would be required by proposed § 110.150(d)(5)(i)) but do not otherwise address verification activities for monitoring.

Proposed § 110.150(b) would not specify the verification activities that must be conducted for monitoring. We request comment on whether proposed § 110.150(b) should do so, and if so, what verification activities should be required.

4. Proposed § 110.150(c)--Verification of Corrective Actions

Proposed § 110.150(c) would require that the owner, operator, or agent in charge of a facility verify that appropriate decisions about corrective actions are being made, as would be required by proposed § 110.145. An example of verification that appropriate decisions about corrective actions are being made is observation of the corrective actions being taken, e.g., by a supervisor. Proposed § 110.150(c) would implement section 418(f)(3) of the FD&C Act and is consistent with the FSIS HACCP regulation for meat and poultry, which includes direct observations of corrective actions as an ongoing verification activity (9 CFR 417.4(2)(ii)). Proposed § 110.150(c) would differ from the NACMCF HACCP guidelines (Ref. NACMCF, 1998), the Codex HACCP guidelines (Ref. Codex 2003), and FDA's HACCP regulations for seafood and juice (§§ 123.8(a)(3)(ii) and 120.11(a)(1)(iv)(B), respectively), which address verification of corrective actions through the review of records (which would be required by proposed § 110.150(d)(5)(i)) but do not otherwise address verification activities for corrective actions.

Proposed § 110.150(c) would not specify the verification activities that must be conducted for corrective actions. We request comment on whether proposed § 110.150(c) should do so, and if so, what verification activities should be required.

5. Proposed § 110.150(d)--Implementation and Effectiveness

Proposed § 110.150(d) would require that the owner, operator, or agent in charge of a facility verify the preventive controls are consistently implemented and are effectively and

significantly minimizing or preventing the hazards that are reasonably likely to occur, including the requirements in proposed § 110.150(d)(1)-(5), as appropriate to the facility and the food. Proposed § 110.150(d) would implement section 418(f)(4) of the FD&C Act, which requires in relevant part verification by "appropriate means" that the preventive controls "are effectively and significantly minimizing or preventing the occurrence of identified hazards."

a. Proposed § 110.150(d)(1)--Review of complaints. Proposed § 110.150(d)(1) would require a review of any consumer, customer, or other complaints to determine whether a complaint relates to the effectiveness of the food safety plan. The role of consumer complaints in evaluating the effectiveness of a food safety plan is reflected in our HACCP regulations for seafood and juice. Our HACCP regulation for seafood (§ 123.8(a)(2)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points. Our HACCP regulation for juice (§ 120.11(a)(1)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether the complaints relate to the performance of the HACCP plan or reveal the existence of unidentified critical control points. FDA notes that the role of consumer complaints is not discussed in the NACMCF guidelines or the Codex guidelines, and their review is not required by the FSIS HACCP regulation for meat and poultry. However, as we discussed in the seafood HACCP proposed rule (59 FR 4142 at 4157), no system is foolproof, and consumer complaints may be the first alert for a processor that deviations are occurring and are not being prevented or uncovered by the processor's HACCP controls.

Further, although most consumer complaints will be related to quality issues, recent experience has demonstrated the value that consumer and customer complaints can provide in bringing attention to possible problems within a facility's preventive controls activities. FDA has received a number of submissions to the Reportable Food Registry (Ref. FDA 2011 RFR Annual Report.) that have suggested that environmental pathogens or food allergen hazards were not adequately addressed in a supplier's food safety plan. Some of these were identified through customer verification testing and others through complaints from consumers to a facility. A facility may also receive alerts as a result of state surveillance and testing programs. (For a discussion of such programs, see section II.A.6.e of this document). Many recall notices identify the results of a state surveillance and testing program as the trigger for a recall (Refs. River Ranch recalls bagged salads, 2011; Del Bueno Recalls Queso Fresco Casero Cheese, 2011; Taylor Farms recalls bagged salads, 2011).

We tentatively conclude that a facility's review of complaints, including complaints from consumers, customers, or other parties, is an important component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards. For example, a facility that has allergen controls in its food safety plan would have reason to question the effectiveness of its plan if the facility received complaints from a consumer about allergic reactions to products to which such controls are applied. We request comment on this requirement to review consumer, customer, or other complaints to determine whether a complaint relates to the effectiveness of the food safety plan.

b. Proposed § 110.150(d)(2)--Calibration. Proposed § 110.150(d)(2) would require calibration of process monitoring instruments and verification instruments. As discussed in section II.D.3 of this document, the combination of monitoring (proposed § 110.140(a)),

recordkeeping (proposed § 110.175), and verification (proposed § 110.150(a) and (d)) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act would be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility would not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. In many instances, monitoring and verification activities rely on instruments (such as a pH meter or a thermometer) that must be calibrated. Calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance that hazards will be significantly minimized or prevented. If an instrument is calibrated against a known reference, the reference standard may also need periodic calibration (e.g., the standard reference thermometer used to calibrate a thermometer used in processing equipment will itself also need to be calibrated periodically).

Instrument calibration is performed on a regular or periodic basis based upon the type of instrument being used and its sensitivity to factors such as the operating environment and the wear and tear of ongoing use. The type of instruments used in a particular facility and the manner of their use will largely determine the need for, and the frequency of, calibration, and the frequency of calibration is often prescribed by the instrument manufacturer. Therefore, proposed § 110.150(d)(2) would not specify a frequency for calibration.

c. Proposed § 110.150(d)(3)--Product testing. Proposed § 110.150(d)(3) would require the performance of finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur. We address the risk-based aspects of finished product testing in section II.E.6 of this

document. Below we address when and how product testing should be used to verify that preventive controls are significantly minimizing or preventing the occurrence of hazards. Proposed § 110.150(e)(1), discussed in section XII.G.6 of this document, would require that the owner, operator, or agent in charge establish and implement written procedures for finished product testing, which must be scientifically valid.

Section 418(f)(4) of the FD&C Act provides for product testing as a verification activity. The testing required by proposed § 110.150(d)(3) for finished products is not the only provision for product testing that would be established in this proposed rule. Other provisions that would establish a role for product testing are proposed § 110.152(c)(1) (which would establish requirements for supplier approval and verification that include an option for product testing in some circumstances and is discussed in section XII.H of this document) and proposed § 110.145(c) (which would establish requirements for corrective actions including, in certain circumstances, product testing if environmental monitoring for environmental pathogens that are reasonably likely to occur, or for appropriate indicator organisms for such pathogens detect the target organism).

Importantly, as described in section II.E.6 of this document, finished product testing is not meant to serve as the sole means on which to ensure the safety of the food. The safety of food is principally ensured by the effective implementation of validated preventive control measures throughout the food chain. Prevention of hazards in foods is much more effective than trying to differentiate safe from unsafe product using testing. Testing in a preventive controls system is intended to verify that control measures, including those related to suppliers and to environmental monitoring, are controlling the hazard.

Proposed § 110.150(d)(3) would not specify particular hazards for which to test. We expect facilities to consider a number of factors, as discussed in section XII.F.4.b of this document, when determining which product tests are appropriate to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. We request comment on whether we should specify hazards for which finished product testing must be conducted, and, if so, for which hazards and which products.

FDA notes that finished product testing is commonly done for microorganisms. As discussed above, an indicator organism is a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. Buchanan, 2000, JFP) . We request comment on the role of indicator organisms in verification testing and the circumstances under which there is benefit to testing for specific indicator organisms. If indicator organisms are appropriate for finished product testing in lieu of or in addition to pathogen testing, we ask for comment on when this would be the case. We request comment on the role of verification testing for chemical hazards, radiological hazards, and physical hazards.

FDA tentatively concludes that there are certain situations in which product testing is particularly useful as a verification measure. For example, finished product testing would be required if:

- The outcome of the hazard analysis conducted under proposed § 110.130 is that a biological hazard is reasonably likely occur in an ingredient and the preventive controls established and implemented under proposed § 110.135 do not include a process control that will significantly minimize the hazard. Examples include cut raw vegetables (such as celery, onions,

leafy greens and tomatoes) that may contain Salmonella or L. monocytogenes and that are intended to be used in RTE foods; nutrition bars in which dry ingredients (such as fruits, nuts, dried milk, soy proteins and chocolate) that may contain Salmonella are formed into a bar without a lethal step; and mixtures of shelled nuts in which the nuts may be contaminated with Salmonella.

- The outcome of the hazard analysis conducted under proposed § 110.130 is that a biological hazard is reasonably likely occur in an ingredient that is added during manufacturing after the stage that applies a process control to significantly minimize biological hazards. Examples include food (such as chips, nuts and cereals) in which untreated seasonings that may contain Salmonella are applied after a heat treatment and food (such as ice cream) to which nuts or other ingredients are added to an ice cream mix that has been pasteurized.

- The outcome of the hazard analysis conducted under proposed § 110.130 is that a biological hazard is reasonably likely occur as a result of handling of a product or exposure of a product to the environment after a process control that significantly minimizes a hazard such that a hazard could be introduced or re-introduced into the product. Examples include the manufacture of nut butters from roasted nuts (where contamination with Salmonella from the environment is a concern); the mixing of dried, treated spices and herbs (where contamination with Salmonella from the environment is a concern); the addition of herbs or vegetables to products such as cream cheese or cottage cheese (where contamination with L. monocytogenes from the environment is a concern); and the manual assembly of sandwiches (where contamination with S. aureus, L. monocytogenes, and enteric pathogens such as Salmonella is a concern).

Proposed § 110.150(d)(3) would not specify the frequency of finished product testing or the number or samples to be tested. The frequency of testing and number of samples tested will depend on factors such as whether ingredients that may contain a hazard have been tested (e.g., as part of a supplier verification program), the extent of the environmental monitoring program, and whether other programs established by the facility provide added assurance that the potential for hazards has been minimized. The number of samples tested should have a scientific basis. Sampling plans and their performance have been described in the literature (Ref. McClure and Lee 2011, ICMSF 2002 Book 7, Chapters 7 & 8) and are included in several Codex documents (Ref. CAC Lm, CAC NMW). As discussed in section II.E.6, in many instances samples can be composited for testing to reduce cost without loss of sensitivity. Even small numbers of composites tested over a year can be useful in detecting an out-of-control process. We discuss the considerations that impact verification testing in more detail in section II.E.6 of this document.

Proposed § 110.150(d)(3) would not require testing finished product for each lot (or some percentage of lots) of product to verify the effectiveness of a process (process verification testing). We discussed process verification testing in the final rule to establish our juice HACCP regulation (66 FR 6138 at 6174; January 19, 2001). Under part 120, most juice is directly treated with a process designed to reduce the target pathogen by 5-logs. In contrast, the treatment of citrus juices consists of cumulative steps, including surface treatments, to achieve a 5-log reduction of the target pathogen. The cumulative process that includes surface treatment provides less assurance that the system is operating as designed (more opportunity for errors) than the application of a 5-log reduction process directly to the juice. FDA concluded that E. coli is an appropriate indicator of loss of process control and, thus, as an additional verification

measure, established a requirement for end product testing of juices that receive surface treatments,(§ 120.25). This verification requires testing 20 ml of finished product for each 1000 gallons of juice, but not less often than every 5 days. FDA established that if two samples in a series of seven tests are positive for E coli, the control measures are deemed inadequate and specific corrective actions must be taken (§ 120.25(e)). This "moving window approach" to process verification testing, in which only the last specified number of tests (e.g., seven in our juice HACCP regulation) are used as the basis for verification of control, is also used by USDA FSIS for verification of meat and poultry HACCP programs at slaughter. Under 9 CFR 310.25(a), meat and poultry establishments test carcasses for E. coli using a moving window approach; under § 9 CFR 310.25(b), FSIS tests carcasses for Salmonella using a moving window approach. The test windows and limits established in 9 CFR 310.25(a) and (b) were based on commodity-specific baseline surveys. FDA is not proposing to require moving window process control verification testing because the commodity-specific baseline surveys currently do not exist for most FDA-regulated commodities; however, individual facilities could set up appropriate moving window process control verification testing based on establishing a plant-specific baseline.

Proposed § 110.150(d)(3) would not require periodic testing for trend analysis and statistical process control. As discussed in section II.E.6 of this document, such testing can provide information to assess whether processes (or the food safety system) are under control over time. However, such analysis provides benefits that go beyond the application of the test results to a single lot of product, as described in section II.E.6. At present, we lack sufficient information to assess whether the food industry is in a position to conduct periodic testing for trend analysis and statistical process control and on training costs that would be incurred to

establish such testing. We request comments on whether there would be a benefit in mandating such analysis. We also request comment on whether the final rule should require periodic testing for trend analysis and statistical process control.

FDA requests comment on our proposed requirements for finished product testing and whether we should specify particular situations or product types for which finished product testing would be required. We request comment on whether the frequency of testing should be specified and whether this should be dependent on the type of product. We also request comment on appropriate sampling plans for finished product testing and the impact of product testing requirements on small businesses. We request comment on whether testing requirements should differ based on the size of the operation.

d. Proposed § 110.150(d)(4)--Requirement for environmental monitoring. Section 418(f)(4) of the FD&C Act, in relevant part, requires that the owner, operator, or agent in charge of a facility verify that "the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means …."

Proposed § 110.150(d)(4) would require the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur, by collecting environmental samples at locations within the facility at a frequency of not less than monthly, and testing the samples to assess whether the preventive controls significantly minimize or prevent the potential for an environmental pathogen to contaminate food. (Later in this document (see section XII.G.6), we discuss proposed § 110.150(e)(1), which

would require that the owner, operator, or agent in charge establish and implement scientifically valid written procedures for environmental monitoring. Proposed 110.150(e)(1)(ii)(B) would require that the written procedures identify locations from which samples would be collected and the number of sites to be tested during routine environmental monitoring. Proposed 110.150(e)(1)(ii)(C) would require that the written procedures identify the test microorganism.

Environmental pathogens of concern

As discussed in section II.D.2.a of this document, any time a food is exposed to the environment, there is the potential for the food to be contaminated with an environmental pathogen. Examples of environmental pathogens that have contaminated foods (and, in particular, RTE foods) include Salmonella spp. and L. monocytogenes. Information on environmental monitoring can be found in the literature (Ref Tompkin, et al. 1999; CAC, 2007 lm; Chen et al. FPT3, 2009; CAC, 2008 PIF; ICMSF, Book 7 Chapter 11).

As discussed in section II.D.2.a of this document, as part of the work of the CGMP Working Group, FDA reviewed its food recall records for recall actions that were classified I or II for calendar years 2008 through 2009 to identify those recalls that took place because of problems that could have been prevented by CGMP-type preventive measures such as proper equipment sanitation, adequate training of employees, review of product labels for accuracy and agreement with the product formulation, and adequate preventive maintenance of equipment (Ref. summary of recall data 2008-2009). FDA also has analyzed data submitted to the RFR during the period September 8, 2009 – September 7, 2010 (Ref. 2011 RFR annual report). Our analysis of the 2008-2009 recall data shows that 25 percent of the recalls evaluated during 2008-2009 were due to microbiological contamination, with almost 8 percent due to contamination with Salmonella spp. and almost 10 percent due to contamination with L. monocytogenes. Our

analysis of the data submitted to the RFR showed that 37.6 percent of 229 primary RFR entries were due to the presence of Salmonella spp. (almost half of which were in low-moisture foods) and 33 percent of 229 primary RFR entries were due to the presence of L. monocytogenes. A robust environmental monitoring program for Salmonella spp. or L. monocytogenes can verify the effectiveness of sanitation controls designed to prevent these environmental pathogens from contaminating food-contact surfaces and food (Ref. Ref Tompkin, et al. 1999; Chen et al. FPT3, 2009). Detection of environmental pathogens (or indicator organisms) in the areas of the facility where foods (particularly RTE foods) are exposed and implementing corrective actions to eliminate the target organism (and the conditions that resulted in the presence of the environmental pathogen or indicator organism) can significantly minimize or prevent the presence of the environmental pathogen in food.

As discussed in sections XII.B.3 and XII.B.4.b of this document, proposed § 110.130(b) would require a hazard identification that must consider hazards that may occur naturally or may be unintentionally introduced; proposed § 110.130(c)(2) would require that the hazard evaluation include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a RTE food is exposed to the environment prior to packaging. The data from recalls and the RFR support a conclusion that Salmonella spp. is a hazard in low-moisture RTE food products (such as spices and seasonings, nuts and nut products, and seed products). When RTE foods such as these are exposed to the environment, FDA expects that most facilities producing such foods would identify Salmonella spp. as a known or reasonably foreseeable hazard under proposed § 110.130(b) and evaluate whether Salmonella spp. contamination from the environment is reasonably likely to occur in the facility under proposed § 110.130(c)(2). A robust environmental monitoring program for Salmonella spp. can verify the effectiveness of

sanitation controls designed to prevent Salmonella spp. from contaminating food-contact surfaces and food (Ref. Chen et al. FPT3 2009). Therefore, when Salmonella spp. from the environment is a hazard that is reasonably likely to occur in a food product, a facility would be required to implement an environmental monitoring program as would be established in proposed § 110.150(d)(4) as a verification measure directed to the implementation and effectiveness of sanitation controls for Salmonella spp.

Likewise, the data from recalls and the RFR support a conclusion that L. monocytogenes is a hazard in refrigerated or frozen RTE food products (such as dairy products, fresh-cut produce, prepared foods such as sandwiches, and frozen foods). When RTE foods such as these are exposed to the environment, FDA expects that most facilities producing such foods would identify L. monocytogenes as a potential hazard under proposed § 110.130(b) and evaluate whether L. monocytogenes is reasonably likely to occur in the facility under proposed § 110.130(c)(2). A robust environmental monitoring program for L. monocytogenes can verify the effectiveness of sanitation controls designed to prevent L. monocytogenes from contaminating food-contact surfaces and food (Ref. CAC 2007 Lm control; Tompkin, et al., 1999; Tompkin, 2002; Scott et al., 2005). Therefore, when L. monocytogenes from the environment is a hazard that is reasonably likely to occur in a food product, a facility would be required to implement an environmental monitoring program as would be established in proposed § 110.150(d)(4) as a verification measure directed to the implementation and effectiveness of sanitation controls for L. monocytogenes. Given the severity of illness caused by L. monocytogenes, a facility would be required to implement such an environmental monitoring program regardless of whether the applicable food product supports the growth of L. monocytogenes.

FDA considered specifying the pathogens (e.g., L. monocytogenes and Salmonella spp.) in the proposed regulation for which environmental monitoring programs would be required to be established in specific types of operations (e.g., those producing refrigerated or frozen RTE foods or low-moisture foods). However, there may be situations in the future in which environmental monitoring programs may prove beneficial in other operations and for other types of pathogens. Thus, we tentatively conclude that the best approach is to require facilities to assess in their hazard analysis whether a hazard from an environmental pathogen, as would be defined in proposed § 110.3, is reasonably likely to occur. If such hazards are reasonably likely to occur, the facility would be required under proposed § 110.130 to identify such pathogens in the written hazard analysis and conduct microbial testing in accordance with proposed § 110.150(d)(4) for environmental pathogens (e.g., Salmonella or L. monocytogenes) or appropriate indicator organisms as a verification activity.

FDA requests comment on whether there are other environmental pathogens of concern for which environmental testing may be appropriate.

Indicator organisms

Where L. monocytogenes has been identified as an environmental pathogen hazard reasonably likely to occur, facilities may choose to monitor the environment for Listeria spp. as an indicator organism for L. monocytogenes and take corrective action based on finding this target organism in the environment. The taking of corrective actions based on the presence of an appropriate indicator organism is protective of public health, since there will be times corrective actions are taken in the absence of the pathogen. As discussed in section II.E.5.c of this document, FDA's current thinking is that Listeria spp. may be an appropriate indicator organism for L. monocytogenes, because tests for Listeria spp. will detect multiple species of Listeria,

including L. monocytogenes. However, FDA's current thinking is that there are no currently available indicator organisms for Salmonella spp. Because there is no indicator organism for Salmonella, environmental monitoring programs will test for the pathogen itself. The lack of an indicator organism means that there will be no "warning" that conditions may be favorable to an environmental pathogen. The finding of Salmonella in the environment, in particular on a food-contact surface, should be rare in facilities that have implemented appropriate preventive control measures.

FDA requests comment on whether there are appropriate indicator organisms for any environmental pathogen other than L. monocytogenes. We further request comment on whether there is benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.

Collection of Samples

Proposed § 110.150(d)(4) would require collecting environmental samples at locations within the facility and testing the samples to assess whether preventive controls significantly minimize or prevent the potential for an environmental pathogen to contaminate food. Proposed § 110.150(d)(4) would require that the frequency of performing environmental monitoring be not less than monthly. FDA expects such environmental monitoring to be conducted with sufficient frequency to detect the environmental pathogen or appropriate indicator organism if present. We tentatively conclude that monthly sampling and testing is a minimum requirement, and that more frequent testing may be needed in certain operations. For example, weekly sampling of each packaging line has been recommended for Salmonella spp. in dry milk product facilities (Ref. Jarl and Arnold, 1982). The frequency of taking environmental samples is dependent on the type

of product, the process, and the risk to the consumer if the food becomes contaminated. For example, the frequency of monitoring for environmental pathogens:

- Should be greatest for foods that are likely to be consumed as RTE or consumed after a minimal treatment that may not adequately reduce the environmental pathogen;
- Should be greater for an environmental pathogen that is frequently introduced into a facility (e.g., L. monocytogenes which is ubiquitous in the environment and can be continually introduced into a facility from many routes, including ingredients, people and objects (Ref. Tompkin et al. 1999) than for an environmental pathogen that is less frequently introduced);
- Should be greater for refrigerated or frozen RTE food products that support growth of L. monocytogenes than for those that do not.
- Should be greater if there is greater risk of a negative impact on public health (e.g., the product is specifically intended for a sensitive population such as infants) than if there is a lesser risk of a negative impact on public health;
- Should be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment; and
- Should increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction (Refs. CAC, 2007 Lm; Tompkin, 2002; Chen et al. FPT3 2009; Jarl and Arnold, 1982).

The frequency of taking environmental samples will vary depending on existing data on the presence of the environmental pathogen of concern in the environment where foods are exposed to the environment. In the absence of information, data should be generated to assist in

determining the frequency of monitoring (Refs. CAC, 2007 Lm; Chen et al. FPT3 2009). We request comment on whether the minimum frequency of at least monthly for environmental monitoring is adequate to assess whether the preventive controls significantly minimize or prevent the environmental pathogens that are reasonably likely to occur.

Testing collected environmental samples

Proposed § 110.150(d)(4) would require that the environmental monitoring test the collected environmental samples for the environmental pathogens or appropriate indicator organisms. (As discussed in section XII.G.6 of this document, proposed § 110.150(e)(1)(ii)(C) would require that the test microorganism(s) be identified in the verification procedures.) As discussed in section II.E.3 of this document, the environmental pathogen of concern will depend on the type of product, the process, and the risk to consumers if the food becomes contaminated.

Although not required by proposed § 110.150(d)(4), facilities may find it useful to routinely conduct molecular typing such as pulsed-field gel electrophoresis (PFGE), ribotyping or polymerase chain reaction (PCR) analysis when environmental pathogens or indicator organisms are detected. This type of testing can identify specific strains that may be persistent in the environment (Proudy et al. 2008; Mullane et al., 2007; Carpentier and Cerf, 2011). As discussed in section II.E of this document, molecular strain typing can identify strains that have the same molecular "fingerprint," which may suggest a common source or a harborage site, and can be useful in investigative sampling.

Records of environmental monitoring

As discussed in the next section of this document, proposed § 110.150(d)(5) would require that records of environmental monitoring and associated corrective actions be reviewed. As discussed in sections XII.F.4.a and XII.F.4.c of this document, when environmental

monitoring detects an environmental pathogen or appropriate indicator organism, proposed § 110.145(c) would require that corrective actions be taken and proposed § 110.145(d) would require that all corrective actions taken in accordance with proposed § 110.145 be documented in records that are subject to verification in accordance with § 110.150(c) and records review in accordance with § 110.150(d)(5).

The review of environmental monitoring records that would be required by proposed § 110.150(d)(5) would be facilitated by organizing the records to promote efficient and effective review on an ongoing basis to determine if there are trends that suggest undetected problems (Ref. ICMSF 7, Ch 11; Tompkin, 2002; Codex 2007, LM). For example, the detection of an environmental pathogen in the same location on a piece of equipment, even though separated in time (e.g., weeks), may indicate a problem that warrants investigation. Likewise, the detection of an environmental pathogen in the same area of the facility on multiple occasions may indicate the need for investigation of the source. Thus, trends may allow the early identification of developing problems before food becomes contaminated. As with the proposed requirement for product testing (proposed § 110.150(d)(3)), FDA is not proposing to require performance of a trend analysis of the environmental monitoring data. (See the discussion of our reasons for not proposing to require trend analysis for product testing data in section XII.G.5.c of this document.) We request comment on whether we should require this type of analysis – e.g., as part of the record review in proposed § 110.150(d)(5).

As discussed in section XII.G.8 of this document, proposed § 110.150(g) would require that the verification procedures be written. Thus, information that proposed § 110.150(e)(1)(ii) would require to be in the verification procedures (i.e., the number and location of the sampling

sites and the test microorganism) would be written. Keeping this information in written form would promote consistency in monitoring for environmental pathogens.

f. Proposed § 110.150(d)(5)--Records review

Proposed § 110.150(d)(5) would require a review of specific records related to monitoring, corrective actions and other verification activities within specified time frames, by a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. Proposed § 110.150(d)(5)(i) would require review of the monitoring and corrective action records within a week after the records are made. Proposed § 110.150(d)(5)(ii) would require review of the records related to consumer, customer, and other complaints, calibration, finished product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made. (As discussed in section XII.J.2 of this document, proposed § 110.175 would list the records that facilities must establish and maintain, including records that document the monitoring of preventive controls as required by § 110.140(c), corrective actions as required by § 110.140(d), and verification activities as required by § 110.150(f)).

Proposed § 110.150(d)(5) would implement section 418(f) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines provide examples of verification activities, including review of the HACCP plan for completeness, review of monitoring records, and review of records for deviations and corrective actions (Ref. NACMCF, 1998). The examples of verification activities in the Codex HACCP Annex include a review of the HACCP plan and its records (Ref. CAC, 2003). Our HACCP

regulations for seafood (§ 123.8(a)(3)(i) through (iii)) and juice (§ 120.11(a)(1)(iv)(A) through (C)) require a review of the records that document the monitoring of critical control points, the taking of corrective actions, the calibrating of any process control instruments used at critical control points, and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The FSIS HACCP regulation for meat and poultry requires a review of all required records (9 CFR 417(a)(2)(iii)).

Proposed § 110.150(d)(5) would establish that the purpose of the review of records would be to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decision were made about corrective actions. We tentatively conclude that review of the records required by proposed § 110.150(d)(5)(i) and (ii) would accomplish these purposes. Reviewing monitoring records can reveal whether they contain information on all the parameters that were to be monitored to determine whether a process is delivered in accordance with the food safety plan. For example, if both the size of food particles to be acidified and the pH of the food after acidification are critical to the safety of the food, review of the monitoring records would demonstrate whether both particle size and pH were monitored and whether the values were within specified parameter values. Reviewing monitoring records can reveal whether a process followed the procedures specified in the facility's food safety plan (e.g., if the monitoring records show the pH of every other batch of an acidified food when the plan specified the measurement of every batch). Review of monitoring records also can reveal whether any information is missing – e.g., a designated lot number – so that the missing information can be quickly identified and added to the record if necessary.

If the review of the records reveals that the records do not contain all information specified by the food safety plan, or that the procedure in the food safety plan was not followed, the facility will not be able to conclude that its preventive controls were implemented in accordance with its food safety plan for those activities. Because the food safety plan establishes the procedures needed to ensure preventive controls are effective, if the records review indicates that the plan is not being followed, e.g., the records are missing critical information or the activities were not performed as specified in the plan, the facility will not be able to conclude its preventive controls were effective. For example, if the records show that food particle size is not being determined or that the particles are too large, acidification of all parts of the particle may not occur rapidly enough to ensure control of pathogens such as C. botulinum. If the plan requires determination of the pH of each batch of product but the records do not show that the pH was measured on all batches, the facility cannot be sure that the pH of those batches is correct, again posing a potential risk from C. botulinum. As a result, the facility would not be able to verify that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

Review of records can also reveal whether appropriate decisions were made about corrective actions. The review should determine whether all the corrective action procedures required by proposed § 110.145(a)(3) have been followed, e.g., that actions are taken to prevent recurrence of the problem, that affected food has been evaluated for safety, and that affected food is prevented from entering commerce unless it can be determined that the food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. For example, a food safety plan may require that each package of product pass through a properly functioning metal detector and that the operator determine every two hours

whether metal test pieces of a specified type and size are rejected when passed through the metal detector. If one of the test pieces was not rejected but production continued until a supervisor doing a verification check noted the problem, then corrective actions should have been taken and a corrective action record produced. A review of the corrective action records should reveal that all packages of product that passed through the metal detector since the last test showing the metal detector was functioning appropriately were held and passed through a functioning metal detector before being released into commerce. The records should also show that the metal detector was adjusted to reject the metal test pieces before it was used again to check product during production.

Proposed §110.150(d)(5) would require that the review of records be performed by a qualified individual (see the discussion in section XII.I of this document regarding the activities that must be performed by a qualified individual as would be established in proposed § 110.155). The review of records is critical to assessing the facility's application of the preventive controls system and, thus, is fundamental to ensuring its successful operation. Our HACCP regulations for seafood (§ 123.8(a)(3)) and juice (§ 120.11(a)(1)(iv)) require that the review of records be conducted by an individual who has successfully completed training in the application of HACCP principles to the processing of the applicable food product at least equivalent to that received under standardized curriculum recognized as adequate by FDA, or who is otherwise qualified through job experience to perform this function. The FSIS HACCP regulation for meat and poultry requires that records be reviewed, "preferably" by an individual trained by successfully completing a course of instruction in the application of the HACCP principles to meat or poultry product processing (9 CFR 417.5(c) and 417.7(b)). The NACMCF HACCP guidelines stress the role of qualified experts in the development and evaluation of a HACCP

plan, and recommend periodic comprehensive verification of the HACCP system by an unbiased, independent authority, internal or external to the food operation, including review of appropriate records from operation of the plan (Ref. NACMCF). The Codex HACCP Annex does not specifically address the need for a qualified individual to review the records other than to recommend that where certain verification activities cannot be performed in-house, verification be performed on behalf of the business by external experts or qualified third parties (Ref. Codex). Under proposed § 110.150(d)(5), the review of records could be performed by or overseen by a qualified individual.

Proposed § 110.150(d)(5)(i) would require review of the monitoring and corrective action records within a week after the records are made. Although proposed § 110.150(d)(5)(i) would establish a more frequent review of these records than recommended in the NACMCF guidelines (which recommend monthly verification of monitoring records and corrective action records), it is consistent with our HACCP regulations for seafood (§ 123.8(a)(3)(i) and (ii)) and juice (§ 120.11(a)(1)(iv)(A) and (B)), which require that the review of monitoring records and corrective action records occur within one week of the day that the records are made. Even for shelf-stable foods (e.g., low-acid canned foods and acidified foods) our experience has demonstrated that review of these kinds of records is a critical verification tool (60 FR 65096 at 65133). The FSIS HACCP regulation for meat and poultry requires records to be reviewed prior to shipping product (9 CFR 417.5(c). As discussed in the seafood HACCP final rule (60 FR 65096 at 65132), review of records needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of a “feedback loop,” with information coming out of the record review process in such a timely manner that it can have

impact on the production of subsequent lots of the product. If a problem with product is discovered during a review of records, all product since the last review could be affected. Although verification prior to shipment provides a valuable added assurance, FDA explained in the preamble to the seafood HACCP final rule (60 FR 65096 at 65132) that with highly perishable products this is not always possible and that a weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records.

Proposed § 110.150(d)(5)(ii) would require review of the records related to consumer, customer, or other complaints, calibration, finished product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made. The frequency of these record reviews will be variable and will depend, in part, on the frequency with which those activities occur, which will be established in the food safety plan. For example, as discussed in section XII.G.5.d of this document environmental monitoring may be conducted monthly in some facilities and weekly in others. Because of the importance of environmental monitoring in identifying situations in which contamination of food from the environment may occur, it would be reasonable to review the results of the tests on the day that they are received. As discussed in section XII.G.5.c of this document, the frequency of finished product verification testing would depend on the food and the hazards reasonably likely to occur in the food. Similar to the results for environmental monitoring, it would be reasonable to review the results of the tests on the day that they are received. The review of calibration records will depend in part on the frequency with which calibrations occur, which will be established in the food safety plan. If calibrations occur daily, it would be reasonable to review these records weekly. Where several instruments are calibrated each month, a monthly review of all the

calibrations would be reasonable. The review of consumer, customer or other complaints will depend on the frequency with which they are received. Consequently, FDA tentatively concludes that setting a specific frequency for review of these records is not warranted. Proposed § 110.150(d)(5)(ii) is, in relevant part, consistent with our HACCP regulations for seafood (§ 123.8(a)(3)(iii)) and juice (§ 120.11(a)(1)(iv)(C)), which require that the review of records of calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities occur within a reasonable time after the records are made.

As noted previously, proposed § 110.150(d)(5) would require a review of records in part to determine whether the preventive controls are effective. A review should determine whether monitoring and corrective actions have been done in accordance with the food safety plan, whether any complaints received indicate a food safety problem, whether the instruments used in monitoring and verification were properly calibrated, whether finished product testing indicated a loss of process control, whether environmental monitoring results indicated that preventive controls minimized or prevented environmental pathogens from contaminating food, and whether supplier verification activities indicated that suppliers are minimizing hazards in raw materials and ingredients. If all the above food safety activities appropriate to the facility have been conducted in accordance with the plan and this is reflected in the records, the facility thus verifies the preventive controls are effective, i.e., that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

6. Proposed § 110.150(e)--Written Procedures for Verification Activities

Proposed § 110.150(e)(1)(i) and (ii) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures to conduct finished product testing (proposed § 110.150(e)(1)(i)) and environmental monitoring (proposed § 110.150(e)(1)(ii)). We are proposing to require that written procedures be established and implemented for finished product testing and environmental monitoring because these procedures are essential to understanding whether the finished product testing and environmental monitoring are adequate to verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. Proposed § 110.150(e)(1)(iii) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments. We are proposing to require written procedures for the frequency of calibration because the frequency of calibration will vary depending on the instrument and the process or verification activity that it pertains to.

We are not proposing to require that written procedures be developed for all verification procedures. In some instances the records of verification activities provide the information needed to understand how the verification activity has been carried out and to assess whether the verification activity is adequately demonstrating that the preventive controls are effective in significantly minimizing or preventing the hazards reasonably likely to occur. For example, we are not proposing to require written procedures for validation, verification of monitoring and corrective actions, review of consumer, customer or other complaints, or calibration of process monitoring instruments and verification instruments (other than for the frequency of calibration). Validation involves a variety of procedures, including evaluation of scientific and technical

information and conducting laboratory and in-plant studies that generally do not follow a standardized protocol or approach. Records of monitoring and corrective actions provide the information needed to understand how the verification activity was carried out. Likewise, conducting and documenting the review of consumer, customer or other complaints provides the needed verification information and having procedures for how the review is conducted provides no additional benefit. In many instances the calibration of process monitoring instruments and verification instruments will be done by contract with other entities and the facility would not have access to the procedures used; having instruments calibrated and documenting the calibration provides the necessary assurance that such instruments will be accurate. However, the frequency of calibration must be specified to ensure that the instruments are calibrated on a schedule appropriate to the instrument and the process it controls.

We request comment on whether we should require written procedures for verification activities other than for finished product testing, environmental monitoring, and the frequency of calibration.

Section 418(f) of the FD&C Act establishes certain requirements for verification, and section 418(h) of the FD&C Act requires that the procedures used by the facility to comply with the requirements of section 418 be included in the written plan. Our HACCP regulations for seafood and juice both require that the HACCP plan be written (§§ 123.6(b) and 120.8(a), respectively) and that procedures for verification be included in the written HACCP plan (§§ 123.6(c)(6) and 120.8(b)(6), respectively). The FSIS HACCP regulation for meat and poultry requires that the establishment maintain a record of the written HACCP plan, including, in relevant part, documents supporting the verification procedures selected and the frequency of those procedures (9 CFR 417.5(a)(2)). Thus, requiring verification procedures to be written

implements the requirements in section 418 of the FD&C Act and is consistent with the requirements in HACCP regulations for seafood, juice, and meat/poultry.

Proposed § 110.150(e)(1)(i) would require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency. We discussed the term "scientifically valid" with respect to testing in section II.E.2. Consistent with our previous discussion of the term "scientifically valid" in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements (68 FR 12157 at 12198; March 13, 2003), we use the term "scientifically valid" to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12157 at 12198).

Proposed § 110.150(e)(1)(ii)(A) would require that procedures for environmental monitoring be scientifically valid. We discuss the meaning of "scientifically valid" immediately above. Proposed § 110.150(e)(1)(ii)(B) would require that procedures for environmental monitoring identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. Proposed § 110.150(e)(1)(ii)(B) would further require that the number and location of sampling sites be sufficient to determine whether preventive controls are effective and include appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces within the manufacturing, processing and packaging environment.

Under proposed § 110.150(d)(4), the purpose of environmental monitoring is to verify the implementation and effectiveness of preventive (i.e., sanitation) controls for environmental

pathogens to assess whether the preventive controls significantly minimize or prevent the potential for environmental pathogens to contaminate food. The monitoring must be designed to find environmental pathogens that remain in the facility after routine cleaning and sanitizing procedures in order to prevent contamination of product that could lead to illness. To accomplish this purpose, there must be a scientific basis for the locations selected for sampling, the number of samples taken, the frequency of sampling, the sampling procedures used and the test methodology. The sampling must be biased – i.e., the locations to be tested must be those in which the environmental pathogens can enter the environment where the food is exposed and those areas where harborage of the pathogen is likely (Ref. ICMSF 7 Ch. 11; Jarl and Arnold, 1982). These may differ for the various organisms of concern and the type of processing facility.

One approach to defining sampling locations is to divide the facility into zones based on the risk with respect to contamination of product. A common industry practice is to use four zones (Ref. ICMSF 7, Ch. 11; Chen et al., FPT3, 2009):

- Zone 1 consists of food contact surfaces;
- Zone 2 consists of non-food contact surfaces in close proximity to food and food contact surfaces;
- Zone 3 consists of more remote non-food contact surfaces that are in the process area and could lead to contamination of zones 1 and 2; and
- Zone 4 consists of non-food contact surfaces, outside of the processing area, from which environmental pathogens can be introduced into the processing environment.

Generally the number of samples and frequency of testing is higher in zones 1 and 2 because of the greater risk of food contamination if the environmental pathogen is detected in these zones. Information on appropriate locations for sampling within these zones can be found

in the literature (Ref. Tompkin et al. 1999; Chen et al. FPT3 2009; Nelson, 1990; Pritchard et al. 1995; Gabis et al., 1989). Facilities should become familiar with locations in which environmental pathogens have been found in other facilities and use this information in selecting sites to sample.

Examples of appropriate food-contact surfaces that would be monitored under proposed §§ 110.150(d)(4) and 110.150(e)(1)(ii)(B) include hoppers, bins, conveyors, tables, slicers, blenders, knives and scrapers. Testing food-contact surfaces for Listeria spp. is a commonly recommended verification measure for facilities producing refrigerated RTE foods (Refs. CAC lm 2007; Tompkin et al, 1999; ICMSF Book 7 Ch 11). Although some literature suggests that routine environmental monitoring for Salmonella in low-moisture food environments would not normally target food-contact surfaces (Chen et al FPT3, 2009), the data (discussed throughout this document) available from investigations of food facilities following outbreaks, recalls, or reports to the RFR warrant including food-contact surfaces in a routine environmental testing program for Salmonella. However, a routine environmental monitoring program for Salmonella may not contain the same level of food-contact surface testing (including the frequency of testing and number of samples collected) as a routine environmental monitoring program for Listeria, because the same benefits may not be achieved. For example:

- L. monocytogenes is usually the environmental pathogen of concern for most wet RTE food production environments. It is important to sample areas where the organisms are likely to be present in relatively high numbers. L. monocytogenes frequently establishes itself in a harborage site on equipment and grows (increases in number) there, where both food and moisture are available. L. monocytogenes organisms work their way out of the harborage site during production and contaminate food.

- Salmonella is usually the environmental pathogen of concern for most dry (e.g., low-moisture) RTE food environments. Equipment used in the production of dry products is rarely wet and, thus, there is no moisture to allow growth of Salmonella. As a result, Salmonella harborage sites are less likely to be found on equipment and are more likely to be found in the environment in locations where food particles lodge and escape a dry cleaning process. When these locations get wet, the Salmonella grows and contaminates other areas of the facility, eventually contaminating food-contact surfaces and food. Nevertheless, sampling food-contact surfaces (e.g., filler hoppers, conveyors, valves, sifter cuffs) can be useful, as can sampling residues such as sifter tailings and product scrapings.

Examples of appropriate non-food-contact surfaces that would be monitored under proposed § 110.150(e)(1)(ii)(B) include exteriors of equipment, equipment supports, control panels, door handles, floors, drains, refrigeration units, ducts, overhead structures, cleaning tools, motor housings and vacuum canisters. Standing water in production areas and areas that have become wet and then have dried are also appropriate places to monitor. Testing non-food-contact surfaces for L. monocytogenes or Listeria spp. is a commonly recommended verification measure for facilities producing refrigerated or frozen RTE foods (Refs. CAC Lm 2007; Tompkin et al, 1999; ICMSF Book 7 Ch 11) and can detect L. monocytogenes that is brought into the plant by people or objects. Corrective actions can prevent transferring the organisms to a food-contact surface (where they can contaminate food) or from establishing a harborage that can serve as a source of contamination. Recommendations for routine environmental monitoring for Salmonella in low moisture food environments generally target non-food-contact surfaces because equipment used in the production of low-moisture foods where Salmonella is the environmental pathogen of concern does not have the moisture to allow Salmonella to grow and,

thus, sampling non-food-contact surfaces for Salmonella may be more effective in finding the organism than sampling food-contact surfaces. Scrapings or residues that accumulate under or above equipment are more useful samples than sponges or swabs of food-contact surfaces (Ref. ICMSF Book 8 Ch 17).

Proposed § 110.150(e)(1)(ii)(C)) would require that the verification procedures identify the test microorganism(s). As discussed in section II.E.3 of this document, the environmental pathogen of concern will depend on the type of product, the process, and the risk to consumers if the food becomes contaminated. As discussed in section II.E.3 of this document, FDA's current thinking is that Listeria spp. may be an appropriate indicator organism for L. monocytogenes, because tests for Listeria spp. will detect multiple species of Listeria, including L. monocytogenes. However, FDA's current thinking is that there are no currently available indicator organisms for Salmonella spp. Because there is no indicator organism for Salmonella, the test organism would be the pathogen itself.

Proposed § 110.150(e)(2) would require that written procedures identify or include the analytical methods used to test finished product or environmental samples. As discussed earlier in this section, proposed §§ 110.150(e)(1)(i) and 110.150(e)(1)(ii)(A) would require that procedures for finished product testing and for environmental monitoring be scientifically valid. Scientific methods are frequently revised to improve accuracy, sensitivity, and applicability to specific uses. Facilities will often send samples to commercial testing laboratories for testing, and such laboratories would be expected to use the most current, applicable methods. Facilities that conduct in-house testing would also be expected to use the most current, applicable methods. In some cases there may be multiple, scientifically-valid analytical methods that are applicable and the analytical methods used may differ among laboratories. Because there may be multiple,

valid analytical methods available and because a facility may send samples to different laboratories, we are providing an option for the written procedures for finished product testing or for environmental monitoring to simply identify the analytical procedures rather than to include them.

7. Proposed § 110.150(f)--Reanalysis

a. Proposed § 110.150(f)(1)--Reanalysis on the initiative of the owner, operator, or agent in charge of a facility. Proposed § 110.150(f)(1)(i) would require that the owner, operator, or agent in charge of a facility conduct a reanalysis of the food safety plan:

- At least once every three years (proposed § 110.150(f)(1)(i)(A));
- Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard (proposed § 110.150(f)(1)(i)(B));
- Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food (proposed § 110.150(f)(1)(i)(C));
- Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established (proposed § 110.150(f)(1)(i)(D)); and
- Whenever a preventive control is found to be ineffective (proposed § 110.150(f)(1)(i)(E)).

For example, if a facility that bottles beverages develops a food safety plan for its products packaged in plastic bottles and subsequently introduces a glass bottling line, the facility would be required to reanalyze its food safety plan because the glass bottling line creates a reasonable potential for a new hazard, i.e., glass particles. Similarly, if a facility that conducts

dry roasting operations for nuts makes design changes to its roasters to increase product throughput, the facility would be required to reanalyze its food safety plan because a design change to equipment that is used to control a hazard that is reasonably likely to occur would be a significant change in the activities conducted at the facility.

The owner, operator or agent in charge of a facility may become aware of a problem due to the finding of a hazard in a food as the result of testing by a regulatory agency (Federal, State, tribal, or foreign government) that would require an analysis of the food safety plan to ensure the hazard is significantly minimized or prevented by appropriate preventive controls. In addition, new hazards can emerge – e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health agencies. For example, L. monocytogenes was not recognized as a food safety hazard until a series of outbreaks of foodborne illness associated with the consumption of foods such as coleslaw and fresh soft cheese in the early 1980s (Ref. Introduction of the FDA/FSIS Listeria risk assessment). As another example, in 2006-2007 there was an outbreak of salmonellosis due to contamination of peanut butter with Salmonella Tennessee (Ref. CDC, 2007 MMWR 56:521-524). This was the first outbreak of foodborne illness caused by peanut butter consumption in the U.S. and it demonstrated the need for manufacturers to address the hazard of Salmonella in this product. Information about outbreaks and ensuing product recalls is widely disseminated, including on FDA's Web site, and modern communication tools make it possible for the owner, operator, or agent in charge of a facility to receive such information automatically. For additional discussion related to the proposed requirement that the owner, operator, or agent in charge of a facility conduct a reanalysis whenever such owner, operator or agent becomes aware of new information about potential hazards associated with the food, see the discussion in section XII.G.6 of this document of

proposed § 110.150(f)(3), which would provide that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

As noted in section XII.F.3, proposed § 110.145(b)(2) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 110.150(f) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented or is found to be ineffective, and a specific corrective action has not been established. If the owner, operator, or agent in charge of a facility has not identified a specific failure as a foreseeable occurrence, the deviation may be the result of a system-wide problem that is not being properly addressed by the food safety plan (e.g., ineffective preventive controls). Thus, an unforeseen failure for which a corrective action was not identified may indicate an ineffective preventive control, and a reanalysis of the food safety plan is warranted. Similarly, when information arises indicating that the preventive control has not been effective in significantly minimizing or preventing a hazard from occurring, a reanalysis must be conducted to determine if the food safety plan should be modified to ensure that the preventive controls implemented are adequate to significantly minimize or prevent a hazard identified as reasonably likely to occur.

Proposed § 110.150(f)(1)(i) would implement sections 418(f)(5) and 418(i) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, the Codex validation guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. FDA notes that the terminology used in relation to the concept of "reanalysis" varies in the regulations and guidelines (e.g., "subsequent validation," "re-validation," "reassessment of the hazard analysis," and "validation" of the HACCP plan). The NACMCF HACCP guidelines include validation of a HACCP plan to ensure that the plan is scientifically and technically sound

and that all hazards have been identified as an important verification activity, and advise a subsequent validation under circumstances such as an unexplained system failure; a significant product, process or packaging change; or the recognition of new hazards (Ref. NACMCF, 1998). The NACMCF HACCP guidelines also discuss the need for a periodic comprehensive verification of the HACCP system, including a technical evaluation of the hazard analysis and each element of the HACCP plan, independent of other verification procedures to ensure that the HACCP plan is resulting in control of the hazards. If the results of the comprehensive verification identify deficiencies, the HACCP team modifies the HACCP plan as necessary (Ref. NACMCF 1998). Likewise, the Codex HACCP Annex recommends that the HACCP application be reviewed and necessary changes made when any modification is made in the product, process, or any step (Ref. Codex HACCP, 2003). The Codex guidelines on validation provide examples of situations that could lead to the need to re-validate a control measure or combination of control measures, e.g., system failure, process changes, and new scientific or regulatory information (Ref. Codex Validation, 2008).

Our HACCP regulation for seafood requires a reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way, or at least annually(§ 123.8(a)(1)). Our HACCP regulation for juice requires an initial validation within 12 months after implementation and at least annually or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way (§ 120.11(b)). The FSIS HACCP regulation for meat and poultry requires that every establishment reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)).

In addition, Federal HACCP regulations for seafood, juice, and meat and poultry require a reassessment of the hazard analysis when a processor does not have a HACCP plan (because the hazard analysis revealed no hazards reasonably likely to occur) and there are changes that could affect whether a food safety hazard now exists (§§ 123.8(c) and 120.11(c), and 9 CFR 417.4(a)(4) for seafood, juice, and meat and poultry, respectively). Each of these HACCP regulations provides examples of changes that may be considered to reasonably affect whether a food safety hazard now exists and, thus, require reassessment of the adequacy of the hazard analysis (§§ 123.8(a)(1) and 120.11(b) and 9 CFR 417.4(a)(4)). Such changes include changes in raw materials or the source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; the intended use or consumers of the finished product; and slaughter or processing methods or systems for meat or poultry.

The requirement in proposed § 110.150(f)(1)(i)(A) that the periodic reanalysis of the food safety plan occur at least once every 3 years would be different from the current requirement in our HACCP regulations for seafood and juice and in the FSIS HACCP regulation for meat and poultry for reassessment (validation) of the adequacy of the HACCP plan to be done "at least annually" (§§ 123.8(a)(1) and 120.11(b) and 9 CFR 417.4(a)(3), respectively). The three-year minimum frequency for the periodic reanalysis of the food safety plan is explicitly required by section 418(i) of the FD&C Act. We tentatively conclude that, as a practical matter, the proposed requirement for reanalysis whenever a significant change is made in the activities conducted at a facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard makes it likely that reanalysis would occur

more frequently than every three years because such changes are likely to occur more frequently than every three years.

Proposed § 110.150(f)(1)(ii) would require that the owner, operator, or agent in charge of a facility complete the required reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first six weeks of production. The purpose of the reanalysis is to identify the need for, and implement, preventive controls in light of a reasonable potential for a new hazard, or a significant increase in a previously identified hazard, that is reasonably likely to occur. It follows that the preventive controls must be in place before making the change that creates the potential for a new hazard or a significant increase in a previously identified hazard. As with initial validation in proposed § 110.150(a)(1)(i), we are proposing to provide the first six weeks of production, when necessary, to implement any additional preventive controls to allow facilities to methodically collect data and information during production to ensure the needed change can be implemented in the facility. Proposed § 110.150(f)(1)(ii) would implement section 418(i) of the FD&C Act. Although proposed § 110.150(f)(1)(ii) has no explicit counterpart in the NACMCF HACCP guidelines, the Codex HACCP guidelines, or Federal HACCP regulations for seafood, juice, and meat and poultry, it is consistent with the importance placed on reanalysis of the HACCP plans in those guidelines and regulations and with requirements to modify the HACCP plan immediately whenever validation reveals the need to do so, as discussed immediately below.

Proposed § 110.150(f)(1)(iii) would require that the owner, operator, or agent in charge of a facility revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. Proposed

§ 110.150(f)(1)(iii) would implement section 418(i) of the FD&C Act, which requires that the written plan be revised "if … a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed." As discussed in section XII.B.2.b of this document, the written hazard analysis is required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur. It is also important to document that a reanalysis has been conducted even if no change has been made, as required by section 418(i) of the FD&C Act. Such documentation demonstrates that a facility has considered all relevant information on the safety of the products being produced, including new information that has become available since the last analysis, and determined that current procedures for implementing preventive controls are adequate to significantly minimize or prevent hazards that are reasonably likely to occur. Our HACCP regulations for juice and seafood, and the FSIS regulation for meat and poultry, require that the HACCP plan be modified immediately whenever a validation/reassessment reveals that the plan is no longer adequate to fully meet the requirements of the HACCP regulations (§§ 120.11(b) and 123.8(a)(1) and 9 CFR 417.4(a)(3) for juice, seafood, and meat/poultry, respectively), although they do not explicitly require documentation of the basis for the conclusion that no additional or revised preventive controls are needed. Although proposed § 110.150(f)(1)(iii) has no explicit counterpart in the NACMCF HACCP guidelines or the Codex HACCP guidelines, it is consistent with the importance placed on reanalysis of the HACCP plans in those guidelines and regulations, and with the written nature of the HACCP plan. The Codex validation guidelines indicate that if a system failure for which a process deviation cause cannot be identified occurs, re-validation may be needed (i.e., reanalysis is needed whenever a preventive control is found to be ineffective) (Ref. Codex Validation 2008).

b. Proposed § 110.150(f)(2)--Requirement for a qualified individual. Proposed § 110.150(f)(2) would require that the reanalysis be performed by a qualified individual. Proposed § 110.150(f)(2) is consistent with proposed §§ 110.126(c) which would require that the food safety plan be developed by a qualified individual. We tentatively conclude that the same qualifications are needed whether initially conducting a hazard analysis and establishing a food safety plan, or reanalyzing a hazard analysis and plan. Under proposed § 110.150(f)(2), the reanalysis could be performed by or overseen by a qualified individual.

c. Proposed § 110.150(f)(3)--Reanalysis on the initiative of FDA. Proposed § 110.150(f)(3) establishes that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding. This authority will be delegated to the Commissioner of Food and Drugs. Proposed § 110.150(f)(2) would implement section 418(i) of the FD&C Act, which provides in relevant part that "[t]he Secretary may require a reanalysis . . . to respond to new hazards and developments in scientific understanding …." As discussed in section XII.G.7.a of this document, new hazards can emerge – e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health agencies. In addition, new developments can occur in the scientific understanding of existing or potential hazards – e.g., if scientists and food safety regulatory agencies develop a better understanding of the causes of these events. For example, the outbreak from Salmonella Tennessee in peanut butter resulted in a greater understanding of the risks posed by environmental contamination and the importance of control of water in facilities producing low-moisture foods (Ref. Scott et al. 2009 FPT1; Chen et al. 2009 FPT2). Information submitted to the RFR – which is a relatively recent addition to the regulatory framework for food safety – has the potential to identify new hazards or routes of contamination even before outbreaks occur.

For example, the January 2011 RFR Annual Report (Ref. 2011 RFR Annual Report) identified a high number of primary reports involving Salmonella in spices and seasonings, and we have requested comments and scientific data and information to assist us in our plans to conduct a risk profile for pathogens and filth in spices (75 FR 20615, April 20, 2010). The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and potential new interventions to reduce or prevent illnesses from contaminated spices.

8. Proposed § 110.150(g)--Requirement for Records for Verification

Proposed § 110.150(g) would require that all verification activities taken in accordance with this section be documented in records. Proposed § 110.150(g) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan and includes verification records as an example of HACCP records in an appendix (Ref. NACMCF 1998). The Codex HACCP Annex gives records of verification procedures performed as an example of records (Ref. Codex 2003). Our HACCP regulations for seafood and juice require that recordkeeping include the calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing (§§123.8(d) and 120.11(a)(2), respectively). The FSIS HACCP regulation for meat and poultry requires records documenting the calibration of process-monitoring instruments, as well as verification procedures and results.

H. Proposed § 110.152--Supplier Approval and Verification Program

1. Requirements of Section 418 of the FD&C Act

Section 418(c) of the FD&C Act specifies, in relevant part, that "[t]he owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances" that:

- "(1) hazards identified in the hazard analysis conducted under [section 418(b)(1) of the FD&C Act] will be significantly minimized or prevented;" and
- "(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under [section 402 of the FD&C Act] or misbranded under [section 403(w) of the FD&C Act]."

Section 418(g) of the FD&C Act specifies that "[t]he owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under [section 418(c) of the FD&C Act], instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under [section 418(f)(4) of the FD&C Act], instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions." Section 418(o)(3) of the FD&C Act defines preventive controls and, as discussed in section X.C.4 of this document, proposed § 110.3 would include the statutory definition in part 110. Under section 418(o)(3)(G) of the FD&C Act, the procedures, practices, and processes described in the definition of preventive controls may include "supplier verification activities that relate to the safety of food."

2. Proposed § 110.152(a)--Requirement for a Supplier Approval and Verification Program

a. Proposed § 110.152(a)(1)--Requirement for establishing and implementing a supplier approval and verification program. Proposed § 110.152(a)(1) would require that, except as provided by proposed § 110.152(a)(6), the owner, operator, or agent in charge of a receiving facility establish and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur. Under proposed § 110.3, a receiving facility would mean, for an article of food, a facility that is subject to part 110, subpart C and that manufactures/processes a raw material or ingredient that it receives from a supplier. A receiving facility will generally use multiple raw materials and ingredients in the manufacturing/processing of a food. Limiting the program to raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur would, as with other preventive controls established in proposed § 110.135, be a risk-based approach that would be consistent with sections 418(c)(1) and (3) of the FD&C Act.

The proposed requirement would not apply to raw materials or ingredients for which no hazard has been identified as reasonably likely to occur. For example, a receiving facility manufacturing RTE salads that is obtaining salt and pepper from a supplier would likely determine there are no hazards reasonably likely to occur in salt, but would identify Salmonella as a hazard in the pepper. The need for a supplier approval and verification program for the pepper would depend on how the pepper will be used by the receiving facility. Under proposed § 110.152(a)(6), discussed below within this section XII.H, a supplier approval and verification program would not be required for raw materials and ingredients for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent the hazards.

Rather, we are proposing to require such a program only when the receiving facility relies on controls applied earlier in the supply chain for hazards that are reasonably likely to occur in the raw material or ingredient. Thus, the receiving facility would develop a supplier approval and verification program for the pepper if it is to be used to season the salad without a treatment applied by the receiving facility that would adequately reduce Salmonella but not if the only use for the pepper is in the preparation of a cooked ingredient for the RTE salads.

Currently, receiving facilities use a variety of means to approve suppliers. For example, the receiving facility may conduct a "pre-assessment" questionnaire or survey to gather information about the supplier's operation and then conduct a pre-approval site visit to assess programs and process capability before conducting an onsite audit verification activity. Some receiving facilities use raw material or ingredient testing to assess compliance with specifications for the raw material or ingredient. FDA is proposing to require an initial onsite audit (as well as periodic onsite audits) where the supplier is controlling the hazard reasonably likely to occur in the raw material or ingredient and is subject to one or more designated foods safety regulations, as proposed in § 110.152(b)(1).

Under proposed § 110.3, a supplier would mean, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food (other than a farm that harvests a raw agricultural commodity that is a fruit or vegetable) that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature. Specifying that the food would be provided to a receiving facility without further manufacturing/processing, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature, would

focus the attention of the receiving facility on a supplier whose activities have the greatest potential to affect any hazards that may be present in the food, either by introducing hazards through its manufacturing/processing activities (e.g., if the supplier provides an RTE food that has the potential to be contaminated with an environmental pathogen) or by conducting activities to significantly minimize hazards (e.g., if a supplier pasteurizes milk that it provides to a facility that makes cheese).

Identifying establishments that manufacture/process food, raise an animal, or harvest food would address all types of establishments that could be suppliers of raw materials or ingredients. Some of these establishments may be facilities that are required to register under section 415 of the FD&C Act. However, a supplier could also be an establishment that is not required to register under section 415 of the FD&C Act (e.g., a farm that provides wheat to be used in the production of flour). As discussed within this section XII.H, some of the proposed requirements for a supplier approval and verification program would depend on whether the supplier is subject to a designated food safety regulation as would be defined in proposed § 110.3.

At present, a farm that harvests a RAC that is a fruit or vegetable is not included within the definition of "supplier," which would have the effect of excluding these foods from the scope of the supplier approval and verification requirement. Section 419 of the FD&C Act requires that FDA conduct rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are RACs for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death. We intend to propose appropriate changes to this regulation to include these foods concurrent with the issuance of the proposed produce safety regulations.

Although raw agricultural commodities that are fruits or vegetables would be temporarily excluded from the supplier verification requirements under our proposed approach, we strongly encourage receiving facilities who conduct onsite audits of farms that harvest raw agricultural commodities, or perform other activities to ensure the safety of these products, to continue these practices as part of their efforts to ensure the safety of the foods they manufacture/process.

The NACMCF HACCP guidelines describe supplier controls as one of the common prerequisite programs for the safe production of food products and recommend that each facility assure that its suppliers have in place effective CGMP and food safety programs (Ref. NACMCF 1998). Likewise, Codex addresses the safety of ingredients in the General Principles of Food Hygiene and recommends that, where appropriate, specifications for raw materials be identified and applied and laboratory tests be conducted to establish fitness for use. Federal HACCP regulations for seafood, juice, and meat and poultry do not include explicit requirements for supplier controls.

Proposed § 110.152(a)(1) is consistent with recommendations from industry trade associations. For example, as discussed in section II.F of this document, the American Spice Trade Association recommends that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. ASTA Spice Guidance 2011). GMA recommends that all suppliers through the food chain consider approval programs for their own suppliers (Ref. GMA Supply Chain Handbook 2008). One of the requirements for GFSI recognition of food safety schemes relates to controls on purchasing and suppliers (Ref. GFSI Guidance Document, 6th Edition).

b. Proposed § 110.152(a)(2)--Required assurance. Proposed § 110.152(a)(2) would require that the supplier approval and verification program provide adequate assurances that the

hazards identified as reasonably likely to occur by the receiving facility are significantly minimized or prevented. Proposed § 110.152(a)(2) would implement section 418(c) of the FD&C Act and is consistent with domestic and international approaches for the application of preventive approaches by the entire supply chain (Refs. NACMCF HACCP guidelines, Codex GPFH, GMA Supply Chain Handbook 2008, and GFSI guidance document V 6.1).

c. Proposed § 110.152(a)(3)--Required elements of a supplier approval and verification program. Proposed 110.152(a)(3)(i) would require that the supplier approval and verification program include a written list of approved suppliers. A written list of approved suppliers is essential to ensuring that raw materials and ingredients are purchased from appropriate suppliers. The list also would be essential in determining that appropriate verification activities in accordance with proposed § 110.152(b) and (c) are being conducted for each approved supplier. Thus, the list is needed for consistent implementation of the supplier approval and verification program by personnel who order raw materials and ingredients, personnel who receive raw materials and ingredients, and personnel who conduct supplier verification activities, as well as for training such personnel. It also is essential to a facility's food safety personnel, any auditors, and to government inspectors. The list would be used during reanalysis, audits, and inspections to verify adherence to the supplier approval and verification program.

Proposed § 110.152(a)(3)(ii) would require that the supplier approval and verification program include for each raw material and ingredient, a written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient. Under proposed § 110.3, a designated food safety regulation would mean a regulation contained in subpart B (Current Good Manufacturing Practice) or subpart C (Hazard Analysis and Risk-Based Preventive Controls) of part 110, part 106 (Infant

Formula Quality Control Procedures), part 107 (Infant Formula), , part 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements), part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers), part 114 (Acidified Foods), part 118 (Production, Storage, and Transportation of Shell Eggs), part 120 (Hazard Analysis and Critical Control Point Systems), part 123 (Fish and Fishery Products), or part 129 (Processing and Bottling of Bottled Drinking Water).

Each of these regulations contains preventive controls, CGMPs, or related requirements that are intended, at least in part, to require the use of processes and procedures that will help a supplier to significantly minimize or prevent the occurrence of biological, chemical, physical, and radiological hazards in food it manufactures/processes, raises or harvests.

Determining which, if any, food safety regulation is applicable will help the receiving facility in approving suppliers by clearly identifying food safety regulations that apply to a specific raw material or ingredient. Such information is essential for conducting appropriate supplier verification activities, because under proposed § 110. 152(e)(2) an audit of a supplier facility must assure compliance with the provisions of the relevant designated food safety regulation or regulations that are relevant to the hazards that are reasonably likely to occur and for which the receiving facility is expecting control by the supplier facility.

As discussed in section II.H.3.a of this document, we are proposing to exclude from the definition of "supplier" farms that harvest a raw agricultural commodity that is a fruit or vegetable, which would have the effect of excluding these foods from the scope of the supplier verification requirements. We intend to propose appropriate changes to this regulation to include these foods concurrent with the issuance of the proposed produce safety regulations.

Proposed § 110.152(a)(3)(ii) also would require that, if the owner, operator, or agent in charge of a receiving facility determines that a supplier is not subject to part 110, subpart C because the supplier is a qualified facility, then the owner, operator, or agent in charge of the receiving facility must obtain written assurance that the supplier meets the conditions for exemption as a qualified facility under proposed § 110.2(a) and that FDA has not withdrawn such exemption under Subpart E. As discussed in section X.B.1 of this document, proposed § 110.2(a) would implement an exemption for a facility that meets the conditions for a "qualified facility" as that term is described in section 418(l)(1) of the FD&C Act. A receiving facility would audit against the requirements of subparts B and C (as would be required by proposed § 110.152(b)) if the supplier is subject to both subparts, but only against subpart B if the supplier facility was exempt from subpart C. Thus, to determine the appropriate verification activities for a specific supplier, a receiving facility must know whether the facility meets the conditions for an exemption under proposed § 110.2(a). Under section 418(l)(3) of the FD&C Act and proposed subpart E, FDA may withdraw an exemption provided under proposed § 110.2(a). Thus, to determine the appropriate verification activities for a specific supplier, a receiving facility also must know whether an exemption under proposed § 110.2(a) has been withdrawn.

Proposed § 110.152(a)(3)(iii) would require that the supplier approval and verification program include verification activities as would be required by proposed § 110.152(b) and (c). (See the discussion of proposed § 110.152(b) and (c) later in this section XII.H.) Proposed § 110.152(a)(3)(iii) would make clear that the verification activities in proposed § 110.152(b) and (c) are part of the supplier approval and verification program but would not otherwise establish specific requirements.

d. Proposed § 110.152(a)(4)--Supplier verification activities when there is more than one type of hazard associated with a raw material or ingredient. Proposed § 110.152(a)(4) would provide that when supplier verification activities are required under §§ 110.152(b) or (c) for more than one type of hazard, the owner, operator, or agent in charge of a receiving facility conduct the verification activity or activities appropriate for each of those hazards. Proposed § 110.152(a)(4) would establish that, in some situations, a single verification activity will be appropriate for multiple hazards. For example, if a receiving facility that uses peanuts as an ingredient in its products obtains roasted peanuts from a supplier that roasts peanuts and tree nuts, and the receiving facility has identified Salmonella and undeclared tree nuts as hazards reasonably likely to occur in the peanuts, a single verification activity such as an audit of the supplier would be appropriate to assess whether the supplier is significantly minimizing or preventing both hazards. Proposed § 110.152(a)(4) would also establish that in other situations, multiple hazards will require more than one verification activity to provide adequate assurances that each hazard is significantly minimized or prevented. For example, if a receiving facility has identified pesticides and aflatoxin as hazards reasonably likely to occur in corn meal it is receiving from a supplier, and the supplier tests for aflatoxin but not pesticides, the receiving facility could obtain the aflatoxin testing results from the supplier but would conduct its own testing for pesticides as a verification activity.

e. Proposed § 110.152(a)(5)--Supplier verification activities when more than one verification activity is needed for a hazard. Proposed § 110.152(a)(5) would establish that, for some hazards, in some situations, under §§ 110.152(b) or (c) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

For example, if a receiving facility is obtaining shredded cheese from a supplier for use in an RTE salad and has identified L. monocytogenes as a hazard reasonably likely to occur because the supplier has had a problem with L. monocytogenes in the past (but has corrected the cause of the problem), the receiving facility would use both auditing and periodic testing (to verify both that pasteurization is adequately reducing L. monocytogenes and that the supplier is preventing contamination from the environment) as verification activities. Because the supplier has had problems with L. monocytogenes, the receiving facility could also determine that audit frequency for this supplier should be increased until it obtains adequate assurances that the hazard is significantly minimized or prevented.

A receiving facility also might find it necessary to conduct more than one verification activity when using a new supplier, until the verification activities provide sufficient assurance that the hazard is significantly minimized or prevented. For example, a receiving facility might determine through an initial audit that a new supplier of cheese has appropriate programs to control L. monocytogenes contamination from the environment; however, until the receiving facility gains experience with the supplier, the receiving facility would also test the cheese to verify control of L. monocytogenes. The frequency of testing would likely be higher initially (e.g., monthly) and then reduced (e.g., quarterly) until the receiving facility builds confidence in the supplier. Subsequently, after a history is established of the supplier significantly minimizing or preventing the hazard, the receiving facility may reduce the testing further, or even eliminate it and rely entirely on auditing.

As another example, Salmonella and L. monocytogenes in RTE raw materials or ingredients that will not be treated further to significantly minimize the hazard pose a greater risk than if they were present in raw materials or ingredients that are used in a food that is not RTE.

Thus, the frequency of verification activities would be increased for RTE raw materials or ingredients that will not be treated further to significantly minimize the hazard. Because of the risk presented by Salmonella and L. monocytogenes in RTE raw materials or ingredients that will not be treated further to significantly minimize the hazard, the receiving facility would also likely conduct multiple verification activities such as audits and periodic testing for the hazard in the raw material or ingredient.

f. Proposed § 110.152(a)(6)--Exception to the requirement to establish and implement a supplier approval and verification program. Proposed § 110.152(a)(6) would provide that the owner, operator, or agent in charge of a receiving facility is not required to establish and implement a supplier approval and verification program for raw materials and ingredients for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur. If the receiving facility's own preventive controls can ensure that the hazard is adequately controlled, there would be no need to establish additional controls on the hazard through a supplier approval and verification program. For example, a receiving facility that uses peanuts as an ingredient in its products and has identified Salmonella as a hazard reasonably likely to occur in the peanuts would not be required to establish a supplier approval and verification program with respect to the hazard Salmonella in peanuts if the receiving facility itself treats the peanuts using a process validated to adequately reduce Salmonella.

For some types of hazards, it is unlikely that a receiving facility would have established and implemented preventive controls that would significantly minimize or prevent those types of hazards at its own establishment and would instead need to rely on controls earlier in the supply chain. For example, it is unlikely that a facility could establish preventive controls (other than

supplier controls) for chemical hazards (such as pesticides, mycotoxins and drug residues) or radiological hazards (such as iodine-131). In other cases, a receiving facility may have established and implemented preventive controls for use at its own establishment, but these preventive controls may not be adequate to control a hazard originating from the supplier. For example, a receiving facility's allergen controls cannot address an undeclared allergen introduced by the supplier through cross-contact.

We request comment on our proposed risk-based approach that receiving facilities would not need a supplier approval and verification program when ingredients will be subjected to preventive controls at the receiving facility that significantly minimize or prevent the hazard.

3. Proposed § 110.152(b)--Requirement for Supplier Verification Activities for Hazards to be Controlled at the Supplier's Establishment, if the Food is Subject to One or More Designated Food Safety Regulations.

Proposed § 110.152(b) would require that the owner, operator, or agent in charge of a receiving facility conduct initial and periodic verification activities for hazards to be controlled at the supplier's establishment, if the raw material or ingredient is subject to one or more designated food safety regulations with regard to the raw material or ingredient. Examples of preventive controls that could be applied at the supplier to control a hazard reasonably likely to occur in an ingredient include process controls (such as roasting nuts); food allergen controls (such as controls on labeling ingredients for allergens); and sanitation controls (such as cleaning procedures designed to prevent L. monocytogenes from establishing a harborage in food processing equipment used to prepare RTE ingredients that support its growth). As discussed immediately below, proposed § 110.152(b)(1) and (2) would require that, when the supplier is controlling the hazard and is subject to one or more designated food safety regulations, the

verification activities must include onsite audits. FDA tentatively concludes that in these circumstances an onsite audit always is necessary to provide adequate assurance that the hazard is significantly minimized or prevented by the supplier. Other verification activities may be needed, but none are sufficient in the absence of an audit. Through an audit conducted onsite, the auditor can observe physical conditions, interview employees, and review records to verify that controls to address the identified hazard are being implemented consistently and, if there is a written plan for controlling the hazard, that the controls are being implemented according to that plan. We tentatively conclude that it is appropriate to require an audit as a verification activity only when there is one or more designated food safety regulations that apply because in the absence of such a regulation there may not be clearly defined processes, procedures, or standards against which the supplier's actions to control the hazards can be evaluated in an onsite audit.

We also tentatively conclude that for some hazards, it will be necessary to conduct more than one verification activity to provide adequate assurances that the hazard is significantly minimized or prevented, as provided in proposed in § 110.152(a)(5). Such could be the case, for example, when there have been compliance problems with control of the identified hazard or when using a new supplier for which the receiving facility has little information to provide assurance the hazard is significantly minimized or prevented. When a facility determines that more than one verification activity is needed, the facility has flexibility to determine what additional verification activities are appropriate as long as they provide the necessary assurance that the hazard is significantly minimized or prevented. We request comment on this approach.

a. Proposed § 110.152(b)(1) –Requirement for initial onsite audit. Proposed § 110.152(b)(1) would require that the owner, operator, or agent in charge of a receiving facility conduct, or obtain documentation of, an onsite audit of the supplier before using the raw material

or ingredient from the supplier. An initial onsite audit is often used by the receiving facility as part of establishing supplier approval status. An onsite audit of the supplier must assure compliance with the provisions of the relevant designated food safety regulation or regulations that are relevant to the hazards that are reasonably likely to occur that the receiving facility is expecting the supplier to control. An initial onsite audit would be conducted before a receiving facility uses the raw material or ingredient from the supplier for the first time; proposed § 110.152(b)(1) would not require the owner, operator, or agent in charge of a receiving facility to conduct an audit before using a raw material or ingredient each time that raw material or ingredient is received. The initial onsite audit can be conducted by an employee of the receiving facility or the receiving facility can obtain documentation of an audit that has been conducted at the supplier by a third party auditor.

For example, before a receiving facility obtains roasted peanuts, for which the receiving facility has identified Salmonella as a hazard, from a supplier that roasts nuts and is subject to subparts B and C of part 110, the receiving facility would audit the supplier's facility (or obtain an audit performed by a third party) to determine whether the roasting process used by the supplier is adequate to significantly minimize Salmonella in peanuts. Because the supplier of roasted peanuts would be subject to subparts B and C of part 110, the audit would include a review of the supplier's food safety plan and ensure compliance with the provisions of subparts B and C relative to control of the Salmonella hazard.

For example, the auditor would review whether the roasting process for the nuts had been validated to significantly minimize Salmonella in peanuts and would review whether the implementation of the roasting procedures was in accordance with the food safety plan, e.g., by observations in the plant and by review of records. If the supplier is not subject to subpart C of

part 110 (e.g., because the supplier meets the definition of a qualified facility) the auditor would consider the requirements of subpart B in assessing whether the supplier is adequately controlling the hazard, e.g., process controls in proposed § 110.80(b). In this case, the auditor would review the roasting process for the nuts to determine if it will significantly minimize Salmonella in peanuts and the roasting procedures being implemented by the facility; the auditor would also review any relevant records the supplier can provide. The results of the audit would then be used by the receiving facility in determining the status of the supplier (e.g., approved, conditionally or provisionally approved, not approved) and, if the supplier is approved, the audit results could be a factor in determining appropriate verification activities (e.g., whether activities other than an annual audit, in accordance with proposed § 110.152(b)(2)(i), are needed) to provide adequate assurances that the hazard is significantly minimized or prevented, in accordance with proposed § 110.152(a)(4).

b. Proposed § 110.152(b)(2)--Requirement for periodic onsite audits. Proposed § 110.152(b)(2)(i) would require that when a hazard that is reasonably likely to occur with a raw material or ingredient is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier at least annually, unless more frequent onsite audits are necessary to adequately verify control of the hazard. The annual audit would include consideration of the standards and requirements of the applicable designated food safety regulations to which the supplier is subject in assessing whether the supplier is adequately controlling the hazard. Hazards for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals are those

which for which a recall of a violative product posing such a hazard is designated as "Class 1" under 21 CFR 7.3(m)(1). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death to humans or animals include pathogens or their toxins in RTE food and undeclared food allergens. For example, if Salmonella, a hazard that can cause serious adverse health consequences or death to humans or animals, is identified as a hazard reasonably likely to occur in peanuts, and the supplier applies a process control, e.g., oil roasting, then an annual audit would be conducted to ensure that the supplier's roasting process is adequate to significantly minimize Salmonella, that the roasting process is being conducted in accordance with the supplier's food safety plan (which is required by subpart C), and that the supplier is in compliance with the provisions in subparts B and C of part 110 (the applicable designated food safety regulations) relevant to control of the hazard.

As another example, undeclared milk in dark chocolate can cause serious adverse health consequences or death to humans. The supplier providing dark and milk chocolate to a receiving facility would be audited annually to ensure that the supplier is preventing cross-contact and appropriately labeling products to prevent undeclared allergens from being present in the raw materials or ingredients provided to the receiving facility.

We tentatively conclude that conducting onsite audits at least annually is necessary for hazards for which there is a reasonably possibility that exposure will result in serious adverse health consequence or death of humans or animals to provide adequate assurance that the hazards identified in the raw material or ingredient are significantly minimized or prevented by the supplier. The annual audit frequency is a minimum frequency. If more frequent onsite audits are necessary to adequately verify control of the hazard, the receiving facility would be required to conduct or obtain documentation of audits more frequently. The frequency of the audit would be

increased based on risk, including the supplier's performance or changes to the supplier's processes or facility. For example, if the receiving facility were to become aware of the supplier's raw materials or ingredients being the source of a hazard, the receiving facility could decide to conduct an audit more frequently than annually, and/or the receiving facility could implement additional verification activities as discussed in section XII.H.3.e. If the supplier were to change the process used to control the hazard, e.g., a change in the roasting time or temperature applied to sesame seeds (which can impact the lethality for the identified hazard of Salmonella), the receiving facility would likely decide to conduct an audit (or require documentation that an audit has been conducted) to provide assurance that the roasting parameters adequately reduce the hazard. If the supplier were to modify the facility producing the raw material or ingredient in a way that could impact the safety of the raw material or ingredient, the receiving facility could decide to conduct or obtain documentation of an audit. For example, construction in a facility has been known to increase the risk of contamination of RTE foods with L. monocytogenes (Ref. Tompkin et al. 1999); a facility receiving an RTE raw material or ingredient for use in manufacturing without a further kill step could decide to conduct or obtain documentation of an audit during the time of construction to assess whether the supplier has adequate controls to prevent contamination during the construction period.

The requirement for annual onsite audits is consistent with GFSI's recommendation for a minimum frequency of one audit per year (Ref. GFSI Guidance Document, 6th Edition). The GFSI guidance also indicates that the frequency of audits may be influenced by a number of factors such as previous audit history, concerns about compliance with an audit scheme's standard, and changes in product technology (Ref. GFSI 6th Edition Guidance). We request comment on the proposed annual onsite audit frequency as well as comment on what criteria, if

any, should be specified for determining whether more frequent audits are necessary. We are aware that there are circumstances in which suppliers are audited multiple times each year due to multiple customer requests (in addition to, in some cases, the company's internal audit). It is not our intent to increase the number of audits of each supplier; rather, we anticipate there will be consolidation of audits and that a supplier will be able to use the results of one audit as documentation for multiple receiving facilities. We request comment on this approach.

Proposed § 110.152(b)(2)(ii) would require that when a hazard that is reasonably likely to occur with a raw material or ingredient is not one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier at least every 2 years, unless more frequent onsite audits are necessary to adequately verify control of the hazard. Examples of hazards that historically have not resulted in serious adverse health consequences or death to humans or animals generally include mycotoxins, drug residues, and hard or sharp foreign objects. We therefore tentatively conclude that a less frequent auditing schedule (every other year instead of annually) is adequate for such hazards, which are less severe then those subject to more frequent auditing. This necessary audit frequency, however, would be increased, for example based on poor supplier performance, or additional verification activities would be implemented as discussed in section XII.H.3.e if necessary to provide adequate assurances that the hazard is significantly minimized or prevented.

We request comment on the proposed frequency of onsite audits when a hazard that is reasonably likely to occur with a raw material or ingredient is not one for which there is a

reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals.

4. Proposed § 110.152(c)--Supplier Verification Activities for Other Hazards.

a. Proposed § 110.152(c) –General requirements. Proposed § 110.152(c) would require that, for a hazard that would not be subject to proposed § 110.152(b), the owner, operator, or agent in charge of a receiving facility conduct one or more of the verification activities listed in proposed § 110.152(c)(1) through (5), as appropriate for the hazard, before using the raw material or ingredient and periodically thereafter. Such hazards include hazards to be controlled at the supplier's establishment and the supplier is not subject to one or more designated food safety regulations with respect to the raw material or ingredient. The frequency of verification activities must be based on the risk associated with the hazard.

Proposed § 110.152(c) sets forth the supplier verification requirements for hazards not specified in proposed § 110.152(b) (proposed § 110.152(b) applies to hazards controlled at the supplier's establishment for which the raw material or ingredient is subject to a designated food safety regulation). These hazards would include hazards to be controlled at the supplier's establishment when the raw material or ingredient in which the hazard occurs is not subject to a designated food safety regulation. In some cases, a hazard that is controlled by a supplier during manufacturing/processing, raising or harvesting is present in a raw material or ingredient, but the supplier is not subject to a designated food safety regulation. For example, a farm that produces corn is not subject to a designated food safety regulation. As stated in section XII.H.4 of this document, because the supplier is not subject to a designated food safety regulation, we tentatively conclude that it is not appropriate to mandate onsite auditing for such a hazard

because there may not be clearly defined processes, procedures, or standards against which the supplier's actions to control the hazards can be evaluated in an onsite audit.

Also included in the hazards subject to § 110.152(c) are hazards for which a supplier, upon receipt of a raw material or ingredient from another entity, takes steps to verify that the hazards have been adequately controlled before the supplier processes the received raw material or ingredient. For example, a receiving facility might identify Salmonella as a hazard reasonably likely to occur in a seasoning mix made by blending milk powder and spices. The supplier of the seasoning mix might not apply a control for Salmonella in its blending operation but instead might conduct verification to ensure that the suppliers of milk powder and spices have used proper controls. Another example is when a supplier conducts testing to verify that its raw material or ingredient supplier has applied a procedure that removes a hazard posed by the potential presence of a pesticide residue in the raw material. We tentatively conclude that, for such hazards, a supplier may not be able to apply a process control during the manufacturing/processing of a raw material or ingredient to adequately reduce the hazard. Because of this, the supplier must rely on testing the incoming raw material or ingredient or on conducting some other activity to verify that the hazard is appropriately controlled by its supplier.

To address hazards not subject to proposed § 110.152(b), proposed § 110.152(c) would require that the receiving facility conduct one or more of the verification activities specified in proposed § 110.152(c)(1) through (4), appropriate for the hazard, before using the raw material or ingredient and periodically thereafter. As set forth in proposed § 110.152(c)(1) through (4), the supplier verification activities that receiving facilities may choose to conduct, if they are appropriate for the hazard, are as follows:

- Periodic onsite audits (proposed § 110.152(c)(1));
- Periodic or lot-by-lot sampling and testing of the raw material or ingredient (proposed § 110.152(c)(2));
- Periodic review of the supplier's food safety records (proposed § 110.152(c)(3)); and
- Other appropriate supplier control verification measures (proposed § 110.152(c)(4)).

These verification procedures, and examples of types of foods/hazards for which they may be appropriate, are discussed below in sections XII.H.5.(b) - (e).

Proposed § 110.152(c) would require that the frequency of verification activities be based on the risk associated with the raw material or ingredient. For example, a receiving facility might obtain ground black pepper from a new supplier that receives peppercorns from a facility that steam-treats the peppercorns to significantly minimize the hazard of Salmonella. Because the ground pepper supplier does not control the hazard of Salmonella in the raw material at the supplier's own establishment, the supplier would not be subject to the mandatory audits required by proposed § 110.152(b). The receiving facility might initially ask its new supplier of ground black pepper to provide lot-by-lot certificates of analysis (COAs) for Salmonella in accordance with a designated sample size and method. (A certificate of analysis is a document that states the results of tests performed on food, as is commonly used in the food industry.) The receiving facility might determine that lot-by-lot COAs are necessary based on the following factors: the lack of a performance history for the new supplier; the seriousness of the hazard (Salmonella is a hazard that can cause serious adverse health consequences or death to humans or animals); and the supplier's reliance on testing each lot of incoming steam-treated, black peppercorns for

Salmonella to verify its raw material supplier's preventive controls for steam treatment rather than applying a preventive control for Salmonella in its grinding facility. Until a performance baseline is established with the supplier, the receiving facility might even conduct its own periodic sampling and testing, in addition to reviewing the COAs from the supplier. Once the supplier has established a history of no Salmonella in the ground black pepper, the receiving facility might decide that it is appropriate to have the supplier provide COAs at some lesser frequency, such as every tenth delivery. The receiving facility also might reduce the frequency of its own verification testing. The receiving facility also would conduct an annual audit of the supplier providing the ground black pepper to ensure the supplier is adequately controlling the hazard of Salmonella contamination from the environment. The audit also could be used to verify the supplier's verification testing results for incoming steam-treated, black peppercorns for Salmonella.

b. Proposed § 110.152(c)(1)--Periodic onsite audits. Proposed § 110.152(c)(1) would provide, as a verification option when appropriate, for periodic onsite audits that the owner, operator, or agent in charge of the receiving facility conducts, or for which the owner, operator, or agent in charge of the receiving facility obtains documentation.

Under proposed § 110.152(c)(1) a receiving facility could determine that it is appropriate to conduct or obtain documentation of an onsite audit to verify control of a hazard subject to § 110.152(c). Using the example provided above involving a seasoning mix, the receiving facility might choose to conduct an audit or use a third-party auditor to conduct an audit of the supplier's operations to verify that the supplier conducts appropriate verification activities for incoming lots of powdered milk and spices to verify that controls for Salmonella are adequate. In this example, the suppliers of powdered milk and spices are also suppliers, and the supplier of the seasoning

mix is a receiving facility with respect to the powdered milk and spices. The verification activity performed with respect to the powdered milk and spices would depend on whether the suppliers of these raw materials or ingredients are controlling the hazard of Salmonella at their facilities or whether control measures are applied farther back in the supply chain. If the suppliers of the powdered milk and spices are treating them to reduce Salmonella, then the supplier of the seasoning mix (as a receiving facility) would conduct an audit to verify the hazard of Salmonella has been significantly minimized or reduced, review the supplier's food safety plan and determine the suppliers are operating in compliance with the provisions relevant to the control of the hazard in any designated food safety regulations to which the facilities are subject (e.g., subpart B and C of part 110) . The receiving facility for the seasoning mix may decide that an audit of the supplier is appropriate to observe the physical blending operation to assure no hazards are introduced during blending. The auditor would review the procedures used by the seasoning mix supplier to ensure that control of Salmonella in the powdered milk and spices is adequate, including a review of the audits the supplier conducts, or for which documentation has been obtained, on the suppliers of the powdered milk and spices. If the supplier of the seasoning mix conducts additional verification measures such as testing the powdered milk or spices for Salmonella, the auditor would review the results of such testing.

The audit frequency for verifying controls applied to address hazards that cause serious adverse health consequences, e.g. Salmonella, would generally be greater than for a hazard that does not, e.g. a mycotoxin. Supplier performance could be another factor that influences audit frequency. After the initial onsite audit, the frequency of the periodic audit for a hazard such a mycotoxins may be annual until a history is developed with the supplier, at which point a re-

evaluation of the supplier could be conducted to determine whether the annual audit could be replaced by one of the other verification activities proposed in this section.

As discussed in section XII.H.7.b below, checking the written control plan of a supplier, if any, is required under proposed § 110.152(e)(2) when an onsite audit is conducted.

c. Proposed § 110.152(c)(2)--Periodic or lot-by-lot sampling and testing by or on behalf of the receiving facility. Proposed § 110.152(c)(2) would provide, as a verification option when appropriate, for periodic or lot-by-lot sampling and testing of the raw material or ingredient from the supplier that the owner, operator, or agent in charge of the receiving facility conducts, or has conducted, for the hazard. Under proposed § 110.152(c)(2), a receiving facility might determine that it is appropriate to conduct periodic or lot-by-lot sampling and testing of a raw material or ingredient before the receiving facility uses it. For example, the receiving facility of the above-described seasoning mix might choose to conduct its own periodic Salmonella testing or use a contracted lab to test samples of seasoning mix, perhaps on a monthly basis. This monthly testing could be conducted until a good history is established for the seasoning mix supplier, after which time the receiving facility could determine it would be appropriate to test less frequently, such as quarterly.

Alternatively, a receiving facility could choose to obtain documentation (such as a COA) of lot-by-lot or periodic testing of the raw material or ingredient that is conducted before the raw material or ingredient is used. This supplier verification method is consistent with the recommendation in GMA's Food Supply Chain Handbook that customers ask suppliers to provide COAs documenting that major analytical parameters for the specific foods, or lots, contained in a specific shipment have been met (Ref. GMA's Food Supply Chain Handbook, 2008).

Although requirements for a COA or other documentation of testing will depend on factors such as the raw material or ingredient involved, information included in a COA might include the following: a description of the food; the name of the supplier; lot number(s) for products in the shipment; the date of production; whether the testing was done in-house or by an outside lab; the date the food was shipped; results of chemical, physical, and/or microbiological analyses; methods of analysis; descriptions of sampling plans used to generate results contained in the COA; and the signature of analysis or person issuing the certificate (Ref. GMA's Food Supply Chain Handbook, 2008).

As with the other verification activities, proposed § 110.152(c)(2) would require that the frequency of testing of raw materials and ingredients be based on the risk associated with the hazard in the food. An example of risk-based sampling was provided in XII.H.5. for a receiving facility and ground black pepper. FDA requests comment on whether we should specify particular situations or product types for which raw material or ingredient testing would be required as a supplier verification activity, and whether the frequency of testing should be specified.

d. Proposed § 110.152(c)(3) –Periodic review by the receiving facility of the supplier's food safety records. Proposed § 110.152(c)(3) would provide, as a verification option when appropriate, for periodic review by the owner, operator, or agent in charge of the receiving facility of the supplier's food safety records (e.g., records of audits of their supplier for the hazard). Under proposed § 110.152(c)(3), a receiving facility could determine that it is appropriate to periodically review a supplier's food safety records for the raw material or ingredient provided. Food safety records are records documenting that the food safety procedures that have been established to control hazards reasonably likely to occur are being

followed and are adequately controlling such hazards. Such records might include, for example, records of a supplier's audit of its supplier's hazard control activities.

Record review would be an appropriate verification activity when, for example, the supplier of a spice mix containing steam-treated black pepper performs onsite audits of its supplier that is steam-treating the black pepper to verify that the identified hazard of Salmonella is being controlled. The supplier of the spice mix containing steam-treated black pepper could provide the receiving facility with copies of the reports of these audits. The supplier of the spice mix might conduct additional verification activities such as periodic testing of the steam-treated black pepper; the receiving facility of the spice mix could also review these food safety records.

Record review would be an appropriate verification activity, for example, if the hazard identified by the receiving facility in the raw material or ingredient is a mycotoxin, such as in corn meal or flour. The receiving facility would verify that the supplier, e.g. the miller, has verified that mycotoxin has been controlled by the miller's supplier by testing the incoming grain for mycotoxins. The receiving facility would conduct a review of the grain mycotoxin testing records at the supplier.

e. Proposed § 110.152(c)(4)--Other appropriate supplier control verification measures. Proposed § 110.152(c)(4) would provide, as a verification option, for other appropriate supplier control verification measures based on the risk associated with the hazard. Under proposed § 110.152(c)(4), a receiving facility could choose to follow any other supplier verification measure that it has established as being appropriate, based on the risk associated with the raw material or ingredient, for verifying that a supplier is adequately controlling (or verifying control of) the hazard, as long as the measure is adequate to verify whether a supplier is adequately controlling a hazard. We are aware that receiving facilities currently uses onsite audits, product testing, and

record review as verification activities for raw materials and ingredients. We request comment on other supplier verification measures that may be appropriate.

As discussed in section XII.H.7.b below, checking the food safety plan of a supplier, if any, is required under proposed § 110.152(e)(2) when an onsite audit is conducted for a raw material or ingredient that is subject to a designated food safety regulation. We have not included this as an activity in proposed § 110.152(c) that could be used by itself for supplier verification, and we tentatively conclude that it would not be appropriate as a stand-alone activity under § 110.152(c). We are concerned that checking a supplier's food safety plan, without auditing the supplier's facility or performing some other verification step, would not provide adequate assurances that a supplier is controlling hazards. We request comment on whether we should permit the use of a verification approach solely involving checking the food safety plan of a supplier and, if so, under what circumstances this verification activity would be appropriate.

5. Proposed § 110.152(d)--Requirement for Records

Proposed § 110.152(d) would require that all supplier verification activities conducted in accordance with this section must be documented in records. The required records would be subject to the requirements of subpart F, as discussed in section XV. Proposed § 110.152(d) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan (Ref. NACMCF 1998). The Codex HACCP Annex recommends that documentation and record keeping should be sufficient to assist the business to verify that the HACCP controls are in place

and being maintained (Ref. Codex 2003). Federal HACCP regulations for seafood, juice and meat and poultry require that recordkeeping document the HACCP plan and its implementation (§ 123.9, § 120.12, and 9 CFR 417.5).

Documentation of supplier verification activities could include audit reports, reports for the raw material or ingredient testing conducted by the receiving facility, supplier COAs, and supplier food safety records. Audit reports could address the audit criteria used, identification of the auditor, the audit observations and findings, and the audit rating, e.g., numerical score, pass/fail. The receiving facility's raw material or ingredient testing reports could address the description of the raw material or ingredient tested, production information, e.g. lot number, the laboratory used, method used, sample size, and the test results compared to specification to be met. The supplier COA could address the description of the raw material or ingredient tested, production information, e.g. lot number, the laboratory used, method used, sample size, and the test results compared to specification to be met. The supplier's testing records could address the supplier's testing of incoming components and/or testing of outgoing raw material or ingredients including corrective actions if test performed did not meet supplier's acceptance criteria.

The receiving facility's food safety personnel need verification documentation, e.g., audit or testing results, as applicable, to determine the acceptability of the supplier's raw materials or ingredients before use. Having such documentation provides a history of supplier performance so risk-based decisions can be made, e.g. a change in verification frequency. The documentation is also essential to personnel who order raw materials and ingredients.

6. Proposed § 110.152(e)--Requirements that apply to onsite audits

a. Proposed § 110.152(e)(1)--Requirements for persons who conduct the onsite audit. Proposed § 110.152(e)(1) would require that an onsite audit be performed by a qualified

individual with the technical expertise obtained by a combination of training and experience appropriate to perform the auditing function. This approach is consistent with the NACMCF HACCP guidelines that acknowledge it is important that individuals doing verification have appropriate technical expertise to perform this function (Ref. NACMCF 1998). The person conducting the audit may be an employee of the receiving facility (second party auditing) or a qualified third party auditing firm. If third party auditing firms are used, GMA recommends requesting an auditor experienced with the food commodity item the supplier produces (Ref. GMA Food Supply Chain Handbook). GMA also recommends that an auditor's competency include education/experience; advanced HACCP training; and a minimum amount of auditing expertise (Ref. GMA Food Supply Chain Handbook). GFSI specifies that an auditor's qualifications include minimum full-time work experience in food or an associated industry; formal training in auditing techniques, initial training for each product category in which the auditor will be expected to be working; audit experience; and continuous professional development (Ref. GFSI Guidance Document 6th Edition).

FDA tentatively concludes that a person performing onsite audits as proposed in § 110.152(b) and 110.152(c) would have training and experience similar to existing industry standards. Proposed § 110.155(b) would require that a qualified individual have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. We recognize that a person qualified to develop and apply a food safety system may not have the training and experience to conduct facility audits. However, we tentatively conclude that a person conducting an onsite audit must have, in addition to auditing skills, the training and

experience to develop and apply a food safety system for the food being produced at the facility being audited. Thus, we are proposing to require in proposed § 110.152(e)(1) that the onsite audit be performed by a qualified individual (as defined in § 110.3) with training and/or experience in the development and application of risk-based preventive controls and the technical expertise required to perform audits. We request comment on FDA's approach on auditor qualifications and whether it is appropriate to require auditors to meet the qualified individual training requirements proposed in § 110.155.

b. Proposed § 110.152(e)(2)--Requirement for content of an onsite audit. Proposed § 110.152(e)(2) would require that if the raw material or ingredient at the supplier is subject to one or more designated food safety regulations, to provide adequate assurance that the hazard is significantly minimized or prevented, an onsite audit must consider such regulations and include a review of the supplier's written plan, if any, including its implementation, for the hazard being audited. Proposed § 110.152(e)(2) sets forth the basic requirements for an onsite audit when the audit concerns a food that is subject to a designated food safety regulation. We tentatively conclude it is appropriate that an onsite audit of the supplier of a food should include an evaluation of the supplier's level of compliance with the particular regulations to which the supplier is subject as they relate to the control of hazards being audited. Thus, an onsite audit conducted by either the receiving facility or a third-party auditor would assess, in the context of the standards and requirements of the applicable designated food safety regulations, whether the measures the supplier has applied are effectively controlling the hazards identified by the receiving facility as reasonably like to occur. Because the designated food safety regulations vary in scope and detail, the parameters and key components of an onsite audit conducted under

§ 110.152(b)(1), (b)(2) or (c)(1) would necessarily vary depending on what regulations applied to the supplier.

We also tentatively conclude that review of the supplier's written plan, if any, and the supplier's implementation of such plan, would be an important part of an effective onsite audit. For example, if the supplier is required by section 418 of the FD&C Act to have a food safety plan, the onsite audit would focus on the plan and assess the implementation of the preventive controls applied by the supplier to address the hazards that the receiving facility has identified as reasonably likely to occur. Preventive controls might include process controls, food allergen controls, sanitation controls, and other controls for biological, chemical, physical, or radiological hazards identified as reasonably likely to occur. For suppliers that are not required to have a food safety plan under section 418 of the FD&C Act but are required to have one under another designated food safety regulation, the onsite audit should include a review of the supplier's written plan, and the supplier's implementation of the plan, to assure that hazards identified by the receiving facility are effectively controlled.

We request comment on these proposed requirements, as well as on whether any other requirements regarding the scope and content of onsite audits are appropriate.

7. Proposed § 110.152(f)--Independence of persons conducing an onsite audit

Proposed § 110.152(f) would require that a person who conducts an onsite audit as set forth in § 110.152(b) or § 110.152 (c) not have a financial interest in the supplier and payment not be related to the results of the activity. Proposed § 110.152(f) would provide that this does not prohibit the owner, operator, or agent in charge of the receiving facility from conducting the audit.

Proposed § 110.152(f) addresses the issue of financial conflicts of interests that might arise in the performance of audits by a person conducting the audit. We recognize the possibility that a conflict of interest might arise when there is a financial relationship between a person that is conducting an audit and the supplier whose procedures the person is reviewing. For example, the owner of an auditing firm might own substantial shares of stock in a supplier that has requested an audit by the firm. On the other hand, § 110.152(b)(1), (b)(2) and (c)(1) permit the receiving facility itself to conduct onsite audits of suppliers and other verification activities under these regulations. We tentatively conclude there is no conflict of interest when a person employed by a receiving facility conducts an audit of a supplier, even when the supplier is an entity under the same corporate ownership as the receiving company. In addition to the person who conducts an onsite audit not having a financial interest in the supplier, we would require in proposed § 110.152(f) that payment for the audit not be based on the outcome of the audit, e.g., that there is a higher payment for the audit when the supplier is substantially in compliance with the provisions against which the supplier is being audited.

We request comment on whether this prohibition reflects the appropriate approach to concerns about conflicts of interest in the performance of audits and, if not, what changes would be appropriate. We also request comment on whether and, if so, how, the regulation should specify what constitutes a financial interest.

8. Proposed § 110.152(g)--Supplier non-conformance

Proposed § 110.152(g) would require that, if the owner operator, or agent in charge of a receiving facility determines through auditing, verification testing, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur, the receiving facility must take prompt action, which may include discontinuing use of the

supplier, to ensure the hazards associated with the raw material or ingredient have been significantly minimized or prevented.

Proposed § 110.152(g) would require a receiving facility to take appropriate action, e.g., corrective actions, if it determines that one of its suppliers is not controlling hazards that the receiving facility has identified as reasonably likely to occur. Such a determination may come from auditing, verification testing, or other means. Regardless of how a receiving facility obtains the information that forms the basis of the determination that its supplier did not control the hazards in the raw material or ingredient, the receiving facility must take action in response to this noncompliance. The appropriate corrective actions by the receiving facility will depend on the circumstances, but could include discontinuing use of the supplier until the cause or causes of the supplier's non-conformance have been adequately addressed. Because the actions to be taken will depend on the specific root cause of the noncompliance, FDA is not proposing the actions to be taken other than to provide that one option is to discontinue use of the supplier. FDA tentatively concludes that because the lack of control of the hazard by the supplier can result in a hazard in the food manufactured/processed at the receiving facility, discontinuing use of the supplier until the supplier can adequately control the hazard is appropriate. FDA requests comment on the requirement to address supplier non-conformance.

I. Proposed § 110.155--Requirements Applicable to a Qualified Individual

Proposed § 110.155(a) would require that a qualified individual prepare the food safety plan (proposed § 110.126(c)), validate the preventive controls (proposed § 110.150(a)(1)), review records for implementation and effectiveness of preventive controls (proposed § 110.150(d)(5)), perform reanalysis of the food safety plan (proposed § 110.150(f)(2), and perform an onsite audit (§ 110.152(e)(1). We have discussed the basis for requiring that a

trained individual perform these functions in our discussion of each applicable proposed provision. We are listing the functions that must be performed by a trained individual in § 110.155(a) for simplicity and are not imposing any additional requirement through this list.

Proposed § 110.155(b) would require that a qualified individual have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. Training or job experience is essential to the effective development and implementation of a hazard analysis and risk-based preventive controls. Only a trained individual or individual qualified by job experience is capable of effectively executing certain activities, such as identifying hazards that are reasonably likely to occur; identifying preventive controls that will address those hazards; evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the hazards that are reasonably likely to occur; determining the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur; determining whether monitoring procedures and corrective action procedures are appropriate; and determining whether specific corrective actions have been appropriate and effective. In addition, the products produced by the food industry are diverse, and the hazards that are reasonably likely to occur in a particular facility depend on a range of factors that vary from one facility to the next.

Proposed § 110.155 is consistent with the NACMCF HACCP guidelines, our HACCP regulations for seafood and juice, and USDA's HACCP regulations for meat and poultry. The

NACMCF HACCP guidelines recommend that experts who are knowledgeable in the food process either participate in or verify the completeness of the HACCP plan (Ref. NACMCF, 1998). Our HACCP regulations for seafood and juice both require that only a trained individual be responsible for developing the hazard analysis (juice only), developing the HACCP plan, verifying and modifying the HACCP plan, and performing the record review (§§ 123.10(a)-(c) and 120.13(a)(1)-(4), respectively). These regulations also provide that job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. USDA's HACCP regulations for meat and poultry require that only an individual who has completed a training course can conduct certain activities, such as development and modification of the HACCP plan (9 CFR § 417.7).

FDA did not conduct HACCP training for persons subject to our HACCP regulations for seafood or juice. However, when implementing those regulations, FDA worked with an alliance of representatives from Federal and State agencies, industry and academia, to create a uniform, core training program that serves as the standardized curriculum against which other course materials can be judged. FDA will be working with an alliance to develop such a standardized curriculum for any final rule establishing requirements for hazard analysis and risk-based preventive controls. Having a standardized curriculum on which facilities, as well as private organizations and academia that conduct training, can base their materials and training would provide a framework to ensure minimum training requirements are met.

Proposed § 110.155(b) also would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. Proposed §

110.155(b) is consistent with HACCP regulations for seafood and juice, which have virtually identical requirements (§§ 123.10 and 120.13(b), respectively). The option in proposed § 110.155(b) would provide flexibility to facilities subject to the rule. Such flexibility may be particularly important for those facilities that have limited technical expertise.

Proposed § 110.155(c) would require that all applicable training be documented in records, including the date of the training, the type of training, and the person(s) trained. Such records would be a simple mechanism to demonstrate that a person has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, as would be required under proposed § 110.155(b) should the qualified individual not be otherwise qualified through job experience to develop and apply a food safety system.

J. Proposed § 110.175--Records Required for Subpart C

1. Requirements of Section 418 of the FD&C Act

Section 418(g) of the FD&C Act, in relevant part, specifies that "[t]he owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under [section 418(c) of the FD&C Act], instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under [section 418(f)(4) of the FD&C Act], instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions."

Section 418(h) of the FD&C Act, in relevant part, specifies that "[t]he owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of [section 418 of the FD&C Act], including analyzing the hazards under [section 418(b) of the FD&C Act] and identifying

the preventive controls adopted under [section 418(c) of the FD&C Act] to address those hazards." Section 418(h) of the FD&C Act also specifies that the written plan, together with the documentation described in Section 418(g) of the FD&C Act, "shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request."

2. Proposed § 110.175--Records Required for Subpart C

Proposed § 110.175(a)(1) through (6) would require that the owner, operator, or agent in charge of a facility establish and maintain the following records:

- The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, recall plan, and the supplier approval and verification procedures;
- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification, including, as applicable, those related to validation; monitoring; corrective actions (including corrective actions for environmental monitoring); review of consumer, customer, or other complaints; calibration of process monitoring and verification instruments; finished product testing; environmental monitoring; records review; and reanalysis;
- Records that document the supplier approval and verification program; and
- Records that document applicable training for the qualified individual.

Proposed § 110.175(a) would not establish any new requirements but merely make it obvious at a glance what records are required under part 110, subpart C. This listing of records is consistent with our approach in part 110, subpart B (see discussion of proposed § 110.120 in section XI.K of this document).

Proposed § 110.175(b) would provide that the records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of part 110, subpart F. As discussed in section XV of this document, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by part 110, including provisions for retention of records and for making records available for official review.

K. Request for Comment on Submission of Facility Profile to FDA

Proposed § 110.126 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, preventive controls, and other records. Traditionally, information of this type has not been reviewed by FDA investigators until they are physically present at a facility and have begun an inspection. In light of the large number of facilities that would be required to have food safety plans under this proposal, FDA recognizes several potential benefits to having a facility's food safety plan in advance of an inspection. Having such plans could aid in the efficient oversight of preventive controls by allowing FDA to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly with biological hazards) and to improve on-site inspections by focusing attention on hazards and preventive controls for which the facility appears to have deficiencies. Facilities would benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. We could also more quickly identify facilities that had not established preventive controls for specific hazards of concern to the agency and advise them to fill such gaps to prevent a problem before it occurs. Also, FDA could use the plans in evaluating

the need for guidance on specific hazards or controls and prioritizing guidance to areas where it is needed most.

FDA tentatively has determined that there are significant obstacles to realizing these benefits from submission of food safety plans, however. The agency would expect to receive a very large number of plans. Further, these plans would be expected to vary significantly in content and format. Assimilating the underlying information in a way that would be useful to the agency would be an immense challenge. Moreover, not all of the information in such plans may be essential to realizing the potential benefits described above. Therefore, to most efficiently realize the potential benefits of having certain information prior to an inspection, FDA is considering whether to require submission to FDA of a subset of the information that would be in a food safety plan. This information, which could be referred to as a "facility profile," could be submitted through an electronic form using a menu selection approach. The use of an electronic form would enhance our ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that we could target inspections to facilities that manufacture, process, or pack, foods that are at increased risk for a food safety problem; to facilities that appear to have insufficient controls to prevent a problem; or to facilities using a control we conclude is ineffective at controlling hazards. The data elements for a facility profile could include some or all of the following:

- Contact information;
- Facility type;
- Products;
- Hazards identified for each product;

- Preventive controls established for each of the identified hazards;
- Third-party audit information (have you had one and which audit firm(s));
- Preventive control employee training conducted;
- Facility size (square footage);
- Full time operation or seasonal;
- Operations schedule;

This information could be submitted at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration. FDA requests comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. We also request comment on any additional benefits that might be obtained from using such an approach and any potential concerns with this approach.

XIII. Proposed Subpart D--Modified Requirements

FSMA provides for the establishment of modified requirements for certain facilities under certain circumstances. In this section of this document, we propose such modified requirements.

A. Proposed § 110.201--Modified Requirements That Apply to a Qualified Facility

1. Requirements of Section 418(l) of the FD&C Act

Section 418(l) of the FD&C Act establishes modified requirements for "qualified facilities." As discussed in section II.B.1.b of this document, section 418(l)(1) of the FD&C Act establishes the conditions for a facility to be a "qualified facility" based on either business size (section 418(l)(1)(B) of the FD&C Act) or a combination of the average monetary value of the food sold and the value of food sold to qualified end users as compared to all other purchasers

(section 418(l)(1)(C) of the FD&C Act), and proposed § 110.3 would establish a definition for "qualified facility" based on section 418(l)(1).

Sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility is exempt from the requirements of sections 418(a) through (i) and (n) of the FD&C Act (i.e., the requirements for hazard analysis and risk-based preventive controls), but must instead submit two types of documentation to the Secretary of HHS. The first type of required documentation relates to food safety practices at the facility, and section 418(l)(2)(B)(i) provides two options for satisfying this documentation requirement. Under section 418(l)(2)(B)(i)(I), the qualified facility may choose to submit "documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective." Alternatively, under section 418(l)(2)(B)(i)(II), the qualified facility may choose to submit "documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary [of HHS], that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law."

The second type of required documentation relates to whether the facility satisfies the definition of a qualified facility. Under section 418(l)(2)(B)(ii) of the FD&C Act, the facility must submit documentation, as specified by the Secretary of HHS in a guidance document, "that the facility is a qualified facility under [section 418(l)(1)(B) of the FD&C Act] or [section 418(l)(1)(C) of the FD&C Act]."

Section 418(l)(7)(A) of the FD&C Act requires that a qualified facility that is exempt from the requirements under sections 418 (a) through (i) and subsection (n), and that does not prepare documentation under section 418(l)(2)(B)(i)(I), provide notification to consumers by one of two procedures, depending on whether a food packaging label is required on the food. With respect to a food for which a food packaging label is required by the Secretary of HHS under any other provision of the FD&C Act, section 418(l)(7)(A)(i) of the FD&C Act requires that a qualified facility "include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed". With respect to a food for which a food packaging label is not required by the Secretary of HHS under any other provisions of the FD&C Act, section 418(l)(7)(A)(ii) of the FD&C Act requires that a qualified facility "prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice."

2. Proposed § 110.201(a)--Documentation to be Submitted

a. Proposed § 110.201(a)(1)--Documentation that the facility is a qualified facility.

Proposed § 110.201(a)(1) would require that a qualified facility submit to FDA documentation that the facility is a qualified facility. Consistent with the conditions in section 418(l)(1) of the FD&C Act for a facility to be a qualified facility, and our proposed definition (proposed § 110.3) of "qualified facility," the documentation would be directed to either the status of the facility as a very small business (as would be defined in proposed § 110.3) or the applicability of conditions for average annual monetary value and the value of food sold to qualified end users as compared to other purchasers (as would be included in the definition of qualified facility in proposed §

110.3). As discussed further in section XIII.A.5, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility is a very small business, otherwise meets the definition of a qualified facility under proposed § 110.3, or both, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 110.201(a)(1). We would not, for example, require that a facility submit financial information to FDA demonstrating its total sales or to the proportion of sales to qualified end users.

Proposed § 110.201(a)(1) also would establish that, for the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011. The conditions related to average annual monetary value established in section 418(l)(1)(C) of the FD&C Act, and the definition of very small business in proposed § 110.3, allow adjustment for inflation. To establish a level playing field for all facilities that may satisfy definition of a qualified facility, we are proposing to establish the baseline year for the calculation in proposed § 110.201(a)(1). We are proposing to establish 2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law. We tentatively conclude that because Congress provided a specific dollar amount in section 418(l)(1)(C)(ii)(II) – i.e., $500,000 – and it provided that the dollar amount should be adjusted for inflation, it is reasonable to establish the baseline year as the year that the law was enacted.

b. Proposed § 110.201(a)(2)--Documentation related to food safety practices at a facility. Proposed § 110.201(a)(2) would provide two options for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility. Proposed § 110.201(a)(2)(i) would allow qualified facilities to submit documentation to demonstrate that the owner, operator, or agent in charge of the facility has identified the potential

hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective to satisfy this requirement.

Proposed § 110.201(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(I) of the FD&C Act, except that proposed § 110.201(a)(2)(i) would specify monitoring the performance of the preventive controls to ensure that such controls are effective (emphasis added). As discussed in section II.B.1.a of this document, under the overall framework of the proposed requirements that would be established in subpart C, monitoring is directed to performance of preventive controls. Thus, proposed § 110.201(a)(2)(i) is consistent with the statute and the overall framework of this proposed rule.

Proposed § 110.201(a)(2)(ii) would provide another option for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility by allowing qualified facilities to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Proposed § 110.201(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(II) of the FD&C Act.

As discussed further in section XIII.A.5 of this document, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility (1) has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or (2) that the facility is in

compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 110.201(a)(2). We would not, for example, require that a facility submit documentation to FDA demonstrating the content of their hazard identification, preventive controls, or monitoring of the implementation of preventive controls; or copies of their non-Federal licenses, inspection reports, certificates, permits, credentials, or certifications.

3. Proposed § 110.201(b)--Procedure for Submission

Proposed § 110.201(b) would require that qualified facilities submit the documentation that would be required by proposed § 110.201(a) by one of two procedures. Proposed § 110.201(b)(1) would provide an option to submit documentation electronically at http://www.access.fda.gov by following the instructions to be provided on that web page. Proposed § 110.201(b)(1) would inform facilities that this website is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. Although electronic submission is not required, proposed § 110.201(b)(1) would encourage electronic submission, which is efficient for FDA and should also be efficient for facilities. Electronic submission generally would be available 24 hours a day, 7 days a week, unless the website is experiencing technical difficulties or is undergoing maintenance.

Proposed § 110.201(b)(1) would provide an option to submit documentation by mail. A qualified facility would have the option to submit documents in a paper format or in an electronic format on a CD-ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. "Mail" would include the U.S. mail and businesses that can deliver documents to the address provided. We

would recommend that an owner, operator or agent in charge of a qualified facility submit by mail only if the qualified facility does not have reasonable access to the Internet. It is not efficient for FDA to receive such documents by mail.

We are not proposing to provide for submission by fax. We expect that there may be technical difficulties or loss or mix-up of some submitted information if we were to allow for submission by fax.

In section XIII.A.5 of this document, we discuss the information that would be submitted.

4. Proposed § 110.201(c)--Frequency of Submission

Proposed § 110.201(c)(1) would require that the documentation that would be required by section § 110.201(a) be submitted to FDA initially within 90 days of the applicable compliance date of the rule. As discussed in section VII of this document, the compliance date for a small business would be six months after the effective date of the rule and the compliance date for a very small business would be 18 months after the effective date of the rule.

Proposed § 110.201(c)(2) would require that the documentation that would be required by proposed § 110.201(a) also must be resubmitted to FDA at least every two years, or whenever there is a material change to the information that would be described in proposed § 110.201(a). For the purposes of proposed § 110.201, a material change would be one that changes whether or not a facility is a "qualified facility." The status of a facility as a qualified facility has the potential to change materially on an annual basis. For example, if a facility reports that it is a very small business (i.e., under proposed § 110.3, is less than $250,000 in total annual sales of food, adjusted for inflation), its total annual sales of food likely would change on an annual basis, and could change so as to exceed $ 250,000. Likewise, if a facility reports that it otherwise satisfies the definition of a qualified facility, its total annual sales of food and value of

food sold to qualified end users as compared to other purchasers likely would change on an annual basis, and could change so as to no longer satisfy the definition of a qualified facility.

5. Information That Would Be Submitted

Consistent with section 418(l)(2)(B)(ii) of the FD&C Act, we intend to issue guidance regarding documentation that would be submitted under proposed § 110.201(a)(1) to demonstrate that a facility is a qualified facility. As discussed in sections XIII.A.2.a and XIII.A.2.b of this document, we tentatively conclude that certified statements from the owner, operator, or agent in charge of a qualified facility would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 110.201(a)(1) and (2).

To inform the guidance required under section 418(l)(2)(B)(ii) of the FD&C Act and any other guidance that may be useful in addressing questions regarding submission of documentation under this subpart, in this document we request comment on an option we are considering regarding the submission of documentation. Specifically, we request comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility. A facility that does not identify itself as a qualified facility would not be prompted to provide additional information under proposed § 110.201(a).

A facility that identifies itself as a qualified facility would be prompted to provide the following information by checking items that apply. Such items could include:

- Whether the facility satisfies the conditions for a qualified facility:
    - As a very small business as that term would be defined in proposed § 110.3;

- As a facility that otherwise satisfies the definition of qualified facility in proposed § 110.3 based on average monetary value of sales and value of food sold to qualified end users as compared to other purchasers; or
- Both of the above.

- Whether the facility :
  - Has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective;
  - Is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries; or
  - Both of the above.

In essence, such a system would provide for self-certification that the facility has appropriate information demonstrating that the facility is a qualified facility and either has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Such a system may include a statement reminding submitters that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. Using such a system, a qualified facility could update the documentation required by proposed § 110.201(a) during the biennial registration required by section 415(a)(3) of the FD&C Act.

6. Proposed § 110.201(d)--Notification to Consumers

Proposed § 110.201(d) would require that a qualified facility that does not submit the type of documentation directed to food safety practices described in § 110.201(a)(2)(i) provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) consistent with section 418(l)(7) of the FD&C Act. If a food packaging label is required, proposed § 110.201(d)(1) would require that the required notification appear prominently and conspicuously on the label of the food. If a food packaging label is not required, proposed § 110.201(d)(2) would require that the required notification appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

Proposed § 110.201(d) would enable consumers to contact the facility where a food was manufactured or processed (e.g., if the consumer identifies or suspects a food safety problem with a product) irrespective of whether the food product bears a label. The use of the term "business address" in section 418(l)(7) of the FD&C Act contrasts with Congress' use of a different term, "place of business," in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. Our regulations interpret "place of business" as requiring only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 C.F.R. 101.5(d)). We tentatively conclude that the use of the

term “business address” in section 418(l)(7) demonstrates Congress’ intent to require the facility’s full address, including the street address or P.O. box, to appear on labels or other required notifications when the facility has opted to not submit documentation directed to food safety practices under section 418(l)(2)(B)(i)(I) of the FD&C Act. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the “place of business” labeling regulation (§ 101.5(d)) to be adequate for notification to consumers for foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 418(l)(7) for the facility’s “business address” to appear on the food label. Requiring the complete business address for this purpose is consistent with our guidance to industry on the labeling of dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Ref. to 2009 guidance). When proposed § 110.201(d) would apply to a food for which a food packaging label is required under any other provision of the FD&C Act, the complete business address would substitute for the “place of business” required under section 403(e)(1) of the FD&C Act and 21 C.F.R. 101.5(d) and would not impose any requirement for a label that would be in addition to any label required under any other provision of the FD&C Act.

7. Records

Proposed § 110.201(e)(1) would require that a qualified facility maintain records relied upon to support the documentation that would be required by § 110.201(a). Proposed § 110.201(a) would not require that a qualified facility establish any new records, but merely retain those that the facility relied upon to support the documentation that would required by proposed § 110.201(a). Proposed § 110.201(e)(2) would establish that the records that a qualified facility must maintain are subject to the requirements of subpart F of part 110. As discussed in section

XV of this document, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by part 110, including provisions for retention of records and for making records available for official review. Together, proposed § 110.201(a) and (b) would make the underlying records qualified facilities would rely on to support their self-certifications available to FDA upon request. We tentatively conclude that it is appropriate to require that the records relied upon to support a self-certified statement be retained and made available to FDA upon request.

B. Proposed § 110.206--Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Briefly, as relevant to proposed § 110.206, specific provisions of section 418 of the FD&C Act require, in relevant part, that the owner, operator, or agent in charge of a facility:

- "[I]dentify and evaluate known or reasonably foreseeable hazards that may be associated with the facility … [and] develop a written analysis of the hazards." (section 418(b) of the FD&C Act);
- "[I]dentify and implement preventive controls … to provide assurances that … hazards identified in the hazard analysis … will be significantly minimized or prevented … [and] the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 [of the FD&C Act] …" (section 418(c) of the FD&C Act);
- "[M]onitor the effectiveness of the preventive controls implemented under [section 418 (c) of the FD&C Act] to provide assurances that the outcomes described in [section 418 (c)] shall be achieved." (section 418(d) of the FD&C Act);

- "[E]stablish procedures to ensure that, if the preventive controls implemented under [section 418(c) of the FD&C Act] are not properly implemented or are found to be ineffective … appropriate action is taken to reduce the likelihood of recurrence of the implementation failure; … all affected food is evaluated for safety; and … all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 [of the FD&C Act] …" (section 418(e) of the FD&C Act);

- "[V]erify that … the preventive controls … are adequate to control the hazards … the owner, operator, or agent is conducting monitoring … [and] is making appropriate decisions about corrective actions … [and] the preventive controls … are effectively and significantly minimizing or preventing the occurrence of identified hazards … [and] there is documented, periodic reanalysis of the plan under [section 418(i) of the FD&C Act] to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats." (section 418(f) of the FD&C Act);

- "[M]aintain, for not less than 2 years, records documenting the monitoring of the preventive controls … instances of nonconformance material to food safety … [and] instances when corrective actions were implemented …" (section 418(g) of the FD&C Act);

- "[P]repare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards … and identifying the preventive controls adopted … to address those hazards." (section 418(h) of the FD&C Act);

- "[C]onduct a reanalysis under [section 418 (b) of the FD&C Act] whenever a significant change is made in the activities conducted at a facility operated by such owner,

operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier." (section 418(i) of the FD&C Act).

In addition to these requirements directed to the owner, operator, or agent in charge of a facility, section 418(m) of the FD&C Act provides, in relevant part, that "[t]he Secretary may, by regulation, exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in ... the storage of packaged foods that are not exposed to the environment."

2. Approach to Modified Requirements under Section 418(m) of the FD&C Act

As discussed in section X.D.4 of this document, proposed § 110.5 would both provide that subpart C does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment (proposed § 110.5(a)) and establish that such a facility is subject to modified requirements in proposed § 110.206 (proposed § 110.5(a)). In the remainder of our discussion of these modified requirements, we refer to "packaged food that is not exposed to the environment" as "unexposed packaged food," and we refer to "unexposed refrigerated packaged food that requires time/temperature control for safety" as "unexposed refrigerated packaged TCS food." As noted in section X.D.2 of this document, we consider "not exposed to the environment" and "unexposed" to mean that the food is in a form that prevents any direct human contact with the food. The modified requirements in proposed § 110.206 would apply to unexposed refrigerated packaged TCS food. In essence, proposed § 110.5 distinguishes between unexposed packaged food and unexposed refrigerated packaged TCS food. This distinction is based on hazards that are reasonably likely to occur during the storage of unexposed refrigerated

packaged TCS food, but are not reasonably likely to occur during the storage of unexposed packaged food that does not require time/temperature control for safety.

When an unexposed packaged food is a refrigerated TCS food, the principal hazard for the unexposed refrigerated packaged TCS food is the potential for the growth of, or toxin production by, microorganisms of public health significance. Information about this hazard for TCS foods in general (i.e., not limited to unexposed packaged food) is widely available (Ref. Food Code Chapter 1 and Annex 3, Chapter 1; IFT report on PHF). In brief, the need for time/temperature control is primarily determined by (1) the potential for contamination with microorganisms of public health significance and (2) the potential for subsequent growth and/or toxin production. Refrigeration has long been used to retard deterioration of the flavor, color, and texture of foods. More importantly, refrigeration helps maintain the microbiological safety of potentially hazardous foods (62 FR 8248; February 24, 1997).

Failure to maintain foods at appropriate temperatures may result in the growth of microorganisms that may have contaminated the foods before, or at the time of, harvest or during processing, handling, or storage. The rate of growth of these microorganisms is reduced as the storage temperature is lowered. Proper refrigeration, therefore, prevents or slows the growth of human pathogens and spoilage microorganisms and reduces the likelihood of foodborne illness (62 FR 8248). A review of the factors that influence microbial growth and an analysis of microbial hazards related to time/temperature control of foods for safety can be found in a report (issued by the Institute of Food Technologists (IFT) under contract to FDA) on the Evaluation and Definition of Potentially Hazardous Foods (Ref. IFT 2001 report) (the IFT report). The IFT report describes properties of common food commodities and the microbiological hazards that may occur from consuming particular food commodities, emphasizing microbial concerns that

would be associated with temperature abuse of the products. The IFT report discusses foods for which time/temperature control may be necessary for safety (Ref. IFT 2001). Most foods that are stored refrigerated have not been processed to eliminate pathogenic sporeformers, including Clostridium botulinum, Bacillus cereus and C. perfringens. If refrigerated foods are exposed to high enough temperatures for sufficient time, these sporeformers may begin to grow and produce toxins. Some strains of C. botulinum and B. cereus can grow at refrigeration temperatures, e.g., some strains of B. cereus grow at 39ºF (4ºC) and some strains of C. botulinum grow at 38ºF (3.3ºC) (Ref. FDA Seafood Hazards and Controls Guide, Appendix 4).

Examples of refrigerated foods that are capable of supporting the growth of pathogenic sporeformers such as B. cereus, C. botulinum and C. perfringens include many prepared soups, filled pastas, and sauces. In addition, some foods may be contaminated with L. monocytogenes, which, as described in section II.D.2.a, can also grow at refrigeration temperatures. Examples of foods that support the growth of L. monocytogenes include milk and soft cheese. Producers of refrigerated foods minimize the contamination of foods with pathogens to the extent possible, particularly if the pathogen can grow under refrigeration conditions. Growth of pathogens is very slow under refrigeration, and the lower the temperature the longer the time for growth (Ref. IFT 2001). Conversely, as refrigeration temperature increases, the growth rate of strains of pathogens that grow slowly under refrigeration increases and food temperatures may get high enough that pathogens that cannot grow at normal refrigeration temperatures (generally in the range of 41-45ºF (5ºC-7ºC)) begin to grow (Ref. IFT 2001). For example, the strains of C. botulinum that have caused most of the outbreaks in the United States do not grow and produce toxin until the temperature reaches 50ºF (10ºC) (Ref. FDA seafood hazards guide). Additional information about the time/temperature control of food to address the potential for

microorganisms of public health significance to grow or produce toxins is available in books on food microbiology that are available for purchase.

Such information is sufficiently well-known and accepted that we tentatively conclude that the outcome of each individual hazard analysis for an unexposed refrigerated packaged TCS food, conducted by the owner, operator, or agent in charge of each individual facility solely engaged in the storage of unexposed packaged food, would be the same. That outcome would be that the potential for the growth of, or toxin production by, microorganisms of public health significance is a hazard reasonably likely to occur in any unexposed refrigerated packaged TCS food. Likewise, information about appropriate preventive controls for this hazard is widely available (Ref. Food Code Chapter 3 and Annex 3 Chapter 3). Such information is sufficiently well-known and accepted that we tentatively conclude that the appropriate preventive control selected by each individual facility solely engaged in the storage of unexposed packaged food would be adequate controls on the temperature of any unexposed refrigerated packaged TCS food.

In light of the general recognition of the hazard that is reasonably likely to occur in a refrigerated packaged TCS food and the appropriate preventive control for that hazard, we tentatively conclude that it is appropriate to specify the hazard and appropriate preventive control in the regulation. Under this approach, it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged food to conduct its own hazard analysis and reach its own conclusion about the hazard and the appropriateness of temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. Instead, what would remain for the facility to do to comply with section 418 of the FD&C Act for the activity of storing an unexposed refrigerated packaged TCS

food would be a subset of the requirements for hazard analysis and risk-based preventive controls that would be established in proposed subpart C to implement section 418 of the FD&C Act. None of these requirements would require a qualified individual. This subset of requirements would be to:

- Implement temperature controls (section 418(c) of the FD&C Act);
- Monitor temperature (section 418(d) of the FD&C Act);
- Take appropriate corrective actions when there is a problem with temperature control (section 418(e) of the FD&C Act);
- Conduct applicable verification activities (review of records) (section 418(f) of the FD&C Act); and
- Establish and maintain certain records (section 418(g) of the FD&C Act).

We also tentatively conclude that it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged food to conduct the reanalysis specified in section 418(i) of the FD&C Act with respect to storing an unexposed refrigerated packaged TCS food. As discussed in section XII.G.6 of this document, reanalysis would apply in determining whether to apply any additional preventive controls and in determining whether to update the written plan. Under our approach, it is FDA who has identified the preventive control, and it would be FDA's responsibility, through rulemaking, to require any additional preventive control. Likewise, under our approach, the facility would not be required to develop a food safety plan and, therefore, would not need to update the plan. If, for example, the facility changes its procedures for temperature control, the specific activities that the facility would be required to conduct (monitoring temperature; taking appropriate corrective actions if there is a problem with temperature control; conducting applicable verification activities; and establishing and

maintaining appropriate records) would be adequate to address the change in procedure for temperature control.

3. Proposed § 110.206--Modified Requirements that Apply to a Facility Solely Engaged in the Storage of Packaged Food that Is Not Exposed to the Environment

Proposed § 110.206(a) would require that the owner, operator or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment conduct certain activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. Briefly, those activities would encompass:

- Establishing and implementing temperature controls (proposed § 110.206(a)(1));
- Monitoring the temperature controls (proposed § 110.206(a)(2));
- If there is a problem with the temperature controls for such refrigerated packaged food, taking appropriate corrective actions (proposed § 110.206(a)(3));
- Verifying that temperature controls are consistently implemented (proposed § 110.206(a)(4)); and
- Establishing and maintaining certain records (proposed § 110.206(a)(5)).

More specifically, proposed § 110.206(a)(1) would require that the owner, operator, or agent in charge of a facility subject to proposed § 110.206 establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food. There are two fundamental questions that the owner, operator, or agent in charge of a facility subject to proposed § 110.206 would need to know the answers to in order to comply with proposed § 110.206 for any given unexposed refrigerated packaged food:

- Is the food a TCS food?
- If the food is a TCS food, what is the appropriate temperature for storage of the food?

The two primary ways in which the owner, operator, or agent in charge of a facility subject to proposed § 110.206 can obtain the answers to these questions are: (1) through information provided by the manufacturer, processor, or packer of the food, either in documents exchanged between the parties in the course of business or by label statements placed on the food by the manufacturer, processor, or packer of the food; and (2) through applicable scientific and technical support literature.

As discussed in section X.D.2 of this document, a citizen petition submitted to FDA (Docket No. FDA-2011-P-0561) asserted that facilities work closely with the food manufacturers to understand the conditions and controls that need to be utilized to ensure the quality of the foods they store and distribute and, in many cases, those conditions and controls are formalized in written contracts. If the conditions for storage are not formalized in written contracts or by other means (e.g., through documents of the trade that travel with a food product when it moves within the supply chain), information relevant to safe storage of the food may be provided by the manufacturer, processor, or packer of the food on the food label. For example, in 1997 FDA published guidelines for labeling food that needs refrigeration by consumers due to the potential for the food to be rendered unsafe due to the growth of infectious or toxigenic microorganisms if "temperature abused" (62 FR 8248, February 24, 1997). FDA recommended that foods requiring refrigeration by the consumer for safety be labeled "IMPORTANT Must be Kept Refrigerated to Maintain Safety" (62 FR 8248 at 8251) and that foods that are intended to be refrigerated but that do not pose a safety hazard if temperature abused be labeled more simply – e.g.; "Keep

refrigerated." Such labeling can provide facilities with the information to identify TCS foods. We tentatively conclude that it would be rare for a facility solely engaged in the storage of unexposed packaged food to not have information regarding whether a refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food. We request comment on this tentative conclusion.

In a situation where the owner, operator or agent in charge of a facility does not have information from the manufacturer, processor, or packer of the food about whether an unexposed refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food, the owner, operator, or agent in charge of the facility could either consult the scientific and technical literature to determine whether a particular food is a TCS food or assume that any unexposed refrigerated packaged food is a TCS food. Information about foods that are TCS foods, and about the appropriate temperatures to address the potential for microorganisms of public health significance to grow, or produce toxin, in food are well-established in the scientific literature. Documents prepared by or on behalf of FDA regarding appropriate time/temperature controls for safety (Refs. to Food Code Annex 3, Chapter 3; Seafood Hazards Guide Appendix 4; and IFT 2001 report) provide numerous references to the primary scientific literature and serve as the basis for time/temperature controls for a variety of foods. The two temperatures commonly cited in these documents as maximum temperatures for safe storage of refrigerated food are 41 ºF (5 ºC) and 45 ºF (7 ºC). The cited maximum temperature depends on the food; in some cases, a maximum storage temperature is established through rulemaking in a regulation. For example:

- Our regulations for the prevention of Salmonella Enteritidis in shell eggs during production, storage, and transportation (§ 118.4(e)) and for refrigeration of shell eggs held for

retail distribution (§ 115.50(b)(2)) require that eggs be held and transported at a temperature not to exceed 45ºF (7ºC).

- The PMO provides for pasteurized Grade "A" milk and milk products to be held at 45ºF (7ºC) (Ref FDA PMO).

- The FDA Food Code, which has been widely adopted in state laws, recommends holding most potentially hazardous (TCS) food at 41ºF (7ºC) or lower (Ref. Food Code, Chapter 3).

Storage of refrigerated food at or below one of these two temperatures (i.e., 41 ºF (5 ºC) or 45 ºF (7 ºC)) consistent with storage temperatures required by regulation or recommended in widely adopted documents such as the PMO and the FDA Food Code would satisfy proposed § 110.206(a).

We consider frozen food to be a subset of refrigerated food. The temperature and time required for a frozen food to become unsafe would result in significant quality issues for such food. Although there have been occasional problems with frozen food being subject to temperatures that allow some thawing in storage and distribution with frozen food, we are not aware of situations in which frozen foods have been associated with the food becoming unsafe. Thus, we tentatively conclude that it would be rare for an unexposed frozen packaged food to be a TCS food.

Proposed § 110.206(a)(2) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food monitor the temperature controls established for unexposed refrigerated packaged TCS food with sufficient frequency to provide assurance that they are consistently performed. Monitoring can be done by use of a continuous temperature-recording device (e.g., a recording thermometer) that indicates and

records the temperature accurately within the refrigeration compartment with a visual check of the recorded data at least once per day. Monitoring as would be required by proposed § 110.206(a)(2) would provide the owner, operator, or agent in charge of the facility with factual information with which to judge whether the temperature control is operating as intended. Proposed § 110.206(a)(2) is modified relative to the analogous monitoring requirement that would be established in proposed § 110.140(a) in subpart C in that proposed § 110.206(a)(2) would not require written procedures for monitoring. The records of monitoring (which would be required by proposed § 110.206(a)(5)(i)) would demonstrate the frequency of monitoring. We request comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

Proposed § 110.206(a)(3) would require that, if there is a problem with the temperature controls for unexposed refrigerated packaged TCS food, the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food take appropriate corrective actions to correct a problem with the control of temperature for any refrigerated packaged food and reduce the likelihood that the problem will recur (proposed § 110.206(a)(3)(i)); evaluate all affected food for safety (proposed § 110.206(a)(3)(ii)); and prevent the food from entering commerce, if the owner, operator, or agent in charge of a facility cannot ensure the affected food is not adulterated under section 402 of the FD&C Act (proposed § 110.206(a)(3)(iii)). Such corrective actions would be necessary if, for example, there was a failure to maintain adequate temperature control. Proposed § 110.206(a)(3) is modified relative to the analogous proposed requirement for corrective actions that would be established in proposed § 110.145(a) in subpart C in that proposed § 110.206(a)(3) would not require written procedures for corrective actions. In essence, there is a single action to correct the problem (i.e.,

to restore temperature control), followed by the need to evaluate the food for safety and to prevent food from entering commerce when appropriate. The corrective actions taken, including information to document that product was not exposed to temperatures and times that would compromise the safety of the product, would be documented in records subject to agency review. It may be necessary for the owner, operator, or agent in charge of the facility to consult with the applicable manufacturer, processor, or packer of the food to determine the appropriate disposition of the food.

Proposed § 110.206(a)(4)(i) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food verify that temperature controls are consistently implemented by calibrating temperature monitoring and recording devices. As discussed in section XII.G.5.b of this document, calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance temperatures are adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food. Proposed § 110.206(a)(4)(i) is analogous to proposed § 110.150(d)(2) in subpart C, which would establish a verification requirement for calibration of process monitoring instruments and verification instruments.

Proposed § 110.206(a)(4)(ii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food verify that temperature controls are consistently implemented by reviewing records of calibration within a reasonable time after the records are made. As discussed in section XII.G.5.f of this document, the purpose of the review of records would be to ensure that the records are complete and that the preventive

controls are effective. If temperature monitoring and recording devices are not properly calibrated, the temperature controls may not be effective. As discussed in section XII.G.5.f of this document, the review of calibration records will depend in part on the frequency with which calibrations occur.

Proposed § 110.206(a)(4)(iii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food verify that temperature controls are consistently implemented by reviewing the records of monitoring and actions taken to correct a problem with the control of temperature within a week after the records are made. As discussed in section XII.G.5.f of this document, the purpose of the review of records would be to ensure that the records are complete, that the temperatures recorded were adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food, and that appropriate actions were taken to correct any problem with the control of temperature for any unexposed refrigerated packaged TCS food. A weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records. Proposed § 110.206(a)(4)(iii) is analogous to proposed § 110.150(d)(5)(ii) in subpart C, which would establish a verification requirement for review of records of monitoring and corrective action records within a week after the records are made.

Proposed § 110.206(a)(4) is modified relative to the analogous proposed verification requirements in proposed § 110.150 in that proposed § 110.206(a)(4) would not require validation, review of consumer, customer or other complaints, product testing, or reanalysis. There is a single control to verify, which limits the need for many of the verification procedures

that might otherwise apply. As noted above, the temperatures to control growth of microbial pathogens are well documented and do not require validation that they are effective in controlling the potential for microorganisms of public health significance to grow, or produce toxin, in food. Under § 101.5, complaints would go to the manufacturer, packer, or distributor of food as identified on the label of the food rather than to a warehouse solely engaged in storage of the food. .Product testing is not a useful verification procedure for this control measure since monitoring provides sufficient information that microbial growth is being controlled. The reasons for not requiring reanalysis were discussed in section XIII.B.2. Proposed § 110.206(a)(4) also is modified relative to the analogous proposed verification requirements in proposed § 110.150 in that proposed § 110.206(a)(4) would not require that a qualified individual perform or oversee the review of records of calibration or records of monitoring and actions taken to correct a problem with the control of temperature. The nature of these records does not require the qualifications that would be required under proposed § 110.155(b).

Proposed § 110.206(a)(5) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food establish and maintain records documenting the monitoring of temperature controls for any unexposed refrigerated packaged TCS food (proposed § 110.206(a)(5)(i)); records of corrective actions taken when there is a problem with the control of temperature for any unexposed refrigerated packaged TCS food (proposed § 110.206(a)(5)(ii)); and records documenting verification activities (proposed § 110.206(a)(5)(iii)). The records that document monitoring would be used to verify that the temperature controls are effectively and significantly minimizing or preventing the growth of, or toxin production by, microorganisms of public health significance. The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are

being made and appropriate corrective actions are being taken. The records that document verification activities would be used to document that this key element of a food safety plan has been implemented. These records would be necessary to demonstrate compliance with the requirements and as such would be useful to inspectors and auditors. Proposed § 110.206(a)(5) is analogous to provisions in proposed §§ 110.140(c), 110.145(d), and 110.150(f) in subpart C, which would require documentation of monitoring, corrective actions, and verification activities, respectively.

Proposed § 110.206(b) would establish that the records that a facility must establish and maintain under proposed § 110.206(a)(5) are subject to the requirements of proposed subpart F. Proposed subpart F would establish requirements that would apply to all records that would be required under part 110. We describe the requirements of proposed subpart F in section XV of this document. Proposed § 110.206(b) is analogous to proposed § 110.175(b) in subpart C.

XIV. Subpart E--Withdrawal of an Exemption Applicable to a Qualified Facility

A. Requirements of Section 418 of the FD&C Act

Section 418(l)(3)(A) of the FD&C Act specifies that, "[i]n the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under [section 418(l) of the FD&C Act], or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under [section 418(l) of the FD&C Act]." Section 418 does not expressly prescribe the procedures for withdrawing an exemption provided to a qualified facility under section 418(l). We tentatively conclude that it is appropriate to be transparent

about the process we would use to withdraw an exemption and that we should include the process in the proposed rule.

B. Proposed § 110.251--Circumstances That May Lead FDA to Withdraw an Exemption Applicable to a Qualified Facility

1. Proposed § 110.251(a)--Withdrawal of an Exemption in the Event of an Active Investigation of a Foodborne Illness Outbreak

Proposed § 110.251(a) would provide that FDA may withdraw the exemption that would be applicable to a qualified facility under proposed § 110.2(a) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility. Proposed § 110.251(a) would implement the statutory language of section 418(l)(3)(A) of the FD&C Act. As discussed in section II.A.6.c of this document, an outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. Food can become contaminated at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. When foodborne illness is associated with food, a traceback investigation may enable us to directly link the illness to the facility or facilities that manufactured, processed, packed, and/or held the food.

For example, in February 2007, the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (CDC) notified FDA of a multi-state outbreak of Salmonella Tennessee infections associated with the consumption of peanut butter (73 FR 55115 at 55118, September 24, 2008). Peanut butter is a non-perishable packaged food, sold in jars. Consumers who became ill had open jars of peanut butter available for testing. Investigators were able to test samples of peanut butter taken from the jars and confirm the presence of

Salmonella Tennessee in the peanut butter. Investigators were able to identify the manufacturer through information required to be on the label of the jars (21 CFR 101.5(a)) and through a product code the manufacturer had voluntarily placed on the jars. This information made it possible for FDA to visit the manufacturing facility the day after we learned of the outbreak from CDC. Investigators were able to use the product code to look in the manufacturing facility for unopened jars of peanut butter manufactured at the same time as the jars available from consumers. Investigators took samples of peanut butter from these unopened jars and confirmed the presence of Salmonella Tennessee in those samples. Because investigators uncovered conditions at the manufacturer's facility that were likely to have caused the contamination and obtained a positive environmental sample, investigators saw no need to further trace the peanuts back to the farm where the peanuts were grown (73 FR 55115 at 55118). In circumstances such as the 2007 peanut butter outbreak, the available data and information from the investigation directly linked the outbreak of foodborne illness to the manufacturing facility.

2. Proposed § 110.251(b)--Withdrawal of an Exemption Based on Conduct or Conditions Associated with a Qualified Facility

Proposed § 110.251(b) would provide that FDA may withdraw the exemption applicable to a qualified facility under proposed § 110.2(a) if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. As an example, we may receive reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a qualified facility that manufactured, processed, packed or held the food. If our investigation finds conduct or conditions associated

with the facility that are material to the safety of the food (for example, conduct or conditions that likely led to the contamination of the food), we would consider withdrawing the exemption applicable to the facility under proposed § 110.2(a) if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a qualified facility, we discover conditions and practices that are likely to lead to contamination of food with microorganisms of public health significance, we would consider withdrawing the exemption provided to the facility under proposed § 110.2(a) if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

C. Proposed § 110.254--Issuance of an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 110.254(a) would provide that, if FDA determines that an exemption applicable to a qualified facility under § 110.2(a) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption. We intend to create and maintain a written record of a determination that the withdrawal of an exemption is warranted and to include the basis for the determination in the written record.

Proposed § 110.254(b) would require that an FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption as part of the withdrawal determination procedure before the order is issued. A Regional Food and Drug Director is an example of an FDA official senior to a District Director. The Deputy Director and Director of the Center for Food Safety and Applied Nutrition are examples of an FDA official senior to the Director of the Office of Compliance. Requiring prior approval of a withdrawal order by a

District Director or an FDA official senior to a District Director is consistent with the approval requirement for a detention order in part 1, subpart K (Administrative Detention of Food for Human or Animal Consumption). Requiring prior approval of a withdrawal order by the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition is consistent with current FDA practices when dealing with foreign firms.

Proposed § 110.254(c) would require that FDA issue an order to withdraw the exemption to the owner, operator, or agent in charge of the qualified facility. The requirements of section 418 of the FD&C Act are directed to the owner, operator, or agent in charge of a facility. We tentatively conclude that the statutory language of section 418 enables FDA to issue an exemption withdrawal order to any of these persons.

Proposed § 110.254(d) would require that FDA issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

D. Proposed 110.257--Contents of an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 110.257(a) through (i) would require that an order to withdraw an exemption applicable to a qualified facility under § 110.2(a) include the following information:

- (a) The date of the order (proposed § 110.257(a));
- (b) The name, address and location of the qualified facility (proposed § 110.257(b));
- (c) A brief, general statement of the reasons for the order, including information relevant to:

- (1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or
- (2) Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility (proposed § 110.257(c)).
- (d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order (proposed § 110.257(d));
- (e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E (proposed § 110.257(e));
- (f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter (21 CFR Part 16), with certain exceptions described in proposed § 110.270 (proposed § 110.257(f));
- (g) The mailing address, telephone number, e-mail address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); (proposed § 110.257(g)); and
- (h) The name and the title of the FDA representative who approved the order (proposed § 110.257(i)).

FDA tentatively concludes that the requirements that we propose in § 110.257 would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal with adequate notice of the basis for our determination to withdraw the exemption and of their opportunity to appeal our determination and to request an informal hearing. The proposed

notification procedures are similar to and consistent with the notification requirements in other regulations involving administrative action, such as administrative detention of food under § 1.393 orders for diversion or destruction of shell eggs under the PHS Act under § 118.12(a)(i), and with procedures for an informal hearing in part 16.

E. Proposed § 110.260--Compliance With, or Appeal of, an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 110.260(a) would require that the owner, operator, or agent in charge of a qualified facility that receives an order to withdraw an exemption applicable to that facility under § 110.2(a) either comply with applicable requirements of this part within 60 calendar days of the date of the order; or appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 110.264. We tentatively conclude that either of the two circumstances that could result in our determination that an exemption should be withdrawn (as described in proposed § 110.251) warrant prompt compliance with the rule in the interest of public health. We tentatively conclude that ten calendar days for the submission of an appeal from the date of the receipt of a withdrawal order is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that comes to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 110.260(b) would establish that submission of an appeal, including submission of a request for an informal hearing, will not delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. For example, the submission of an appeal of a withdrawal order with a request for an informal hearing under

proposed § 110.260(b) would not prevent FDA from simultaneously detaining food from the facility under section 304(h) of the FD&C Act, seizing food from the facility under section 304(a) of the FD&C Act, or seeking or enforcing an injunction under section 302 of the FD&C Act.

Proposed § 110.260(c) would require that, if the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order. Proposed § 110.260(c) would make clear that the 60 calendar day time frame for compliance applies regardless of whether the owner, operator, or agent in charge of a facility requests, and FDA grants, a hearing. As already discussed, FDA tentatively concludes that the circumstances that lead to a determination that an exemption should be withdrawn warrant prompt compliance in the interest of public health.

F. Proposed § 110.264--Procedure for Submitting an Appeal

Proposed § 110.264(a) would require that, to appeal an order to withdraw an exemption applicable to a qualified facility under § 110.2(a), the owner, operator, or agent in charge of the facility must (1) submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, e-mail address, or facsimile number identified in the order within 10 calendar days of the date of the order; and (2) respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

Allowing the owner, operator, or agent in charge of the facility to submit an appeal in person, by mail, e-mail, or fax would provide for flexibility as well as speed. For example, submitting in person would give the owner, operator, or agent in charge direct knowledge that the request for appeal had been delivered and received. E-mail and fax are instantaneous, and overnight mail delivery services are readily available to those who choose to use them; however, the ten day time frame for appeal of the order would not require the use of overnight mail delivery. For clarity, proposed § 110.264(a) would repeat the 10 calendar day time frame that would be established in proposed § 110.260(a)(2) and would not establish any new requirement. Any appeal would need to be written in order for FDA to evaluate the basis for the appeal. We are proposing that a written appeal would need to address with particularity all of the issues raised in the withdrawal order and include all supporting documentation so that we would be able to issue a final determination as to the disposition of the appeal solely on the basis of the materials submitted as part of the written appeal.

Proposed § 110.264(b) would provide that, in a written appeal of the order withdrawing an exemption provided under § 110.2(a), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in §110.267. Requesting an informal hearing does not mean that a hearing will be held, because we may deny the request (see discussion of proposed § 110.267(b) in the next section of this document). However, if the owner, operator, or agent in charge of the facility does not request an informal hearing at the time the written appeal is submitted, the owner, operator, or agent in charge of the facility will not be entitled to an informal hearing. Instead, FDA will make a final decision based on the written appeal and its supporting materials.

G. Proposed § 110.267--Procedure for Requesting an Informal Hearing

Proposed § 110.267(a)(1) would provide that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility may request an informal hearing. Proposed § 110.267(a)(1) would restate an option that would be included in proposed § 110.264(b) to highlight the opportunity to request an informal hearing. Proposed § 110.267(a)(2) would require that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility must submit any request for an informal hearing together with its written appeal submitted in accordance with § 110.264 within 10 calendar days of the date of the order. We tentatively conclude that requiring submission of a request for an informal hearing in writing at the time that the owner, operator, or agent in charge of the facility would be required to submit a written appeal is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 110.267(b) would establish that a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. Proposed § 110.267(b) would also provide that if the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial. Under proposed § 110.264(a), a written appeal would be required to respond with particularity to the facts and issues contained in the withdrawal order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies. If the materials submitted do not directly address the facts and issues

contained in the withdrawal order in a manner that suggests that there is a dispute regarding the material facts contained in the order, the presiding officer may determine that an informal hearing is not warranted. The presiding officer may include written notice of the determination that a hearing is not justified as part of the final decision on the appeal.

H. Proposed § 110.270--Requirements Applicable to an Informal Hearing

Proposed § 110.270(a) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, except as provided by proposed § 110.270(b), the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA. We tentatively conclude that, if we grant a request for an informal hearing, holding the hearing within 10 calendar days, or within an alternative time frame as agreed upon in writing, is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed 110.270(b) would establish that the presiding officer may require that a hearing conducted under this subpart E be completed within 1 calendar day, if appropriate. We tentatively conclude that, if we grant a request for an informal hearing, limiting the time for the hearing itself to be completed within 1 calendar day is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 110.270(c)(1) through (7) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, FDA must conduct the hearing in accordance with part 16, except that:

- (1) The order withdrawing an exemption under §§ 110.254 and 110.257, rather than the notice under § 16.22(a), provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.
- (2) A request for a hearing under this subpart E must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.
- (3) Section 110.274, rather than § 16.42(a), describes the FDA employees who preside at hearings under this subpart.
- (4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.
- (5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer’s report of the hearing and any comments on the report by the hearing participant under § 110.270(c)(4) are part of the administrative record.

- (6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

- (7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 110.270(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

Under § 16.1(b), the procedures in part 16 apply when a regulation provides a person with an opportunity for a hearing on a regulatory action under part 16. Section 418 of the FD&C Act does not expressly provide for a hearing if circumstances lead FDA to determine that an exemption provided to a qualified facility under proposed § 110.2(a) should be withdrawn. However, we tentatively conclude as a matter of agency discretion that providing an opportunity for a hearing by regulation in this subpart of the proposed rule would provide appropriate process to the owner, operator, or agent in charge of a qualified facility subject to withdrawal of the facility's exemption. We also tentatively conclude that the modified part 16 procedures contained in this proposed rule would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order sufficient fairness and due process while enabling FDA to expeditiously adjudicate an appeal of a withdrawal order for which an informal hearing has been granted.

Section 16.119 provides that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35. Proposed § 110.270(c)(6) would specify that these procedures for reconsideration and stay would not apply to the process of withdrawing an exemption provided under proposed § 110.2(a). The circumstances that may lead FDA to withdraw an exemption include an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility, or our determination that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. Such circumstances require prompt action. Under § 16.120, a qualified facility that disagrees with FDA's decision to withdraw an exemption provided under § 110.2(a) has an opportunity for judicial review in accordance with § 10.45.

I. Proposed § 110.274--Presiding Officer for an Appeal and for an Informal Hearing

Proposed § 110.274 would require that the presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director. Under § 16.42(b), an officer presiding over an informal hearing is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action. An order for the withdrawal of an exemption applicable to a qualified facility must be approved by a District Director or an official senior to a District Director. It is therefore necessary that appeals of a decision to issue a withdrawal order should be handled by persons in positions senior to the District Directors. The

Regional Food and Drug Director is such a person and could be from the same region where the facility is located, provided that the Regional Food and Drug Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice. Alternatively, the Regional Food and Drug Director could be from a different region than the region where the facility is located, for example in the event the Regional Food and Drug Director for the region in which the facility is located is the FDA official who approved the withdrawal order. Any Office Director of FDA's Office of Regulatory Affairs could preside at a hearing, provided that the Office Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice.

J. Proposed § 110.277--Time Frame for Issuing a Decision on an Appeal

Proposed § 110.277(a) would require that, if the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed. Under proposed § 110.251, FDA would issue a withdrawal order either in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility or if we determine that an exemption withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food located at the facility. We tentatively conclude that we will need 10 calendar days to review the written appeal and the materials submitted with the written appeal, and that a final decision confirming or revoking a withdrawal order should be issued as quickly as possible in the interest of the public health and to provide reasonable due process that would come to closure sufficiently in

advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 110.277(b)(1) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and, if FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 110.270(c)(4), and must issue a final decision within the 10-calendar day period after the hearing is held. We tentatively conclude that it is appropriate to grant the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order the opportunity to review and submit comments to the presiding officer's report because the report is part of the record of a final agency action (see discussion of proposed § 110.284 in section XIV.L of this document) that is not subject to further reconsideration by FDA. The presiding officer would have discretion to determine whether to revise the report of the hearing in light of any comments that might be submitted by any of the hearing participants.

Proposed § 110.277(b)(2) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and if FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed. We tentatively conclude that ten calendar days for the presiding officer to issue a final decision is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order, would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal, and is in the interest of public health.

K. Proposed § 110.280--Revocation of an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 110.280(a) through (c) would establish that an order to withdraw an exemption applicable to a qualified facility under § 110.2(a) is revoked if:

- (a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or
- (b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or
- (c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

We tentatively conclude that an order to withdraw an exemption may be revoked in one of two manners. First, we are proposing that the FDA officer responsible for adjudicating the appeal and presiding over a hearing, if one is granted, may expressly issue a written decision revoking the order within the specified 10 calendar day time frames. Second, we are proposing that the failure of the FDA officer responsible for adjudicating an appeal to issue a final decision expressly confirming the order within the specified time frames will also serve to revoke the order. We tentatively conclude that fairness would warrant the revocation of a withdrawal order if FDA is unable to meet the proposed deadlines for expressly confirming an order.

L. Proposed § 110.284--Final Agency Action

Proposed § 110.284 would establish that confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of section 702 of title 5 of the United States Code (5 U.S.C. 702). A confirmation of an order withdrawing an exemption therefore would be reviewable by the courts under section 702 of title 5 and in accordance with § 10.45 (21 CFR § 10.45).

M. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(2) to include part 110, subpart E, relating to the withdrawal of an exemption applicable to a qualified facility, to the list of regulatory provisions under which regulatory hearings are available.

XV. Proposed Subpart F--Requirements Applying to Records That Must Be Established and Maintained

A. Relevant Statutory Provisions

FDA is proposing to create a new Subpart F to establish requirements applying to records that must be established and maintained according to the requirements of this proposed rule. As discussed in section XII.J of this document, section 418 of the FD&C Act prescribes several requirements relevant to recordkeeping. The statutory provisions that are most relevant to proposed subpart F are:

- Section 418(a) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility "maintain records of [monitoring the performance of preventive controls] as a matter of routine practice";
- Section 418(b)(3) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility "develop a written analysis of the hazards";

- Section 418(g) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain certain records for not less than 2 years. The records identified in section 418(g) include "records documenting the monitoring of the preventive controls implemented under [section 418(c) of the FD&C Act], instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under [section 418(f)(4) of the FD&C Act], instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions"; and

- Section 418(h) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility "prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section…" and that "[s]uch written plan, together with documentation described in [section 418(g) of the FD&C Act], shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request";

- Section 418(n)(1)(A) of the FD&C Act, which provides, in relevant part, that FDA shall "promulgate regulations…to establish science-based minimum standards for… documenting hazards… and documenting the implementation of the preventive controls under this section";

- Section 402(a)(4) of the FD&C Act, which provides that food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"

- Section 701(a) of the FD&C Act [21 U.S.C. 371(a)], which provides FDA with authority to promulgate regulations "for the efficient enforcement of [the FD&C Act]"; and

- Section 361(a) of the Public Health Service Act [42 U.S.C. 264(a)], which provides FDA with authority to "make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."

- Section 418(l)(2)(B) of the FD&C Act, which requires a qualified facility to submit documentation to the Secretary related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws.

B. Proposed § 110.301 - Records Subject to the Requirements of this Subpart F

Proposed § 110.301(a) would establish that, except as provided by proposed § 110.301(b) and (c), all records required by part 110 would be subject to all requirements of proposed subpart F. FDA tentatively concludes that the requirements in subpart F describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts aid plants and facilities in compliance with the requirements of part 110; and allow plants and facilities to show, and FDA to determine, compliance with the requirements of part 110.

Proposed § 110.301(b) would establish that the requirements of proposed § 110.310 apply only to the written food safety plan and is discussed in more detail in Part D of this section.

Proposed § 110.301(c) would provide that the requirements of § 110.305(b), (d), (e), and (f) do not apply to the records required by § 110.201(e). As discussed in section XIII.A.7 of this

document, proposed § 110.201(e) would require that a qualified facility maintain records relied upon to support the self-certification that would be required by § 110.201(a). Such documentation would be directed to the financial basis (and, when applicable, percentage of sales to qualified end users) as well as to food safety practices at the qualified facility, and could range from invoices to a food safety plan to an operating license issued by a state or local authority. Such records would not be expected to satisfy the provisions of proposed § 110.305(b), (d), (e), and (f) (which we discuss in the next section of this document). To make clear that a qualified facility need not comply with provisions that do not apply to its records, we are proposing to specify that those provisions do not apply to such records.

C. Proposed § 110.305--General Requirements Applying to Records

Proposed § 110.305 contains general requirements that would apply to records that would be required under part 110, including the format for required records, the recording of actual values and observations obtained during monitoring, when records must be created, and information that must be included in each record.

1. Proposed § 110.305(a)

Proposed § 110.305(a) would require that the records be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. True copies of records should be of sufficient quality to detect whether the original record was changed or corrected in a manner that obscured the original entry (e.g., through the use of white-out). Proposed § 110.305(a) would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system. The proposed requirement allowing true copies is consistent with other regulations such as our Good Manufacturing Practices (GMPs) regulation for dietary

supplements (§ 111.605(b)) and provides options that may be compatible with the way records are currently being kept in plants and facilities.

Proposed § 110.305(a) also would require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by part 110 may be retained electronically, provided that they comply with part 11..

FDA tentatively concludes that it is appropriate to apply the requirements of part 11 to the records that would be required to be kept under part 110. However, we request comment on whether there are any circumstances that would warrant not applying part 11 to records that would be kept under part 110. For example, would a requirement that electronic records be kept according to part 11 mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which we determined to be the case in the regulation Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (69 FR 71562; December 9, 2004 (the BT records regulation)) For the purposes of the records requirements in the BT records regulation, we concluded that it was not necessary for new recordkeeping systems to be established as long as current practices would satisfy the requirements of the Act and, therefore, we exempted the records from the requirements of part 11 (21 CFR § 1.329(b)). We also exempted records related to certain cattle materials prohibited from use in human food and cosmetics from part 11 (21 CFR §§ 189.5(c)(7) and 700.27(c)(7), respectively). We also seek comment on whether we should allow additional time for electronic records to be kept in accordance with part 11.

Comments should provide the basis for any view that the requirements of part 11 are not warranted.

2. Proposed § 110.305(b)

Proposed § 110.305(b) would require that records contain the actual values and observations obtained during monitoring. It is neither possible to derive the full benefits of a preventive controls system, nor to verify the operation of the system, without recording actual values and observations to produce an accurate record. Notations that monitoring measurements, such as heat treatment temperatures, are ‘‘satisfactory’’ or ‘‘unsatisfactory,’’ without recording the actual times and temperatures, are vague and subject to varying interpretations and, thus, will not ensure that controls are working properly. In addition, it is not possible to discern a trend toward loss of control without actual measurement values. Proposed § 110.305(b) is consistent with our HACCP regulations for seafood and juice, specifically § 123.6(c)(7) and §120.12(b)(4), respectively. In addition, our HACCP regulation for juice also requires that records documenting the monitoring of critical control points and their critical limits include recording of actual times, temperatures, or other measurements (§ 120.12(a)(4)(i)).

3. Proposed § 110.305(c), (d) and (e)

Proposed § 110.305(c), (d) and (e) would require that records be accurate, indelible, and legible (proposed § 110.305(c)); be created concurrently with performance of the activity documented (proposed § 110.305(d)); and be as detailed as necessary to provide a history of work performed (proposed § 110.305(e)). Proposed § 110.305(c) and (d) would ensure that the records are useful to the owner, operator, or agent in charge of a plant or facility in complying with the requirements of part 110, for example, in documenting compliance with monitoring requirements and verifying compliance with the food safety plan. These proposed requirements

would also ensure that the records would be useful to FDA in determining compliance with the requirements of part 110. Proposed § 110.305(e) would provide flexibility to plants and facilities to tailor the amount of detail to the nature of the record. These proposed requirements are consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and our HACCP regulations for seafood and juice. Consistent with the definition of "monitor" in proposed § 110.3, the NACMCF guidelines assert that monitoring is a planned sequence of observations or measurements to not only assess whether a CCP is under control but to also produce an accurate record for future use in verification (Ref. NACMCF). The Codex guidelines advise that efficient and accurate record keeping is essential to the application of a HACCP system (Ref. CODEX). Our HACCP regulations for seafood and juice require that processing and other information be entered on records at the time that it is observed (§§ 123.9(a)(4) and 120.12 (b)(4), respectively).

4. Proposed § 110.305(f)

Proposed § 110.305(f) would require that the records include (1) the name and location of the plant or facility; (2) the date and time of the activity documented; (3) the signature or initials of the person performing the activity; and (4) where appropriate, the identity of the product and the production code, if any. The name and location of the plant or facility and the date and time would allow the owner, operator, or agent in charge of a plant or facility (and, during inspection, an FDA investigator) to assess whether the record is current, to identify when and where any deviation occurred, and to track corrective actions. The signature of the individual who made the observation would ensure responsibility and accountability. In addition, if there is a question about the record, a signature would ensure that the source of the record will be known. Linking a record to a specific product (and, when applicable, the production code) would enable the owner,

operator, or agent in charge of a facility to isolate product that has not been processed properly when there has been a problem, thereby limiting the impact of the problem (such as the need to reprocess product or to recall product) to only those lots with the problem.

Proposed § 110.305(f) is consistent with the NACMCF HACCP guidelines and our HACCP regulations for seafood and juice. The NACMCF HACCP guidelines recommend that all records and documents associated with CCP monitoring be dated and signed or initialed by the person doing the monitoring (Ref. NACMCF). Our HACCP regulations for seafood and juice require that all records include the name and location of the processor; the date and time of the activity that the record reflects; the signature or initials of the person performing the operation; and where appropriate, the identity of the product and the production code, if any (§§ 123.9(a) and 120.12 (b), respectively).

D. Proposed § 110.310--Additional Requirements Applying to the Food Safety Plan

Proposed § 110.310 would require that the owner, operator, or agent in charge of a facility sign and date the food safety plan upon initial completion (proposed § 110.310 (a)) and upon any modification (proposed § 110.310(b)). Such a signature would provide direct evidence of the owner, operator, or agent's acceptance of the plan and commitment to implementation of the plan. Additionally, the signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist. The proposed requirement for signing and dating is consistent with our HACCP regulations for seafood and juice, which require that the HACCP plan be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor and be dated and signed upon initial acceptance; upon any modification; and upon

verification of the plan (for seafood) or upon verification and validation (for juice) (§§ 123.6(d) and 120.12 (c) for seafood and juice, respectively).

E. Proposed § 110.315--Requirements for Record Retention

Proposed § 110.315 contains requirements on the length of time records that would be required under part 110 must be retained and allowances for offsite storage of records under certain circumstances.

1. Proposed § 110.315(a) and (b)

Proposed § 110.315(a) would require that all records that would be required by part 110 be retained at the plant or facility for at least 2 years after the date they were prepared. Proposed § 110.315(b) would require that records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 110.126) or records that document validation of the written food safety plan (§ 110.150(a)). Proposed § 110.315(a) and (b) implement subsection 418(g) of the FD&C Act, which requires certain records to be maintained for not less than 2 years. The 2-year timeframe for all records required by part 110 is consistent with the length of time that nonperishable food products, on average, can be expected to be in commercial distribution plus a reasonable time thereafter to ensure that the records are available for verification activities. As we noted in the proposed BT records regulation (68 FR 25188 at 25198; May 9, 2003), according to information provided to FDA by the food industry, the minimum time for processed food products to clear the food production and distribution/retail system is 3 years. In addition, the average distribution time between harvesting and final retail sale of frozen fruits and vegetables is approximately 3 to 24 months (68 FR 25188 at 25198). In

the final BT records regulation, we concluded that 2 years was the minimum time records related to nonperishable foods for the purpose of identifying immediate previous sources and immediate subsequent recipients should be kept (69 FR 71561 at 71602-3; December 9, 2004). The 2-year record retention requirement is also consistent with our HACCP regulations for seafood and juice, which both require that records be retained for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products (§§ 123.9(b)(1) and 120.12(d)(1), respectively); and with the requirement in the seafood HACCP regulation that records relating to the general adequacy of equipment or processes, including scientific studies and evaluations, be retained for at least 2 years after their applicability to the product being produced at the facility (§ 123.9(b)(2)). While FDA established shorter records retention requirements for records related to perishable foods in the BT records, seafood HACCP, and juice HACCP regulations, in this case Congress determined and specified in section 418(g) of the FD&C Act that the minimum retention period for the majority of the records required under part 110 for all foods, regardless of perishability, is 2 years. Therefore, FDA tentatively concludes that the same requirement should apply to all records required under this section, regardless of the perishability of the food to which the record relates. This would simplify plants' or facilities' duties in compliance because there would only be one 2-year retention period to apply to any record required under part 110. This 2-year retention period would run either from the date the record was prepared, for day-to-day operational records; or from the date at which use of the record is discontinued, for records relating to the general adequacy or equipment or processes (e.g., the written food safety plan and records that document validation of the written food safety plan).

2. Proposed § 110.315(c)

Proposed § 110.315(c) would provide that, except for the food safety plan, use of offsite storage for records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan would be required to remain onsite. FDA realizes that the proposed requirements for recordkeeping could require some plants or facilities to store a significant quantity of records, and that there may not be adequate storage space in the plant or facility for all of these records. Providing for offsite storage of most records after 6 months would enable a facility to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available.

Proposed § 110.315(c) also would provide that electronic records are considered to be onsite if they are accessible from an onsite location. Computerized systems within corporations can be networked, allowing for the sending and receiving of information in a secure fashion to all of the different food processing facilities of that corporation worldwide. This type of system can be used to provide access at multiple locations to records from multiple plants or facilities.

Proposed § 110.315(c) is consistent with our HACCP regulations for seafood and juice. Our HACCP regulation for seafood provides for transfer of records if record storage capacity is limited on a processing vessel or at a remote processing site, if the records could be immediately returned for official review upon request (§ 123.9(b)(3)). Our HACCP regulation for juice permits offsite storage of processing records after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of

request for official review and considers electronic records to be onsite if they are accessible from an onsite location (§ 120.12(d)(2)).

3. Proposed § 110.315(d)

Proposed § 110.315(d) would provide that if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request. Allowing for transfer of records will give practical storage relief to seasonal operations or those closed for other reasons for prolonged periods. Proposed § 110.315(d) is consistent with our HACCP regulations for seafood and juice, which provide for transfer of records for facilities closed for prolonged periods (between seasonal packs, in the case of juice) if the records could be immediately returned for official review upon request (§ 123.9(b)(3) and 120.12(d)(3) for seafood and juice, respectively).

F. Proposed § 110.320--Requirements for Official Review

Proposed § 110.320 would require that all records required by part 110 be made promptly available to FDA upon oral or written request. Proposed § 110.320 implements subsection 418(h) of the FD&C Act and is necessary in order for FDA to determine compliance with the requirements of part 110. Proposed § 110.320 is consistent with our HACCP regulations for seafood and juice, which require that all records required under those rulemakings be available for review and copying at reasonable times (§§ 123.9(c) and 120.12(e), respectively).

Proposed § 110.320 does not explicitly require a facility to send records to the agency rather than making the records available for review at a facility's place of business. FDA requests comment on whether proposed § 110.320 should be modified to explicitly address this circumstance, and if so, whether FDA should require that the records be submitted electronically.

Obtaining a facility's food safety plan without going to a facility could be useful to FDA in a number of different circumstances, such as to determine whether a recently identified hazard is being addressed by affected facilities.

G. Proposed § 110.325--Public Disclosure

Proposed § 110.325 would establish that all records required by part 110 are subject to the disclosure requirements under part 20 of this chapter. FDA's regulations in 21 CFR part 20, the Freedom of Information Act (FOIA) [5 U.S.C. 552], the Trade Secrets Act [18 U.S.C. 1905], and the FD&C Act govern FDA's disclosures of information, including treatment of commercial confidential information (CCI) and trade secret information. Our general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule.

Proposed § 110.325 is consistent with, but framed differently than, the disclosure provisions of the HACCP regulations for seafood and juice (§§123.9(d) and 120.12(f), respectively). Proposed § 110.325 is framed similarly to the disclosure provisions for records that must be kept under part 118 (Prevention of Salmonella Enteritidis in Shell Eggs During Production) (the shell egg production rule). Under § 118.10(f), records required by part 118 are subject to the disclosure requirements under part 20.

XVI. FSMA's Rulemaking Provisions

A. Content (Requirements in Section 418(n)(3) of the FD&C Act

1. Requirements of section 418 of the FD&C Act

Section 418(n)(3) of the FD&C Act specifies that the regulations promulgated under section 418(n)(1)(A) shall:

- "(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm;"
- "(B) comply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the facility, and collection of information (as defined in section 3502(3) of such Act), associated with such regulations;"
- "(C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and"
- "(D) not require a facility to hire a consultant or other third party to identify, implement, certify, or audit prevent[ive] controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party."

2. Section 418(n)(3)(A)

Implementing section 418 through this proposed rule would provide sufficient flexibility to be practicable for all sizes and types of facilities. As discussed in section II.C of this document, subpart C of the proposed rule (and related requirements) are consistent with HACCP principles. Like HACCP, the preventive controls system proposed in this document would provide flexibility for facilities to tailor their food safety plans to their specific foods and operating conditions. This proposal would allow facilities to establish only those preventive controls that are applicable to their circumstances, and to choose among multiple options wherever there are different ways to significantly minimize or prevent a hazard that is reasonably likely to occur.

In addition, the specific provisions of proposed subpart C (and related requirements) have been designed to maximize their flexibility and practicability wherever it is possible to do so consistently with the requirements of section 418 of the FD&C Act. For example:

- As discussed in section XII.A.2 of this document, proposed § 110.126(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf.
- As discussed in section XII.A.3 of this document, proposed § 110.126 would allow facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical and, thus, would provide flexibility for facilities in the development of their food safety plans.
- As discussed in section XII.C of this document, proposed § 110.135 would provide flexibility with regard to preventive controls by allowing flexibility to establish the parameters and the maximum/minimum values for the selected control.
- As discussed in section XII.C.2 of this document, for process controls, food allergen controls, sanitation controls, and other controls, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes available to it that would provide the assurances that would be required by proposed § 110.135(a).
- As discussed in section XII.F.4 of this document, proposed § 110.145(c) would not specify how corrective actions for environmental monitoring must be performed, such as the number of sites to test when the test organism is found in a facility, or how to clean and sanitize the surfaces on which the test organism was detected, to provide facilities with sufficient

flexibility to develop and implement aggressive and appropriate corrective actions to find and eliminate the source of the contamination in the environment.

- As discussed in section XII.G.5.c of this document, proposed § 110.150(d)(3) would provide flexibility with respect to verification testing of product by not specifying specific products that must be tested, the hazards to test for, the frequency of testing, or the number of samples.

- As discussed in section XII.H.3 of this document, proposed § 110.152(b) would provide flexibility for the owner, operator, or agent in charge of a receiving facility to either conduct audits or obtain documentation of an audit that has been conducted at the supplier by a third party auditor. This would allow for consolidation of audits such that a supplier would be able to use the results of one audit as documentation for multiple receiving facilities.

- As discussed in section XII.H.5 of this document, proposed § 110.152(c) would provide that, for supplier verification programs, facilities would have the flexibility to choose appropriate verification activities when the hazard is not controlled at the supplier's establishment under a designated food safety regulation.

- As discussed in section XII.G of this document, proposed § 110.155(b) would provide flexibility for the qualified individual to be either an employee of the facility or an individual not employed by the facility (such as individuals associated with universities, trade associations, and consulting companies). Proposed § 110.155(b) would also provide flexibility for the qualified individual to be qualified either through training or job experience.

- As discussed in section XV.C.1 of this document, proposed § 110.305(a) would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system.

- As discussed in section XV.C.3 of this document, proposed § 110.305(e) would provide flexibility to facilities to tailor the amount of detail in their records to the amount necessary to provide a history of the work performed.

Section 418(m) of the FD&C act also provides us with the authority to exempt certain facilities from the requirements of section 418, or to modify those requirements. As discussed in section X.B.9 of this document, we propose to use this authority to exempt facilities that solely engage in the storage or raw agricultural commodities, other than fruits and vegetables, intended for further distribution or processing (§ 110.2(j)). As discussed in section X.D of this document, we also propose to establish modified requirements for facilities solely engaged in the storage of packaged food that is not exposed to the environment under this authority (§§ 110.5 and 110.206). These proposed modified requirements are specifically designed to be targeted to the specific circumstances of such facilities and therefore to be practicable for such facilities.

We are also proposing to define the terms "small business" and "very small business" in proposed § 110.3. As discussed in sections VII, X.B.6, and X.B.1 of this document, the proposed rule provides flexibility for small and very small businesses in multiple ways. These special provisions based on business size enhance the flexibility of the proposed rule for businesses of all sizes. First, FDA proposes to allow small and very small businesses more time to come into compliance with Section 418 after the effective date of the rule (6 months and 18 months, respectively). FDA expects that this would assist small and very small businesses in making changes that would be required for compliance.

Second, FDA is proposing two exemptions from proposed subpart C that would be available in part based on business size. The proposed exemption for qualified facilities in § 110.2(a) would be available to very small businesses, and to certain other businesses based in

part on business size, as set forth in that proposed section. Qualified facilities would be subject instead to the modified requirements in proposed § 110.201, which themselves provide significant flexibility. For example, proposed § 110.201(a) would not specify the form of documentation required for a qualified facility to show that it is in fact a qualified facility, or to demonstrate its own hazard analysis and preventive control system or compliance with state, local, county, or other applicable non-Federal law. Instead, FDA is proposing to accept self-certification of compliance with these requirements, provided that facilities retain the documentation on which they rely and make such documentation available to FDA upon request (§ 110.201(e) and related requirements in proposed subpart F).

In addition, under section 103(c) of FSMA, we have conducted a science-based risk evaluation of certain on-farm activities. Based on that risk evaluation, as discussed in section X.B.6 of this document, we are proposing to exempt facilities that are small or very small businesses engaged only in certain low-risk activity/food combinations from the requirements of section 418. We have identified a significant number of activity/food combinations that we would consider to be low-risk when conducted on-farm by small and very small businesses, set forth in the proposed exemption in § 110.2(g) and (h).

Finally, as discussed in section VII of this document, FDA is proposing to begin enforcement of section 418 of the FD&C Act for all facilities subject to that section only after providing a sufficient time period following publication of the final rule for facilities to come into compliance. Specifically, FDA is proposing that businesses would be required to comply with the final rule 1 year after its publication in the Federal Register. Further, FDA is proposing to allow an additional 6 months for small businesses and an additional 18 months for very small businesses to come into compliance with the final rule. Providing additional time for businesses

to comply, with the most time given to the smallest businesses, helps to make the regulation practicable for all sizes of facilities.

3. Section 418(n)(3)(B)

In implementing section 418 through this proposed rule, FDA has complied with chapter 35 of title 44, United States code (commonly known as the 'Paperwork Reduction Act' (PRA)), with special attention to minimizing the burden (as defined in section 3502(2) of such Act (44 U.S.C. 3502(2))) on the facility, and collection of information (as defined in section 3502(3) of such Act (44 U.S.C. 3502(3))), associated with the proposed rule. Under section 3502(2) of the PRA, "burden" means "time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency." Under section 3502(3) of the PRA, "collection of information" means, in relevant part, "the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for … answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons…."

In section XXI of this document, we discuss how this proposed rule complies with the requirements of the PRA. In addition, in implementing section 418 of the FD&C Act, we have paid special attention to minimizing burden and collection of information associated with the proposed rule.

As discussed immediately above in section XVI.A.2, we are proposing requirements that provide significant flexibility for different sizes and types of facilities. By making these requirements flexible enough to be practicable for different sizes and types of facilities, the proposed rule also avoids creating unnecessary information collection burden for facilities,

because facilities should be able to tailor their recordkeeping to their specific circumstances while still complying with the requirements of the proposed rule.

In addition, the only requirements we are proposing that constitute collections of information are those that are necessary to meet the requirements of section 418 of the FD&C Act and to efficiently enforce that section. Section 418 requires facilities to establish and maintain certain records, such as the written food safety plan (sections 418(b)(3) and 418(h)), records of monitoring of preventive controls (section 418(g)), records of instances of nonconformance material to food safety (section 418(g)), records of the results of testing and other appropriate means of verification (section 418(g)), records of implementation of corrective actions (section 418(g)), and records of the efficacy of preventive controls and corrective actions (section 418(g)). Section 418(h) also requires facilities to make those records promptly available to FDA upon request. In this proposed rule, FDA has interpreted these requirements in a manner calculated to minimize the associated burden and to minimize recordkeeping requirements beyond those explicitly provided for by the statute to those that are essential to implementation and enforcement of section 418. For example:

- As discussed in section XII.3 of this document, FDA is proposing to interpret section 418(h) not to require written procedures for conducting a hazard analysis or written procedures for establishing preventive controls, thereby avoiding unnecessary recordkeeping burden.

- As discussed in section XII.4 of this document, proposed § 110.126 would allow facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical and, thus, would

minimize the number of different documents that need to be included in the food safety plan and the recordkeeping burden associated with that plan.

- As discussed in section XII.C.7 of this document, FDA is proposing that written corrective action procedures would not be required for sanitation deviations when the owner, operator, or agent in charge of a facility takes corrective action in accordance with proposed § 110.135(d)(3)(iii), because there would be little benefit in requiring written corrective action procedures for the many sanitation deviations that could occur for which the corrective actions that would need to be taken are very general.
- As discussed in section XII.D.2 of this document, proposed § 110.137 would require facilities to establish recall plans only for foods in which there is a hazard reasonably likely to occur, not for all foods, thereby avoiding unnecessary recordkeeping burden.
- As discussed in section XII.G.6 of this document, FDA is proposing to require written verification procedures only for finished product testing and environmental monitoring. FDA is not proposing to require written verification procedures for validation; verification of monitoring and corrective actions; review of consumer, customer, or other complaints; or calibration of process monitoring instruments and verification instruments, other than for the frequency of calibration).
- As discussed in section XII.H.3.e of this document, FDA is not proposing to require written procedures for supplier approval and verification activities.

4. Section 418(n)(3)(C)

In implementing section 418 through this proposed rule, FDA is proposing to acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.

As discussed in section XII.B.2.a of this document, proposed § 110.130(a)(1) would identify the purpose of the hazard analysis - i.e., to determine whether there are hazards that are reasonably likely to occur. As such, there is a single standard that applies to all covered foods when determining whether preventive controls are required. Proposed § 110.130(a)(1) would require that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. If a food presents no hazard reasonably likely to occur, no preventive controls would need to be established. For foods that present hazards reasonably likely to occur, facilities would be required to establish preventive controls in keeping with one general set of requirements set forth in proposed § 110.135. Thus, proposed subpart C simultaneously acknowledges differences in risk among foods and applies a single standard to all foods subject to that subpart.

In addition, the proposed rule acknowledges differences in risk by establishing exemptions and modified requirements in certain cases. We discuss these proposed exemptions and modified requirements in sections X.B and X.D of this document. The proposed rule would exempt all of the following from proposed subpart C: qualified facilities; activities subject to part 123 (seafood HACCP) and in compliance with that part; activities subject to part 120 (juice HACCP) and in compliance with that part; activities subject to part 113 (LACF) and in compliance with that part with respect to microbiological hazards addressed in that part; manufacturing, processing, packing, or holding of dietary supplements in compliance with part 111 (dietary supplement CGMPs) and section 761 of the FD&C Act (serious adverse event reporting); activities subject to section 419 of the FD&C Act (standards for produce safety); on-farm low-risk activity/food combinations conducted by small or very small businesses engaging

only in such activities; alcoholic beverages and limited amounts of non-alcohol prepackaged food at alcohol-related facilities; and facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. In addition, the proposed rule includes modified requirements for facilities solely engaged in the storage of packaged food that is not exposed to the environment. The proposed exemptions and modified requirements implement specific statutory authorities allowing for those exemptions and modifications, indicating that Congress intended that there should be some differences in the requirements for certain foods, certain facilities, and certain activities, depending on risk and on other aspects of the regulatory environment. This proposed rule strikes what FDA considers to be an appropriate balance between acknowledging differences in risk and minimizing the number of separate standards applied to separate foods.

5. Section 418(n)(3)(D)

This proposed rule would not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventive controls. As discussed in section XII.G of this document, proposed § 110.155(a) would require that a qualified individual conduct certain required activities, and proposed § 110.155(b) would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. The option in proposed § 110.155(b) would provide flexibility to facilities subject to the rule. Providing an option to use a consultant or other third party as the qualified individual to conduct specific functions would not require using a consultant or other third party. These proposed

provisions are merely permissive and FDA tentatively concludes that they are consistent with the requirements of section 418(n)(3)(D) of the FD&C Act.

B. Consistency With HACCP

1. Requirements of Section 418 of the FD&C Act

Section 418(n)(5) of the FD&C Act specifies that, "[i]n promulgating the regulations [required by section 418(n)(1)(A) of the FD&C Act], the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of [FSMA], including the Grade 'A' Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date."

2. Overview of FDA's Review of Hazard Analysis and Preventive Controls Programs

FDA has conducted the review of regulatory hazard analysis and preventive control programs and internationally-recognized standards required by section 418(n)(5) of the FD&C Act. To do so, we reviewed the following domestically recognized standards:

- NACMCF's "Hazard Analysis and Critical Control Point Principles and Application Guidelines" (Ref. NACMCF);
- FDA's regulation in part 120 (Hazard Analysis and Critical Control Points (HACCP) Systems) for juice ;
- FDA's regulation in part 123 (Fish and Fishery Products);
- FSIS' regulation in 9 CFR 417 (Hazard Analysis and Critical and Control Point (HACCP) systems) for meat and poultry products; and

- The Grade "A" Pasteurized Milk Ordinance (PMO), specifically the National Conference on Interstate Milk Shipments HACCP alternative found in Appendix K (the PMO HACCP Appendix) (Ref. PMO).

We also reviewed the following internationally recognized standards:

- The Codex Annex to the Recommended International Code of Practice - General Principles of Food Hygiene on the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Ref. Codex);
- The European Parliament and Council of the European Union Regulation (EC) No 852/2004 on the Hygiene of Foodstuffs (the EU regulation) (Ref. EU 852/2004);
- The requirements for food safety programs in the Australia New Zealand Food Standards Code (the FSANZ Code) (Ref. FSANZ Code); and
- The Canadian Food Inspection Agency's Food Safety Enhancement Program (the CFIA FSEP) (Ref. CFIA).

We compared the key features of our proposed requirements to implement section 418 of the FD&C Act (i.e., the proposed requirements that would be established in subpart C of part 110) to the listed domestic and international food safety standards. The key features we compared are:

- Requirement for a food safety plan;
- Requirement for a hazard analysis;
- Requirement for preventive controls, including a requirement for control parameters and maximum or minimum values;
- Requirement for a recall plan;
- Requirement for monitoring procedures;

- Requirement for corrective actions;
- Requirement for verification procedures;
- Requirements for a supplier approval and verification program;
- Requirements applicable to a qualified individual; and
- Requirement for records.

The two most widely applied guidelines are the NACMCF HACCP guidelines and the Codex HACCP Annex. As discussed in section II.C.1 of this document, the NACMCF HACCP guidelines and the Codex HACCP Annex evolved over time, and revisions that NACMCF made to its recommendations in 1992 and 1997 were patterned after changes made in Codex HACCP documents. Thus, the NACMCF HACCP guidelines and the Codex HACCP Annex are similar in their recommendations, although the specific wording is not always identical. In general, domestic standards are patterned after the NACMCF HACCP guidelines and the international standards are patterned after the Codex HACCP Annex.

As noted in section II.C.2 of this document, throughout this document we identify the sections of FSMA applicable to specific proposed provisions and describe how the proposed provisions relate to HACCP principles as established in the NACMCF HACCP guidelines, the Codex HACCP Annex and Federal HACCP regulations for seafood, juice, and meat and poultry. We do not elaborate throughout the document on how the proposed provisions relate to the PMO HACCP Appendix or international standards other than the Codex HACCP Annex (i.e., the EU regulation, the FSANZ Code, and the CFIA FSEP). However, for the purpose of the review required by section 418(n)(5) of the FD&C Act, we discuss all of these standards. We also developed a table showing how the proposed requirements of subpart C compare to the listed

domestic and international food safety standards; that table is a reference to this document (Ref. Table).

In other sections of this document, we refer to "Federal HACCP regulations for seafood, juice, and meat and poultry." For the purpose of the review required by section 418(n)(5) of the FD&C Act, we refer to "domestic" regulations rather than "Federal" regulations.

3. Comparison of Preventive Control Programs

a. Requirement for a food safety plan. Proposed § 110.126 would require that the owner, operator or agent in charge of a facility prepare (or have prepared) and implement a written food safety plan. As discussed in section II.C.3 of this document, NACMCF describes five preliminary tasks in the development of a HACCP plan and seven HACCP principles that apply in implementing a HACCP plan (Ref. NACMCF, 1998). The Codex HACCP Annex also describes these five preliminary tasks and seven HACCP principles, although the specific descriptions are not always identical to those in the NACMCF HACCP guidelines (Ref. Codex 2003). The domestically recognized standards and all international standards except the FSANZ Code focus on "HACCP systems" to control hazards; the FSANZ Code uses the term "food safety program."

Consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex, all domestic HACCP regulations and the PMO HACCP Appendix require that food establishments as specified in the regulation or standard operate in accordance with the seven HACCP principles. All domestic regulations and the PMO HACCP Appendix require a written HACCP plan (which in this proposed regulation is a food safety plan) whenever the hazard analysis identifies hazards that are reasonably likely to occur. The international standards require, in general, that food establishments as specified in the regulation or standard operate in accordance

with the seven HACCP principles as described by Codex. FSANZ requires the food safety program to be written, and CFIA FSEP requires the HACCP plan to be written, but the EU regulation has no explicit requirement that HACCP plans be written.

Proposed § 110.126 would require a written "food safety plan," the term used by FSMA in section 418(h), rather than require a "HACCP plan." Proposed § 110.126 would specify the contents of the food safety plan, including the (1) written hazard analysis; (2) written preventive controls; (3) written monitoring procedures; (4) written corrective action procedures; (5) written verification procedures; (6) written recall plan; and (7) written list of approved suppliers and written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient. The contents of a written HACCP plan in domestic HACCP regulations are similar but not identical, and include the (1) list of hazards; (2) CCPs; (3) critical limits; (4) monitoring procedures; (5) corrective action procedures; (5) verification procedures; and (6) record-keeping procedures. The PMO HACCP Appendix requires that the HACCP plan include process flow diagrams (also a requirement in the FSIS HACCP regulation for meat and poultry, but not included in the contents of the HACCP plan). FSANZ requires that the food safety program (1) identify hazards; (2) identify where hazards can be controlled and the means: (3) provide for monitoring; (4) provide for corrective actions; (5) provide for regular review for adequacy; and (6) provide for appropriate records of compliance. The CFIA FSEP requires that the HACCP plan include all relevant information needed to conduct the five preliminary steps in addition to the seven HACCP principles. The EU regulation has no explicit requirement for the contents of a HACCP plan other than requiring food business operators to put in place procedures based on the HACCP principles.

b. Requirement for a hazard analysis. Proposed § 110.130 would require that a hazard analysis be conducted to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine those hazards reasonably likely to occur. As discussed in section XII.B of this document, proposed § 110.130 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex, all domestic HACCP regulations, the PMO HACCP Appendix, and international standards require that a hazard analysis be conducted. Domestic HACCP regulations specify that the outcome is to determine the hazards reasonably likely to occur for the product being produced, which is consistent with the FSANZ requirement that a food business identify the potential hazards that may be reasonably expected to occur in all food handling operations. This outcome is implied by the EU regulation, which requires identifying any hazards that must be prevented, eliminated or reduced to acceptable levels.

c. Requirement for preventive controls, including a requirement for control parameters and maximum or minimum values. Proposed § 110.135 would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented. Proposed § 110.135 also would require that preventive controls include, as appropriate to the facility and the food, parameters associated with the control of the hazard and the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

As discussed in section XII.C of this document, proposed § 110.135 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix require the inclusion of CCPs and critical limits in the HACCP plan to control hazards that are identified as reasonably likely to occur. Consistent with the Codex HACCP Annex, the CFIA FSEP and the EU regulation also require the inclusion of CCPs and critical limits in the HACCP plan. FSANZ requires the identification of where, in a food handling operation, each hazard can be controlled, without referring to these as CCPs, and the means of control, but does not specify the establishment of critical limits.

d. Requirement for a recall plan. Proposed § 110.137 would require that a recall plan be established for food in which there is a hazard that is reasonably likely to occur. The CFIA FSEP provides for recall plans as a prerequisite program in the HACCP system. None of the other domestic or international standards include a provision for a recall plan as part of HACCP requirements. Although not part of the Codex HACCP Annex, the Codex GPFH specify that managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market (Ref. Codex GPFH, 2003).

e. Requirement for monitoring procedures. Proposed § 110.140 would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. As discussed in section XII.E of this document, proposed § 110.140 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP

Appendix require monitoring procedures (and the frequency) for CCPs to ensure compliance with critical limits. Consistent with the Codex HACCP Annex, international standards require monitoring, although Codex does not specify that the monitoring system include the frequency of monitoring. The EU regulation requires establishing and implementing effective monitoring procedures at CCPs. The CFIA FSEP requires documented monitoring procedures for each CCP and these must specify any tests, measurements or observations to assess whether the control measure is functioning as intended and the critical limits are met. FSANZ requires that the food safety program provide for the systematic monitoring of controls.

f. Requirement for corrective actions. Proposed § 110.145 would require that the owner, operator, or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. As discussed in section XII.F of this document, proposed § 110.145 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix require establishing corrective actions (or corrective action plans) for deviations from established critical limits. Proposed § 110.145 also would require that corrective actions be taken if a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective. This provision of proposed § 110.145 is consistent with corresponding requirements in domestic HACCP regulations for corrective actions when there is no corrective action plan for a specific deviation.

Consistent with the Codex HACCP Annex, international standards require corrective actions. The EU regulation and the CFIA FSEP require establishing corrective actions when monitoring indicates that a critical control point is not under control. FSANZ requires that the

food safety program provide for appropriate corrective action when the hazard is found not to be under control. However, only the CFIA FSEP requires that documented deviation procedures specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that the control measure is not functioning as intended or; the critical limits are not met.

g. Requirement for verification procedures. Proposed § 110.150 would require that the owner, operator, or agent in charge of a facility establish specific verification and validation procedures and activities. As discussed in section XII.G of this document, proposed § 110.150 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, domestic HACCP regulations and the PMO HACCP Appendix require a list of the verification procedures (including validation in the HACCP regulation for juice and the PMO HACCP Appendix), and the frequency of performing these procedures. Consistent with the Codex HACCP Annex, international standards (except FSANZ) require the establishment of verification procedures. The EU regulation requires procedures to verify that the HACCP system is working effectively and the CFIA FSEP requires documentation of verification procedures. FSANZ does not specifically require verification procedures but requires that the food safety program provide for the regular review of the program by the food business to ensure its adequacy.

In addition to validation, proposed § 110.150 would require specific verification activities, including a review of any consumer, customer, or other complaints to determine whether a complaint relates to the effectiveness of the food safety plan; calibration of process monitoring instruments and verification instruments; performance of scientifically valid finished product testing, when appropriate based on risk, to assess whether the preventive controls

significantly minimize or prevent the hazards that are reasonably likely to occur; performance of environmental monitoring for any environmental pathogens that are reasonably likely to occur; records review; and reanalysis. Several of these requirements are found in domestic standards. For example, the HACCP regulations for seafood and juice require a review of any consumer complaints to determine whether a complaint relates to the effectiveness of the food safety plan. All domestic HACCP regulations and the PMO HACCP Annex require calibration of monitoring instruments. The HACCP regulations for seafood and juice and the PMO HACCP Annex provide for optional in-process or end-product testing as a verification activity. All domestic HACCP regulations and the PMO HACCP Appendix require record review as a verification activity, and all provide for an annual reanalysis; both of these are specified by the NACMCF guidelines as verification activities. Other than the FSANZ requirement that the food safety program provide for the regular review of the program to ensure its adequacy, the only international standard that provides specific verification activities is the CFIA FSEP, which requires observation of monitoring and corrective actions (which is also a requirement of the FSIS HACCP regulation for meat and poultry), records review and, when applicable, product testing.

h. Requirement for a supplier approval and verification program. Proposed § 110.152 would require that the owner, operator, or agent in charge of a facility establish and implement a supplier approval and verification program for raw materials and other ingredients for which the receiving facility has identified hazards that are reasonably likely to occur. The specific details of when such a program would be required and the activities associated with such a program are described in section XII.H of this document. There are no explicit requirements for such a program in any of the domestic or international standards. However, all standards require the

identification of hazards, the implementation of controls for those hazards, and verification activities to ensure hazards are controlled. Proposed § 110.152 is consistent with these requirements; we have simply segregated this program in order to better focus the specific activities that would apply.

i. Requirements applicable to a qualified individual. Proposed § 110.155 would establish the requirements applicable to a qualified individual. We use the term "qualified individual" to refer to an individual who is qualified by training or job experience to conduct certain food safety activities as would be specified in proposed subpart C. As discussed in section XII.I of this document, proposed § 110.155 is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Proposed § 110.155 is also consistent with the PMO HACCP Appendix, in which only a person who has met certain qualifications (i.e., through specific training) can carry out certain requirements related to the HACCP system. The NACMCF HACCP guidelines stress the importance of ensuring that individuals have appropriate training to develop and maintain the HACCP system. Similarly, the Codex HACCP Annex emphasizes that training is essential for effective implementation of HACCP. The EU regulation requires "food business operators" to ensure that those responsible for the development and maintenance of procedures based on the HACCP principles have received adequate training in the application of the HACCP principles. The CFIA FSEP requires that the individuals responsible for monitoring, deviation and verification procedures have received adequate training.

j. Requirement for records. Proposed § 110.175 would list the records that would required for proposed subpart C, including the food safety plan, records that document the monitoring of preventive controls, records that document corrective actions, records that

document verification activities, and records that document applicable training for the qualified individual. Proposed § 110.175 is consistent with the requirements for records in the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix, which require records to include the hazard analysis, HACCP plan, and records of monitoring, corrective actions and verification activities. The Codex HACCP Annex also specifies documentation, including the hazard analysis and CCP and critical limit determination, and records for monitoring, corrective actions and verification procedures. The EU regulation requires records to demonstrate the effective application of the HACCP measures. Similarly, FSANZ requires that the food safety program provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program. The CFIA FSEP requires record keeping to demonstrate the effective application of the critical control points and to facilitate official verifications by the CFIA or other competent authority.

Proposed subpart F would establish requirements that apply to the required records, including requirements for records to be accurate and to include specific information and for record retention. These record-keeping requirements are consistent with the requirements for records in all domestic HACCP regulations, but such details are not found in international standards other than the CFIA FSEP.

XVII. Analysis of Economic Impacts

A. Benefit-Cost Analysis

XVIII. Initial Regulatory Flexibility Analysis

XIX. Unfunded Mandates

XX. Small Business Regulatory Enforcement Fairness Act (SBREFA)

XXI. Paperwork Reduction Act of 1995

XXII. Analysis of Environmental Impact

XXIII. Federalism

XXIV. Comments

XXV. References

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 110

Food packaging, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter 1 is amended as follows:

PART 1 – GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Section 1.227 is revised to read as follows:

§ 1.227 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Calendar day means every day shown on the calendar.

Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) Domestic facility means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) Foreign facility means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)),

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(6)), or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and

nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ``Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack,

or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations.

Trade name means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between the Food and Drug Administration (FDA) and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies under § 1.233(e) another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's

commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

3. Section 1.241 is amended by revising paragraph (a) to read as follows:

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of it's facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

4. Section 1.276 is amended by revising paragraph (b)(9) to read as follows:

§ 1.276 What definitions apply to this subpart?

* * * * *

(9) Manufacturer means the last facility, as that word is defined in § 1.227, that manufactured/processed the food. A facility is considered the last facility even if the food

undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a de minimis nature. If the food undergoes further manufacturing/processing that exceeds an activity of a de minimis nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

* * * * *

5. Section 1.328 is amended by alphabetically adding definitions for "Harvesting" "Mixed-type facility," and "Packing" and revising the definitions for "Farm," "Holding," and "Manufacturing/processing" to read as follows:

§ 1.328 What definitions apply to this subpart?

* * * * *

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that

transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Holding means storage of food. Holding facilities include: Warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals

and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

* * * * *

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

PART 16 – REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

6. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

7. In § 16.1, in paragraph (b)(2) , add the following entry in numerical order to read to read as follows:

* * * * *

(b) * * *

(2)* * *

§§ 110.251 through 110.284 (part 110, subpart E), relating to withdrawal of an exemption applicable to a qualified facility.

* * * * *

8. Revise part 110 to read as follows:

PART 110—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart A—General Provisions

Sec.

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 110.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether a food is adulterated (1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or (2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of part 110 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(uu)).

(c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 110.2 Exemptions.

(a) Except as provided by subpart E of this part, subpart C of this part does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in § 110.201.

(b) Subpart C of this part does not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 of this chapter with respect to such activities.

(c) Subpart C of this part does not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 of this chapter with respect to such activities.

(d)(1) Subpart C of this part does not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 113 of this chapter with respect to such activities.

(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.

(e) Subpart C does not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).

(f) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(g) Subpart C of this part does not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership:

(1) Packing or re-packing (including weighing or conveying incidental to packing or re-packing) of:

(i) Intact fruits and vegetables (for purposes of paragraph (g) and paragraph (h) of this section only, “intact fruits and vegetables” refers only to fruits and vegetables other than seeds for consumption, peanuts, and tree nuts);

(ii) Grains and grain products;

(iii) Seeds for consumption;

(iv) Peanuts and tree nuts;

(v) Honey (raw and pasteurized);

(vi) Maple sap for syrup and maple syrup; and

(vii) Acid foods made into jams, jellies and preserves.

(2) Sorting, culling, or grading incidental to packing or storing of:

(i) Intact fruits and vegetables;

(ii) Grains and grain products;

(iii) Seeds for consumption;

(iv) Peanuts and tree nuts;

(v) Honey (raw and pasteurized); and

(vi) Maple sap for syrup and maple syrup.

(3) Storing (ambient, cold and controlled atmosphere) of:

(i) Intact fruits and vegetables;

(ii) Grains and grain products;

(iii) Seeds for consumption;

(iv) Peanuts and tree nuts;

(v) Honey (raw and pasteurized);

(vi) Maple sap for syrup and maple syrup; and

(vii) Acid foods made into jams, jellies and preserves.

(h) Subpart C of this part does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following:

(1) When conducted on a farm mixed-type facility's own raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (those grown or raised on

that farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:

(i) Artificial ripening of intact fruits and vegetables;

(ii) Boiling/evaporation of maple sap to make maple syrup;

(iii) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables, seeds for consumption, or peanuts or tree nuts (e.g., coating apples with caramel, coating seeds or nuts with spices);

(iv) Chopping peanuts and tree nuts;

(v) Drying/dehydrating intact fruits and vegetables where the drying creates a distinct commodity (e.g., drying fruits or herbs);

(vi) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);

(vii) Making jams, jellies and preserves from acid foods (e.g., acid fruits); and

(viii) Salting seeds for consumption, raw peanuts, and raw tree nuts.

(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:

(i) Making honey (including extraction and filtration);

(ii) Making maple syrup (including filtration and boiling/evaporation);

(iii) Artificial ripening of intact fruits and vegetables;

(iv) Cooling intact fruits and vegetables using cold air;

(v) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables, seeds for consumption, and peanuts and tree nuts (e.g., coating apples with caramel, coating seeds or nuts with spices);

(vi) Chopping peanuts and tree nuts;

(vii) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables and seeds for consumption;

(viii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);

(ix) Labeling (including stickering) intact fruits and vegetables, grain and grain products, seeds for consumption, intact single-ingredient peanuts or tree nuts (shelled and unshelled), honey, and maple sap or syrup;

(x) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

(xi) Mixing/blending intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup;

(xii) Packaging (other than modified atmosphere or vacuum packaging) intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup;

(xiii) Packaging peanuts or tree nuts using modified atmosphere or vacuum methods;

(xiv) Salting seeds for consumption and peanuts and tree nuts;

(xv) Sifting grain or grain products and seeds for consumption;

(xvi) Shelling intact fruits and vegetables (e.g., beans and peas such as black-eyed peas, kidney, lima, and pinto beans), seeds for consumption, and peanuts and tree nuts;

(xvii) Sorting, culling and grading (other than when incidental to packing or storage) intact fruits and vegetables, grain and grain products, seeds for consumption, peanuts and tree nuts, honey, and maple sap or syrup;

(xviii) Treating intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (e.g., fumigation); and

(xix) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

(i)(1) Subpart C of this part does not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) Subpart C of this part does not apply with respect to food other than alcoholic beverages at a facility described in (i)(1), provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(j) Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k) Subpart B of this part does not apply to "farms" (as defined in § 1.227 of this chapter), activities of "farm mixed-type facilities" (as defined in § 1.227) that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Cross-contact means the unintentional incorporation of a food allergen into a food.

Designated food safety regulation means a regulation contained in part 106 of this chapter (Infant Formula Quality Control Procedures), part 107 of this chapter (Infant Formula), subpart B of this part (Current Good Manufacturing Practice) or subpart C of this part (Hazard Analysis and Risk-Based Preventive Controls) of part 110, part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements), part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers), part 114 of this chapter (Acidified Foods), part 118 of this chapter (Production, Storage, and Transportation Of Shell Eggs), part 120 of this chapter (Hazard Analysis and Critical Control Point Systems), part 123 of this chapter (Fish and Fishery Products), or part 129 of this chapter (Processing and Bottling of Bottled Drinking Water).

Environmental pathogen means a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in § 1.227 of this chapter.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Hazard means any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

Hazard reasonably likely to occur, in the context of supplier controls, means a hazard for which a prudent owner, operator, or agent in charge of a receiving facility would establish controls or verify that the supplier has controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being received in the absence of those controls.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Lot means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that

subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located

(a) In the same State as the qualified facility that sold the food to such restaurant or establishment; or

(b) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility as to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold

directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including processed food, for which the food is normally eaten, or it is reasonably foreseeable that the food would be eaten, without further processing that will significantly minimize biological hazards.

Reasonably foreseeable hazard means a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food.

Receiving facility means, for an article of food, a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part 110, a business employing fewer than 500 persons.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food (other than a farm that harvests a raw agricultural commodity that is a fruit or vegetable) that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

Very small business means, for purposes of this part 110, a business that has less than $250,000 in total annual sales of food, adjusted for inflation.

Water activity (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Applicability of subparts C and D to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(a) Subpart C of this part does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(b) A facility solely engaged in the storage of packaged food that is not exposed to the environment is subject to the modified requirements in § 110.206 of subpart D of this part.

Subpart B—Current Good Manufacturing Practice

§ 110.10 Personnel.

The plant management must take all reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination

until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against cross-contact of food.

(c) Education and training.

(1) Each person engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof, must receive training, as appropriate to the person's duties upon hiring and periodically thereafter. The training must include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility.

(2) Each person engaged in manufacturing, processing, packing or holding food (including temporary and seasonal personnel), or in the supervision thereof, must have the training, in combination with education or experience, to perform the person's assigned duties.

(3) Plant management must establish and maintain records that document required training of personnel, including the date of the training, the type of training, and the person(s) trained.

(d) Supervision. Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 110.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to reduce the potential for cross-contact. The potential for cross-contact and contamination must be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass

suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for cross-contact.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 110.35 Sanitary operations.

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials.

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) Pest control. Pests must not be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.

(1) Food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food or food-contact surfaces.

(e) Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food and food-contact surfaces.

(f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination.

§ 110.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) Water supply. The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts food or food-contact surfaces must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal must be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food and food contact surfaces.

(e) Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food or food-contact surfaces, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) Rubbish and offal disposal. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

§ 110.40 Equipment and utensils.

(a) All plant equipment and utensils must be so designed and of such material and workmanship as to be adequately cleanable, and must be properly maintained.

(1) The design, construction, and use of equipment and utensils must preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(2) All equipment must be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(3) Food-contact surfaces must be corrosion-resistant when in contact with food.

(4) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents.

(5) Food-contact surfaces must be maintained to protect food from cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and cross-contact.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food must be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§ 110.80 Processes and controls.

(a) General. (1) All operations in the manufacturing, processing, packing and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) All reasonable precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if permissible, treated or processed to eliminate the contamination.

(b) Raw materials and ingredients. (1) Raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for

processing into food and must be stored under conditions that will protect against cross-contact and contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross-contact. Containers and carriers of raw materials must be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food.

(2) Raw materials and ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with current Food and Drug Administration regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.

(4) Raw materials, ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable Food and Drug Administration regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against cross-contact and contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated.

(7) Liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact and contamination.

(8) Raw materials and ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents cross-contact.

(c) Manufacturing operations. (1) Equipment and utensils and finished food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding, must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures must be taken to protect finished food from cross-contact and contamination by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in cross-contact or contaminated food. Food transported by conveyor must be protected against cross-contact and contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food must be constructed, handled, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination.

(8) Effective measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food or, if the adulterated food is capable of being reconditioned, it must be reconditioned using a method that has been proven to be effective.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against cross-contact and contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay.

Thermophilic growth and contamination in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against cross-contact and contamination.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, including acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food must not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for cross-contact or contamination of the human food.

§ 110.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food as well as against deterioration of the food and the container.

§ 110.110 Defect Action Levels

Natural or unavoidable defects in food for human use that present no health hazard:

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods when it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food not be prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, or the requirements in this part that food manufacturers, processors, packers, and holders must observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

§ 110.120 Records required for subpart B.

(a) Plant management must establish and maintain records that document required training of personnel.

(b) The records that plant management must establish and maintain are subject to the requirements of subpart F of this part.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 110.126 Requirement for a food safety plan.

(a) Food safety plan. The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan.

(b) Contents of a Food Safety Plan. The food safety plan must include:

(1) The written hazard analysis as required by § 110.130(a)(2);

(2) The written preventive controls as required by § 110.135(b);

(3) The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by § 110.140(a);

(4) The written corrective action procedures as required by § 110.145(a)(1);

(5) The written verification procedures, and the frequency with which they are to be performed as required by § 110.150(e)(1);

(6) The written recall plan as required by § 110.137(a); and

(7) The written list of approved suppliers and the written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient as required by § 110.152(a)(3)(i) and (ii).

(c) Qualified individual. The food safety plan must be prepared by a qualified individual.

§ 110.130 Hazard analysis.

(a) Requirement for a hazard analysis.

(1) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur.

(2) The hazard analysis must be written.

(b) Hazard identification. The hazard identification must consider hazards that may occur naturally or may be unintentionally introduced, including:

(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance;

(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, food or color additives, and food allergens;

(3) Physical hazards; and

(4) Radiological hazards.

(c) Hazard evaluation.

(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

(2) The hazard analysis must include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging.

(3) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the facility and equipment;

(iii) Raw materials and ingredients;

(iv) Transportation practices;

(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;

(vii) Storage, and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors.

§ 110.135 Preventive controls for hazards that are reasonably likely to occur.

For hazards indentified in the hazard analysis as reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Preventive controls must be written.

(c) Preventive controls must include, as appropriate to the facility and the food:

(1) parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, and refrigerating foods, and

(2) the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

(d) Preventive controls must include, as appropriate:

(1) Process controls. Process controls must include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur.

(2) Food allergen controls. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from cross-contact, including during storage and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) Sanitation controls.

(i) Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls must include procedures for the:

(A) Cleanliness of food contact surfaces, including food contact surfaces of utensils and equipment;

(B) Prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(ii) The owner, operator or agent in charge of a facility must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraph (d)(3)(i)(A) or (B) of this section.

(iii) The owner, operator, or agent in charge of a facility is not required to follow the corrective actions established in § 110.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(3)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraph (d)(3)(i)(A) or (B) of this section.

(iv) All corrective actions taken in accordance with paragraph (d)(3)(ii) must be documented in records that are subject to verification in accordance with § 110.150(c) and records review in accordance with § 110.150(d)(5)(i).

(4) Recall plan. Recall plan as required by § 110.137.

(5) Supplier program. Supplier approval and verification program as required by § 110.152.

(6) Other controls. Preventive controls must include any other controls necessary to satisfy the requirements of paragraph (a) of this section.

(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:

(i) Monitoring as required by § 110.140;

(ii) Corrective actions as required by § 110.145; and

(iii) Verification as required by § 110.150.

(2) The recall plan established in § 110.137, and the supplier approval and verification program established in § 110.152, are not subject to the requirements of paragraph (e)(1) of this section.

§ 110.137 Recall plan for food in which there is a hazard that is reasonably likely to occur.

For food in which there is a hazard that is reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must establish a written recall plan for the food.

(b) The recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food – e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

§ 110.140 Monitoring.

(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.

(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed.

(c) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 110.150(b) and records review in accordance with § 110.150(d)(5)(i).

§ 110.145 Corrective actions.

(a) Corrective action procedures.

(1) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;

(ii) All affected food is evaluated for safety; and

(iii) All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Corrective action in the event of an unanticipated problem. If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:

(1) Take corrective action to identify and correct the problem to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (a)(2)(iii) of this section; and

(2) Reanalyze the food safety plan in accordance with §110.150(f) to determine whether modification of the food safety plan is required.

(c) Corrective actions for environmental monitoring. If environmental monitoring in accordance with § 110.150(d)(4) identifies the presence of an environmental pathogen or appropriate indicator organism, the owner, operator, or agent in charge of a facility must take corrective actions that include:

(1) Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;

(2) Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;

(3) Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated;

(4) Conducting finished product testing when appropriate; and

(5) Performing any other corrective actions necessary to prevent reoccurrence of the contamination.

(d) Documentation. All corrective actions taken in accordance with this section must be documented in records that are subject to verification in accordance with § 110.150(c) and records review in accordance with § 110.150(d)(5)(i).

§ 110.150 Verification.

(a) Validation. Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 110.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(1) Must be performed by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first six weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and

(3) Need not address:

(i) The food allergen controls in § 110.135(d)(2);

(ii) The sanitation controls in § 110.135(d)(3);

(iii) The recall plan in § 110.137; and

(iv) The supplier approval and verification program in § 110.152.

(b) Monitoring. The owner, operator, or agent in charge of a facility must verify that monitoring is being conducted, as required by § 110.140.

(c) Corrective actions. The owner, operator, or agent in charge of a facility must verify that appropriate decisions about corrective actions are being made, as required by § 110.145 and § 110.135(d)(3)(iv).

(d) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, by conducting activities that include the following, as appropriate to the facility and the food:

(1) Review of any consumer, customer, or other complaints to determine whether a complaint relates to the effectiveness of the food safety plan;

(2) Calibration of process monitoring instruments and verification instruments;

(3) Performance of finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur;

(4) Performance of environmental monitoring, for a microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur, by collecting environmental samples at locations within the facility at a frequency of not less than monthly, and testing the samples to assess whether the preventive controls significantly minimize or prevent the potential for an environmental pathogen to contaminate food;

(5) Review of the following records within the specified timeframes, by a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within a week after the records are made.

(ii) Records of consumer, customer, or other complaints, calibration, finished product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made.

(e)(1) Written procedures for verification activities. The owner, operator, or agent in charge of a facility must establish and implement written procedures for:

(i) Conducting finished product testing. Procedures for finished product testing must be scientifically valid and must include the procedures for sampling and the sampling frequency; and

(ii) Conducting environmental monitoring. Procedures for environmental monitoring must:

(A) Be scientifically valid;

(B) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be sufficient to determine whether preventive controls are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces within the manufacturing, processing, packing and holding environment; and

(C) Identify the test microorganism(s);

(iii) The frequency of calibrating process monitoring instruments and verification instruments.

(2) Written procedures must identify or include the analytical methods used to test finished product or environmental samples.

(f) Reanalysis.

(1) The owner, operator, or agent in charge of a facility must:

(i) Conduct a reanalysis of the food safety plan;

(A) At least once every 3 years;

(B) Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;

(C) Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food;

(D) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and

(E) Whenever a preventive control is found to be ineffective.

(ii) Complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production; and

(iii) Revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

(2) The reanalysis must be performed by a qualified individual.

(3) FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

(g) Documentation. All verification activities taken in accordance with this section must be documented in records.

§ 110.152 Supplier approval and verification program.

(a) Supplier approval and verification program. (1) Except as provided in paragraph (a)(6) of this section, the owner, operator, or agent in charge of a receiving facility must establish

and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur.

(2) The supplier approval and verification program must provide adequate assurances that the hazards identified as reasonably likely to occur by the receiving facility are significantly minimized or prevented.

(3) The supplier approval and verification program must include:

(i) A written list of approved suppliers;

(ii) For each raw material and ingredient, a written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient. If the owner, operator, or agent in charge of a receiving facility determines that a supplier is not subject to part 110, subpart C because the supplier is a qualified facility, then the owner, operator, or agent in charge of the receiving facility must obtain written assurance that the supplier meets the conditions for exemption as a qualified facility under § 110.2(a) and that FDA has not withdrawn such exemption for the supplier under subpart E of this part; and

(iii) Verification activities as required by paragraphs (b) and (c) of this section.

(4) When supplier verification activities are required under paragraph (b) or (c) of this section for more than one type of hazard, the owner, operator, or agent in charge of a receiving facility must conduct the verification activity or activities appropriate for each of those hazards. In some situations, a single verification activity will be appropriate for multiple hazards. In other situations, multiple hazards will require more than one verification activity to provide adequate assurances that each hazard is significantly minimized or prevented.

(5) For some hazards, in some situations under paragraph (b) or (c) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

(6) The owner, operator, or agent in charge of a receiving facility is not required to establish and implement a supplier approval and verification program for raw materials and ingredients for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur.

(b) Supplier verification activities for hazards to be controlled at the supplier's establishment, if the raw material or ingredient is subject to one or more designated food safety regulations. The owner, operator, or agent in charge of a receiving facility must conduct the following initial and periodic verification activities for hazards to be controlled at the supplier's establishment, if the supplier is subject to one or more designated food safety regulations with regard to the raw material or ingredient:

(1) Initial onsite audit. The owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier.

(2) Periodic onsite audits.

(i) When a hazard that is reasonably likely to occur with a raw material or ingredient is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the

supplier at least annually, unless more frequent onsite audits are necessary to adequately verify control of the hazard.

(ii) When a hazard that is reasonably likely to occur with a raw material or ingredient is not one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier at least every 2 years, unless more frequent onsite audits are necessary to adequately verify control of the hazard.

(c) Supplier verification activities for other hazards. For a hazard that is not subject to paragraph (b) of this section, the owner, operator, or agent in charge of a receiving facility must conduct one or more of the verification activities listed in paragraph (c)(1) through (4) of this section, as appropriate for the hazard, before using the raw material or ingredient and periodically thereafter. Such hazards include hazards to be controlled at the supplier's establishment and the supplier is not subject to one or more designated food safety regulations with respect to the raw material or ingredient. The frequency of verification activities must be based on the risk associated with the hazard.

(1) Periodic onsite audits that the owner, operator, or agent in charge of the receiving facility conducts, or for which the owner, operator, or agent in charge of the receiving facility obtains documentation.

(2) Periodic or lot-by-lot sampling and testing of the raw material or ingredient from the supplier that the owner, operator, or agent in charge of the receiving facility conducts, or has conducted, for the hazard.

(3) Periodic review by the owner, operator, or agent in charge of the receiving facility of the supplier's food safety records (e.g., audits of their supplier for the hazard).

(4) Other appropriate supplier control verification measures based on the risk associated with the hazard.

(d) Records. All supplier verification activities conducted in accordance with this section must be documented in records.

(e) Onsite audit. (1) An onsite audit must be performed by a qualified individual with the technical expertise obtained by a combination of training and experience appropriate to perform the auditing function; and

(2) If the raw material or ingredient at the supplier is subject to one or more designated food safety regulations, to provide adequate assurance that the hazard is significantly minimized or prevented an onsite audit must consider such regulations and include a review of the supplier's written plan, if any, including its implementation, for the hazard being audited.

(f) Independence of persons conducting an onsite audit. A person who conducts an onsite audit as set forth in paragraph (b) or (c) of this section must not have a financial interest in the supplier and payment must not be related to the results of the activity. This does not prohibit the owner, operator, or agent in charge of the receiving facility from conducting the audit.

(g) Supplier non-conformance. If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur, the receiving facility must take prompt action, which may include discontinuing use of the supplier, to ensure the hazards associated with the raw material or ingredient have been significantly minimized or prevented.

§ 110.155 Requirements applicable to a qualified individual.

(a) A qualified individual must:

(1) Prepare the food safety plan (§ 110.126(c)).

(2) Validate the preventive controls (§ 110.150(a)(1)).

(3) Review records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 110.150(d)(5)).

(4) Perform reanalysis of the food safety plan (§ 110.150(f)(2)).

(5) Perform an onsite audit (§ 110.152(e)(1).

(b) A qualified individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(c) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 110.175 Records required for subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, recall plan, written list of approved suppliers, and the written determination of which designated food

safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient.

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to

(i) Validation,

(ii) Monitoring,

(iii) Corrective actions, including corrective actions for environmental monitoring,

(iv) Review of consumer, customer or other complaints,

(v) Calibration of process monitoring and verification instruments,

(vi) Finished product testing,

(vii) Environmental monitoring,

(viii) Records review, and

(ix) Reanalysis;

(5) Records that document the supplier approval and verification program; and

(6) Records that document applicable training for the qualified individual.

(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Modified Requirements

§ 110.201 Modified requirements that apply to a qualified facility.

(a) Documentation to be submitted. A qualified facility must submit the following documentation to the Food and Drug Administration (FDA):

(1) Documentation that the facility is a qualified facility as defined in § 110.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) Documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) Documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(b) Procedure for submission. The documentation required by paragraph (a) of this section must be submitted to FDA by one of the following means:

(1) Electronic submission. To submit electronically, go to http://www.access.fda.gov and follow the instructions. This website is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) Submission by mail. To submit documents in a paper format or in an electronic format on a CD-ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. We recommend that an owner, operator or agent in charge of a facility submit by mail only if the facility does not have reasonable access to the Internet.

(c) Frequency of submission. The documentation required by paragraph (a) of this section must be:

(1) Submitted to FDA initially within 90 days of the applicable compliance date of this part; and

(2) Resubmitted at least every 2 years, or whenever there is a material change to the information described in paragraph (a) of this section. For the purpose of this section, a material change is one that changes whether or not a facility is a "qualified facility."

(d) Notification to consumers. A qualified facility that does not submit documentation under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities), as follows:

(1) If a food packaging label is required, the notification required by paragraph (c)(1) of this section must appear prominently and conspicuously on the label of the food.

(2) If a food packaging label is not required, the notification required by paragraph (c)(1) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(e) Records.

(1) A qualified facility must maintain those records relied upon to support the documentation required by § 110.201(a).

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

§ 110.206 Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) If there is a problem with the temperature controls for such refrigerated packaged food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected food for safety; and

(iii) Prevent the food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

(ii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged food; and

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility

§ 110.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

FDA may withdraw the exemption applicable to a qualified facility under § 110.2(a):

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(b) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

§ 110.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) If FDA determines that an exemption applicable to a qualified facility under § 110.2(a) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.

(b) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 110.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 110.2(a) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 110.270;

(g) The mailing address, telephone number, e-mail address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(h) The name and the title of the FDA representative who approved the order.

§ 110.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) The owner, operator, or agent in charge of a qualified facility that receives an order to withdraw an exemption applicable to that facility under § 110.2(a) must either:

(1) Comply with applicable requirements of this part within 60 calendar days of the date of the order; or

(2) Appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 110.264.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA,

unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order.

§ 110.264 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 110.2(a), the owner, operator, or agent in charge of the facility must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, e-mail address, or facsimile number identified in the order within 10 calendar days of the date of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 110.2(a), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in §110.267.

§ 110.267 Procedure for requesting an informal hearing.

(a) If the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 110.264 within 10 calendar days of the date of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial.

§ 110.270 Requirements applicable to an informal hearing.

If the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request:

(a) Except as provided by paragraph (b) of this section, the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 110.254 and 110.257, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the

Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 110.274, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Sections 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 110.270(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 110.270(c)(5) constitutes

the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 110.274 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 110.277 Time frame for issuing a decision on an appeal.

(a) If the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 110.270(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 110.280 Revocation of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 110.2(a) is revoked if:

(a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 110.284 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 110.301 Records subject to the requirements of this subpart F.

(a) Except as provided by paragraphs (b) and (c) of this section, all records required by this part are subject to all requirements of this subpart F.

(b) The requirements of § 110.310 apply only to the written food safety plan.

(c) The requirements of § 110.305(b), (d), (e), and (f) do not apply to the records required by § 110.201(e).

§ 110.305 General requirements applying to records.

Records must: (a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(b) Contain the actual values and observations obtained during monitoring;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§ 110.310 Additional requirements applying to the food safety plan.

The food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility:

(a) Upon initial completion; and

(b) Upon any modification.

§ 110.315 Requirements for record retention.

(a) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated

the written food safety plan (§ 110.126) or records that document validation of the written food safety plan (§ 110.150(a));

(c) Except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 110.320 Requirements for official review.

All records required by this part must be made promptly available to FDA upon oral or written request.

§ 110.325 Public disclosure.

Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart G – Reserved

Dated: _____.