DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

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 also is proposing to revise certain definitions in FDA's current regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for "farms." 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.

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DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 120 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. FDA-2011-N-0920 and/or RIN 0910-AG36, 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 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

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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.

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule:

Jenny Scott,

Center for Food Safety and Applied Nutrition (HFS-300),

Food and Drug Administration,

5100 Paint Branch Pkwy.,

College Park, MD 20740,

240-402-2166.

With regard to the information collection:

Domini Bean,

Office of Information Management,

Food and Drug Administration,

1350 Picard Dr.,

PI50-400T,

Rockville, MD 20850,

domini.bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

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Executive Summary

Purpose and Coverage of the Proposed Rule

The proposed rule would revise FDA's current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food in two fundamental ways. First, it would add new preventive controls provisions as required by the FDA Food Safety Modernization Act (FSMA). In general, with some exceptions the new

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preventive controls provisions would apply to facilities that are required to register with FDA under FDA's current food facility registration regulations. These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take any appropriate corrective actions, and maintain records documenting these actions. Second, the proposed rule would update, revise, or otherwise clarify certain requirements of our CGMP regulations, which were last updated in 1986.

In addition, this proposed rule would clarify the scope of the exemption for "farms" in FDA's current food facility registration regulations and make corresponding clarifications to FDA's current regulations for the establishment, maintenance, and availability of records. These clarifications would affect who would be subject to the current regulations for registration and recordkeeping as well as the new preventive controls requirements that would be established by this proposed rule.

To put these changes in context, and to provide legal, regulatory, scientific, and technical information relevant to the new provisions, we provide several sections of background. This background discusses the history of food regulation and current regulatory framework, provides an overview of the provisions of FSMA applicable to this proposed rule, explains the principles and history of the use of Hazard Analysis and Critical Control Point (HACCP) systems, and describes a variety of hazards that have been associated with foods and food safety problems (including outbreaks of foodborne illness) that have resulted from these hazards. An Appendix also describes the role of testing as a verification measure in a food safety system, and the role of supplier approval and verification programs in a food safety system.

Summary of the Major Provisions of the Proposed Rule

The proposed rule would implement the requirements of FSMA for covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the proposed rule would establish requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls for hazards that are reasonably likely to occur;
- Monitoring;
- Corrective actions;
- Verification; and
- Associated records.

The application of the preventive controls would be required only in cases where facilities determine that hazards are reasonably likely to occur. We do not expect that all possible preventive measures and verification procedures would be applied to all foods at all facilities.

The proposed rule would also establish a series of exemptions (including modified requirements in some cases) from the requirements for hazard analysis and preventive controls. Facilities that manufacture, process, pack or hold food and that are required to register with FDA under section 415 of the FD&C Act would be required to comply with the proposed regulation unless they are covered by an exemption. The table immediately below summarizes these proposed exemptions in general terms. Importantly, the table in this Executive Summary does not include all the details that you must consider to determine whether an exemption applies to

you. We provide those details in the proposed regulation (proposed § 117.5) and explain them in section X.C of this document.

Proposed Exemptions from the New Requirements for Hazard Analysis and Risk-Based Preventive Controls

| Who or What Would Be Exempt From the Requirements for Hazard Analysis and Risk-Based Preventive Controls | Notes |
|---|---|
| "Qualified Facility" as defined by FSMA:<br><br>• Business with average annual sales of < $500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or<br><br>• Very small business<br>• Option 1: Average annual sales of < $250,000<br>• Option 2: Average annual sales of < $500,000<br>• Option 3: Average annual sales of <$1,000,000 | FDA is proposing three options for defining "very small business" and requests comment on which to adopt in a final rule.<br><br>Modified requirements would apply - i.e., a qualified facility would be required to:<br>• Notify FDA about its status; and<br>• Either:<br>o Notify FDA that it is addressing hazards through preventive controls and monitoring; or<br>o Notify FDA that it complies with applicable local regulations, and notify consumers of the name and complete business address of the facility where the food was manufactured or processed. |
| • Low risk, on farm activities performed by small business (< 500 employees)<br><br>-or-<br><br>• Low-risk, on-farm activities performed by a very small business<br>o Option 1: very small = <$250,000<br>o Option 2: very small = <$500,000<br>o Option 3: very small = <$1,000,000 | Small and very small on-farm businesses conducting these low risk activities would be exempt from most of the rule's requirements.<br><br>We would define the low-risk activities that qualify for the exemption, including the specific foods to which they relate (such as re-packing intact fruits and vegetables, or grinding/milling/cracking/crushing grains) |
| Activities that are subject to the seafood HACCP requirements of part 123 (21 CFR part 123) | The facility must be in compliance with part 123. |
| Activities that are subject to the juice HACCP requirements of part 120 (21 CFR part 120) | The facility must be in compliance with part 120. |
| Activities that are subject to the "low-acid canned food" requirements of part 113 (21 CFR part 113) | • The exemption applies only with respect to microbiological hazards.<br>• The facility must be in compliance with part 113. |
| The manufacturing, processing, packing, or holding of a dietary supplement that is subject to the CGMP requirements of part 111 (21 CFR part 111) | • The facility must be in compliance with part 111.<br>• The facility must be in compliance with requirements for serious adverse event reporting for dietary supplements |
| Activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety) | Elsewhere in this issue of the Federal Register, FDA is proposing standards for produce safety. |

| Who or What Would Be Exempt From the Requirements for Hazard Analysis and Risk-Based Preventive Controls | Notes |
|---|---|
| Alcoholic beverages at a facility that 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 | The exemption also would apply to food other than alcoholic beverages at such a facility, provided that the food is in prepackaged form and constitutes not more than 5 percent of the overall sales of the facility. |
| Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing | A facility that stores raw agricultural commodities that are fruits and vegetables would not be exempt. |
| A facility solely engaged in the storage of packaged food that is not exposed to the environment | Modified requirements would apply for the storage of refrigerated packaged food. |

The proposed rule also would establish the conditions under which an exemption granted to a "qualified facility" could be withdrawn, and the procedures that would be followed to withdraw such an exemption. The proposed rule would establish requirements that would apply to all records that would be required by the various proposed provisions. The proposed recordkeeping provisions would implement specific requirements of FSMA regarding records associated with the new provisions for hazard analysis and risk-based preventive controls and would allow facilities to show, and FDA to determine, compliance with the regulatory requirements.

The proposed rule would require that a qualified individual 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 required reanalysis of a food safety plan. The proposed rule also would establish minimum requirements for the "qualified individual," who would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a

food safety system. Only a trained individual or individual qualified by job experience is capable of effectively executing these activities.

FDA is requesting comment on when and how other elements of a preventive controls system are an appropriate means of implementing the statutory directives, including: a product testing program, an environmental monitoring program, and a supplier approval and verification program, as appropriate.

Costs and Benefits

We summarize the domestic annualized costs of the three options for the proposed rule in the table immediately below. We are unable to estimate the benefits of the proposed rule. Instead we show the Breakeven Illness Percentage for each of the three options for the proposed rule. This is calculated by dividing the number of illnesses that would have to be prevented annually under each option by the total estimated number of illnesses attributable to FDA-regulated food products under the scope of each option of the proposed rule. This ignores the costs to foreign firms and benefits to foreign consumers.

| | Total Domestic Costs Annualized at 7 Per Cent over 7 Years | Annual Breakeven Illness Percentage |
|---|---|---|
| Proposed Rule with Very Small Business Defined as Less Than or Equal to $250,000 in Annual Revenue | $475 million | 24 |
| Proposed Rule with Very Small Business Defined as Less Than or Equal to $500,000 in Annual Revenue | $395 million | 20 |
| Proposed Rule with Very Small Business Defined as Less Than or Equal to $1,000,000 in Annual Revenue | $319 million | 16 |

I. Introduction

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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 (CDC). This is a significant public health burden that is largely preventable. While many illnesses are the result of improper food handling practices in the home and food service settings, which would not be addressed by this proposed rule, FDA believes that improvements to its current good manufacturing practice (CGMP) regulations in part 110 (21 CFR part 110), including those prescribed by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-533), can play an important role in reducing foodborne illness.

FSMA, 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.

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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 FDA of 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.

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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 (USDA) 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, and the United States has one of the safest food supplies in the world, 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 percent 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 http://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, 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. A proposed rule on foreign supplier verification is closely interconnected to this rule on preventive controls for human food, and is expected to publish soon.

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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 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).

**Deleted:** 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. ¶

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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,

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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. 1).

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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. 1).

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2. Other Food Safety Regulations Established by FDA

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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

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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. 2). 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).

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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

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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

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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).

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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; and 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 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.

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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.

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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.

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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 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

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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 spp. 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 spp., except for shell eggs that have been specifically processed to destroy all viable Salmonella spp. 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.

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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).

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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. 3) and the juice HACCP regulation (Ref. 4). In other cases, we issue guidance that is more narrowly focused in scope or is not directly targeted to assisting industry in

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complying with a particular food safety regulation. For example, we have issued guidance that addresses the chemical contamination of candy with lead (Ref. 5) and guidance on measures to address the risk for contamination by Salmonella spp. in food containing a peanut-derived product as an ingredient (Ref. 6).

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. 7 Ref. 7), 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 spp. (Ref. 8).

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

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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)).

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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. 9).

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. 10). 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. 11) (Ref. 12).

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.

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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.

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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 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. 13). The Foodborne Outbreak Online Database (FOOD) allows the public direct access to information on foodborne outbreaks reported to CDC (Ref. 14).

In July 1995, the Foodborne Diseases Active Surveillance Network (FoodNet) was established as a collaborative program among CDC, 10 state health departments, USDA's Food Safety and Inspection Service (FSIS), and FDA. FoodNet conducts surveillance for infections caused by specific pathogenic microorganisms as diagnosed by laboratory testing of samples

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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. 15). Information from FoodNet is used to assess the impact of food safety initiatives on the burden of foodborne illness (Ref. 16).

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 FDA and FSIS. Using

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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 (Ref. 17). 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 a web-based information network (the Electronic Laboratory Exchange Network, or eLEXNET) (Ref. 18) 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 spp., Listeria monocytogenes,), aflatoxin, antibiotics, undeclared allergens, heavy metals, and other threats to

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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).

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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 (Ref. 19) (Ref. 20 ) (Ref. 21) (Ref. 22) (Ref. 23) (Ref. 24), with correspondingly significant disruption and cost for industry and consumers.

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e. State surveillance and reporting programs. State food safety agencies are involved in identifying contaminated food by conducting surveillance testing (Ref. 25). 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

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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. 26). FDA coordinates 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. 18). FDA also participates in 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. 17).

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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.

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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. 27).

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We also engage in consumer outreach in partnership with non-governmental entities. Most prominently, HHS, USDA, and the U.S. 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. This partnership, 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. 28).

FDA also conducts its own independent informational outreach efforts specifically designed for consumers (Ref. 29) and for educators (Ref. 30).

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## 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.

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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.C.1 of this document, we discuss a proposed exemption for qualified facilities (proposed § 117.5(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 § 117.201).

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.C.2 through X.C.4 of this document, we discuss proposed exemptions for activities that are subject to part 123 (proposed § 117.5(b)), part 120 (proposed § 117.5(c)), part 113 (proposed § 117.5(d)), section 419 of the FD&C Act (proposed § 117.5(f)), or the manufacturing, processing, packing, and holding of dietary supplements (proposed § 117.5(e)).

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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.C.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.C.7 of this document, we discuss proposed exemptions related to such facilities (proposed § 117.5(i)).

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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.

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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.C.1 of this document. (§ 418(l)(1)(B) of the FD&C Act).

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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. 31). The study is available in the docket established for this proposed rule (Ref. 32). We request comment on that study. In section X.B.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; hereinafter the section 415 registration regulations) 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)).

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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 section 415 registration regulations to enhance the implementation of section 415 and to clarify the definition of the term "facility."

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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:

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- "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

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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 section VIII.G 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 and request comment on that approach. The final approach will consider comments received to this proposed rule.

In sections VIII.J and X.C 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 § 117.5(g) and (h)). In section VIII.J of this document, we 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 and we seek comment on this proposal.

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.C.8 of this document, in accordance with

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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 117.

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 117 would apply to such facilities (proposed § 117.7). 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 § 117.206).

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 plans to propose a separate regulation applicable to certain hazards that may be associated with a food facility that manufactures, processes, packs or holds animal food. Establishments that manufacture, process, pack, or hold food for both humans and animals should consider this proposed rule as well as the

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future proposed rule directed to CGMPs and hazard analysis and risk-based preventive controls for food for animals, 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

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advisory committee chartered under USDA (Ref. 33). 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. 34). 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. 34). 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

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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

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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

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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). 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." Although the approach in section 418 and this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls.

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

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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. 35).

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. 34). 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.

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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. 34). 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. 34). 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. 34). 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

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of a food safety hazard (Ref. 34). 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. 35)) 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. 34). 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. 34). While the HACCP system is intended to prevent deviations in a planned process from occurring, total prevention can rarely, if ever, be achieved.

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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. 34). 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.

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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

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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

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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. 36). 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).

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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. 36). 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

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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).

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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. 34). 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

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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.

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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. 37).

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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 Codex General Principles of Food Hygiene (GPFH) (Ref. 35). The European Union (EU) and other countries around the world have begun to require that foods be processed using a HACCP system. 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. 38) (the EU Regulation), the Australia-New Zealand Food Standards Code (Ref. 39), and the Canadian Food Inspection Agency's Food Safety Enhancement Program (Ref. 40), all of which are based on the Codex HACCP Annex.

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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. 41). (See section II of the Appendix to this document 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, such as experts/authorities in NACMCF (Ref. 34), Codex (Ref. 35), FSANZ (Ref. 39), CFIA (Ref. 40), and the European Union (Ref. 38). 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. 42). 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. 43).

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. 35) has become the reference for international food safety requirements. The Codex GPFH recommends a HACCP approach wherever possible to enhance food safety (Ref. 44). 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. 43).

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## 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 (Ref. 45) (Ref. 46). 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. 47). 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 spp., 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. 45). (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).

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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. 46). In addition, microorganisms can change their characteristics by acquiring genes, including those for virulence, from other microorganisms (Ref. 48).

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2. Microbiological, Chemical, Physical, and Radiological Hazards

In the following discussion of hazards, we highlight 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. 49). 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. 50). The incidence of foodborne illness due to Salmonella spp. has not declined significantly in the last 15 years (Ref. 50). Salmonella spp. can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems (Ref. 49) (Ref. 51). 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. 49) (Ref. 51).

Listeria monocytogenes

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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. 50). L. 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 (Ref. 52) (Ref. 53). 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. 54). 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. 54) (Ref. 55).

The risk of illness from L. monocytogenes associated with a particular food is dependent on five key factors (Ref. 52) (Ref. 53):

- 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.

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In 2003, FDA and 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. 53). 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. 56). 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. 54). 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. 45).

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,

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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. 49).

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. 57). 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

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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. 45).

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. 58). 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. 59). In these two reports, the second most common reason for such recalls was microbiological contamination (Ref. 58) (Ref. 59). 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 spp. (7.6 percent). In the first annual report on the Reportable Food Registry, the three main pathogens associated with the 229 primary reports received by the RFR were Salmonella spp. (37.6 percent), L. monocytogenes (14.4 percent), and E. coli O157:H7 (2.6 percent) (Ref. 60). In the second annual report on the Reportable Food Registry, the three main pathogens associated with the 225 primary reports received by the RFR were Salmonella spp. (38.2 percent), L. monocytogenes (17.8 percent), and E. coli O157:H7 (0.4 percent) (Ref. 61).

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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. 62). (Salmonella spp. 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 (Ref. 63). Investigators detected Salmonella spp. in environmental samples collected at the manufacturer's facility as well as in finished product (Ref. 64) (Ref. 65). Two years later, in 2008-2009, another large Salmonella outbreak was linked to peanut butter and peanut paste (Ref. 66) (Ref. 67). Implicated products included contaminated peanut butter consumed at institutional settings and peanut crackers made with the contaminated peanut butter as an ingredient (Ref. 66). This single outbreak resulted in 714 confirmed cases of illnesses, including 166 hospitalizations, and 9 deaths (Ref. 67). 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 (Ref. 68) (Ref. 69) .
- 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 (Ref. 51) (Ref. 70).

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- 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. 71). An investigation at the plant revealed the potential for product contamination due to deficiencies in cleaning and plant and equipment maintenance (Ref. 72).

- 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. 73) (Ref. 74). 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. 75).

- 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. 76) (Ref. 77). E. coli O157:H7 was found in unopened packages of cookie dough in the production facility, although it was not the outbreak strain (Ref. 77) (Ref. 78).

- In 2011, an outbreak of listeriosis from cantaloupes was attributed to insanitary conditions at a facility that washed, packed, cooled, and stored intact cantaloupes (Ref. 79) (Ref. 80). The outbreak appears to have occurred due to a combination of factors, including pooled water on the floor of the facility (which was also difficult to clean), poorly designed equipment (not easily cleaned and sanitized) that was previously used for a different commodity, no pre-cool step, a truck parked near the packing area that had visited a cattle operation, and possible low level contamination from the growing/harvesting operation (Ref. 79).

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,

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decomposition resulting in the production of toxins such as histamine, unapproved 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. 81). 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 by a living animal before slaughter, 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 (Ref. 82) (Ref. 83) (Ref. 84) (Ref. 85).

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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. 86) (Ref. 87). Heavy metals (such as lead) can lead to adverse health consequences (such as impaired cognitive development in children) (Ref. 88).

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 and 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. 88) and liver cancer as the result of chronic exposure to the mycotoxin aflatoxin (Ref. 89 (Ref. 90).

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. 91) (Ref. 92) (Ref. 93). A recent study by CDC estimates that approximately 3 million children in the United States (3.9 percent) have food allergies (Ref. 94). This study also reported that the prevalence of food allergies increased by 18 percent in this age group between 1997 and 2007 (Ref. 94).

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

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food protein (Ref. 95) (Ref. 96) (Ref. 97). 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. 98), and as many as 100-150 deaths in the United States each year (Ref. 99) (Ref. 100). For children under 18 years of age, CDC estimates that there are approximately 9,500 food allergy-related hospitalizations per year (Ref. 101). The signs and symptoms associated with allergic reactions can range from oral irritation and swelling to cardiovascular collapse (Ref. 102).

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. 101). 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. 58). 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

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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. 59). 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. 103). 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. 104).

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 first 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. 60). 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

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recalled after shards of broken glass were found in some packages (Ref. 105) and in May 2011 several types of English muffins and bread products were recalled due to possible contamination with small pieces of metal (Ref. 106).

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e. Radiological hazards. Radiological contamination of foods is a rare event. Examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium-235, uranium-238, plutonium-239, strontium-90, iodine-131, and cesium-137. 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 (Ref. 107) (Ref. 108). 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. 109).

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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. 109).

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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 (Ref. 58) (Ref. 59).

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3. Preventing Food Safety Problems

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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. 34). 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

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for seafood, juice, and meat and poultry.) Codex has issued guidelines for HACCP systems (Ref. 35), and several industrialized nations or unions have mandated HACCP for part or all of their food industries (Ref. 38) (Ref. 39) (Ref. 40).

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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

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. 34) (Ref. 110). 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. 111) (Ref. 112). 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. As discussed in the Appendix to this document (see sections J.C, I.E, and J.F of the Appendix), 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.

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Each type of testing provides information applicable to managing hazards in foods, depending on the food and process. We discuss the role of testing as a verification measure in a food safety system in section I of the Appendix to this document.

F. The Role of Supplier Approval and Verification Programs in a Food Safety System

The development of a supplier approval and verification program can be 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. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help 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 can help provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or

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ingredients. We discuss supplier approval and verification programs in more detail in section II of the Appendix to this document.

## 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 changes to 21 CFR Part 1, Subparts H, I, and J under the FDA Food Safety Modernization Act and the FD&C 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 1, Subparts H, I, and J

Section 103(c)(1)(A) of FSMA requires that 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 (Registration of Food Facilities) 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 section 415 registration regulations (21 CFR subpart H) 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 the scope of the exemption for "farms" provided by section 415 of the FD&C Act. The proposed rule also 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). FDA's legal authority to modify these regulations is derived from section 103(c) of FSMA and 21 U.S.C. 414, 415, 381(m) and 371(a).

**Deleted:** 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 ...

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**Deleted:** 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. ¶

## B. Changes to Current 21 CFR Part 110

FDA's legal authority to require Current Good Manufacturing Practices 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.

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.)

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**Deleted:** 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).¶

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**Deleted:** ; 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.

C. 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 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. Further, 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

**Deleted:** 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 …

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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.

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, C, XIII, and XIV of this document, we discuss proposed provisions (proposed § 117.5(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

**Deleted:** 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. ¶

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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.

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. Certain activities would be required to be conducted (or overseen) 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

**Deleted:** 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.

**Deleted:** 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.¶

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address those hazards determined to be reasonably likely to occur, procedures for monitoring, corrective actions, and verification, and a recall plan. The written plan and other documentation would be required to be made promptly available to FDA upon oral or written request.

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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.

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## IV. Public Meeting and Preliminary Stakeholder Comments

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### 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 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

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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 FDA to conduct inspections.

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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. 113). 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. 114).

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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 be limited to "major food allergens," as defined in the FD&C Act.

We propose a definition of "food allergen" (proposed § 117.3) in section X.B.4 of this document and discuss proposed requirements for preventive controls directed to food allergens (proposed § 117.135(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.

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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 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 J in the Appendix to this document discusses a number of issues associated with environmental monitoring and product testing. Although we are not including provisions for

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environmental monitoring or product testing in this proposed rule, in section XII.J of this document, we request comment on these issues.

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, because 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

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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.

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G. Comments on Guidance and Outreach

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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.

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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 No. 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

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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 § 117.135 (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 § 117.3) in section X.B.4 of this document. We discuss our proposed definition for "qualified facility" (proposed § 117.3) in section X.B.4 of this document; our proposed exemption from subpart C for a "qualified facility" (proposed § 117.5(a)) in section X.C.1 of this document; proposed modified requirements for a "qualified facility" (proposed § 117.201) in section XIII.A

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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.K 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.

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FDA is proposing modified requirements for warehouses solely engaged in the storage of packaged food that is not exposed to the environment in proposed § 117.7 (discussed in section X.D of this document) and proposed § 117.206 (discussed in section XIII.B of this document).

## V. Placement of Regulatory Requirements

We are proposing to establish the revised umbrella CGMP requirements, together with the new requirements for hazard analysis and risk-based preventive controls, in proposed part 117. As discussed in section XVII of this document, we are proposing to remove current part 110 after the compliance date for all businesses to be in compliance with the requirements of new part 117.

## 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 implement section 103 of FSMA. Second, it would update, revise, or otherwise clarify certain requirements of our current regulations in part 110. The new provisions and revisions to the current CGMP requirements would be established in part 117. Under the proposed rule, new part 117 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

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**Deleted:** 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. ¶

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As required by section 103(c) of FSMA, the proposed rule also

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- 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, Subparts H, I, and J

To implement section 103(c) of FSMA, the proposed rule would revise certain definitions in FDA's current section 415 registration regulations. These revisions would 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 the scope of the exemption for "farms" provided by section 415 of the FD&C Act. The proposed rule also 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). .

C. Proposed Revisions to General Provisions of 21 CFR Part 110 (Part 110) (Proposed Part 117, Subpart A)

The proposed rule would both revise current provisions of subpart A of part 110 and add new provisions to subpart A as it would be established in proposed part 117. The new provisions would include specified exemptions for certain facilities, or for certain activities conducted by facilities, from the proposed requirements for hazard analysis and preventive controls in proposed part 117, subpart C. The proposed exemptions would be consistent with requirements established by FSMA or discretion provided by FSMA. The subjects of the specified exemptions relate to:

- A "qualified" facility;

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**Deleted:** 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.

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Add a provision establishing that the operation of a facility that manufactures, processes, packs, or holds food for sale

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Establish

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- Activities subject to our existing HACCP regulations for seafood and juice, our regulations governing microbiological hazards in low acid canned foods, and our dietary supplement CGMP regulations;
- Activities of a facility that are subject to the Standards for Produce Safety in section 419 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;
- Certain low-risk manufacturing/processing activity/food combinations conducted on a farm by a small or very small business;
- The receipt, manufacturing, processing, packing, holding, and distribution of alcoholic beverages and other prepackaged food sold in conjunction with alcoholic beverages (e.g., gift baskets);
- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing; 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.

D. Proposed Revisions to Current Good Manufacturing Practice Requirements of Part 110 (Proposed Part 117, Subpart B)

In order to modernize current CGMP requirements, the proposed rule would make revisions including:

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**Deleted:** in part 120 (proposed § 110.2(c); under section 418(j)(1)(B) of the FD&C Act);¶ Activities applicable to the

**Deleted:** 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

**Deleted:** (proposed § 110.2(e); under section 103(g) of FSMA);

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**Deleted:** (proposed § 110.2(j); under section 418(m) of the FD&C Act);

**Deleted:** (proposed § 110.5; under section 418(m) of the FD&C Act).

**Deleted:** <#>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.¶

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- Modernizing and updating the language throughout (e.g., by replacing the word "shall" with the word "must" and by using certain terms consistently throughout proposed part 117);
- Deleting certain provisions containing recommendations, including the specific temperatures for maintaining refrigerated, frozen or hot foods;
- Clarifying that certain CGMP provisions requiring protection against contamination require protection against cross-contact of food as well to address allergens; and
- Proposing that provisions directed to preventing contamination of food and food-contact substances be directed to preventing contamination of food-packaging materials as well.

E. Proposed New Requirements for Hazard Analysis and Risk-Based Preventive Controls (Proposed Part 117, Subpart C)

1. Written Food Safety Plan

We propose to require that the owner, operator, or agent in charge of a facility have and implement a written food safety plan that includes as applicable:

- A hazard analysis;
- Preventive controls;
- Monitoring procedures;
- Corrective action procedures;
- Verification procedures; and
- A recall plan.

2. Written Hazard Analysis

We propose to require that the written hazard analysis identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at

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the facility to determine whether there are hazards that are reasonably likely to occur, including biological, chemical, physical, and radiological hazards. The hazard analysis would include an evaluation of the identified hazards 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.

3. Written Preventive Controls

We propose to 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; and
- Any other necessary controls.

4. Written Recall Plan

We propose to require that the written recall plan be developed for food with hazards that are reasonably likely to occur.

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A supplier approval

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5. Monitoring

We propose to require the 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.

6. Corrective Actions

We propose to require that facilities establish and implement written corrective action procedures that would be used if preventive controls are not properly implemented and take corrective actions in the event of an unanticipated problem.

7. Verification

We propose to require that facilities conduct certain verification activities, including:

- Validation of a subset of the preventive controls;
- Verification that monitoring is being conducted;
- Verification that appropriate decisions about corrective actions are being made; and
- Verification that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur.

We also propose to require reanalysis of the food safety plan at least once every 3 years and more often when circumstances warrant.

8. Qualified Individual

We propose to establish qualification requirements for a "qualified individual," who would be required to do or oversee the preparation of the food safety plan, validation of

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<#>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; ¶ ...

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preventive controls, review of records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and reanalysis of a food safety plan. A "qualified individual" would be required to successfully complete training with a standardized curriculum 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.

9. List of Required Records

We propose to establish a list of records that would be required under proposed subpart C, including the written food safety plan and records documenting monitoring of preventive controls, corrective actions, verification, and applicable training for the qualified individual.

F. Proposed New Provisions for Modified Requirements (Proposed Part 117, Subpart D)

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: Implementing the modified requirements specified in section 418(l) of the FD&C Act for facilities that satisfy the statutory criteria for a "qualified facility," we propose to establish requirements that include:
  - Submission to FDA of documentation that the facility is a qualified facility; and
  - 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

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<#>Records that document the supplier approval and verification program; and¶
<#>Records that document applicable training for the qualified individual.¶

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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.

- Facilities solely engaged in the storage of packaged food that is not exposed to the environment: Acting on the discretion provided to FDA by section 418(m) of the FD&C Act, we propose to 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 the following records:
  - Records documenting the monitoring of temperature controls;
  - Records of corrective actions; and
  - Records documenting verification activities.

We seek comment on these proposed requirements.

**Deleted:** <#>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. ¶

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G. Proposed New Provisions for Withdrawal of an Exemption Applicable to a Qualified Facility (Proposed Part 117, Subpart E)

Proposed subpart E would implement the provisions of section 418(l)(3) of the FD&C Act and establish the conditions under which an exemption granted to a "qualified facility" could be withdrawn, and the procedures that would be followed to withdraw such an exemption.

H. Proposed New Recordkeeping Requirements (Proposed Part 117, Subpart F)

Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of proposed part 117, including:

- General requirements related to the content and form of records;
- Additional requirements specific to the food safety plan;
- Requirements for record retention;
- Requirements for official review of records by FDA; and
- Public disclosure.

## 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 tentatively concludes that it is appropriate to provide a sufficient time period following

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<#>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.¶
**Deleted:** : 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.
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**Deleted:** <#>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.¶
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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.

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 can take time to implement a food safety system that would require, among other things, performance of a hazard analysis, development of preventive controls, and monitoring of preventive controls.

FDA is proposing that the final rule would be effective 60 days after publication in the Federal Register, with staggered compliance dates. However, we recognize that businesses of all sizes may need more time to comply with the new requirements established under FSMA. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. FDA also believes that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements established under FSMA, and 3 years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements established under FSMA. 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.

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FDA also is proposing to modernize the existing CGMP requirements, and businesses already subject to current part 110 will be subject to the modernized CGMPs that would be established in proposed part 117. FDA believes that it is reasonable to allow for the same compliance periods for the modernized CGMPs as for the other provisions in proposed part 117 so that a facility would be subject to all of the relevant provisions in proposed part 117 at the same time. To provide for this staggered implementation of the modernized CGMPs, FDA is proposing to establish the revised regulations in a new part (i.e., part 117) so that current part 110 can remain unchanged and in effect for compliance purposes until all businesses have reached the date when they must be in compliance with new part 117. Thus, as discussed in section XVII of this document, we are proposing that current part 110 be removed on the date that is 3 years after the date of publication of the final rule.

## VIII. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

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### A. Section 103(c) of FSMA

#### 1. Clarification of the Activities That Are Included As Part of the Definition of the Term "Facility" under Section 415 of the FD&C Act

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." Section 415 of the FD&C Act, in turn, 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. The registration requirement in section 415 of the FD&C Act does not apply to farms. Our regulations that implement section 415 and require food facilities to register with FDA are established in part 1 (21 CFR part 1), subpart H (Registration of Food Facilities) (the section 415 registration regulations).

To implement sections 103(c)(1)(A) and (B) of FSMA, 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. In the remainder of this section VIII of this document:

- We discuss the current legal and regulatory framework for farms under sections 415 and 418 of the FD&C Act, including requirements for registration of food facilities in the section 415 registration regulations. (See section VIII.B.)
- We explain why we tentatively conclude that rulemaking is needed to implement sections 103(c)(1)(A) and (B) of FSMA. (See section VIII.C.)
- We explain how the status of a food as a raw agricultural commodity (RAC) or a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act. We also articulate a comprehensive set of organizing principles that form the basis for proposed revisions to the section 415 registration regulations. (See section VIII.D.)

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- We describe our proposed revisions to the definitions in the section 415 registration regulations, based on the organizing principles articulated in section VIII.D, to clarify the treatment of activities that are included as part of the definition of the term "facility" in those regulations and to enhance and clarify the application of those definitions. We also describe conforming changes to part 1, subpart I (Prior Notice of Imported Food) (hereinafter the prior notice regulations, established under section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) (hereinafter the "BT Act")) and part 1, subpart J (Establishment, Maintenance, and Availability of Records) (hereinafter the section 414 recordkeeping regulations, established under section 414 of the FD&C Act). (See section VIII.E.)
- We describe the impact of the proposed revisions to the definitions in the section 415 registration regulations on farms and on "farm mixed-type" facilities. A "farm mixed-type" facility conducts activities that are outside the scope of the definition of "farm" (e.g., slicing or chopping fruits or vegetables) even though it also conducts activities that are within the scope of the definition of farm (e.g., growing and harvesting crops or raising animals). Conducting activities outside the definition of "farm" triggers the requirements in the section 415 registration regulations) and, thus, brings the facility within the scope of section 418 of the FD&C Act. (See section VIII.F.)

2. Science-Based Risk Analysis Covering Specific Types of On-Farm Manufacturing, Processing, Packing and Holding Activities

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 a draft Qualitative Risk Assessment (the section 103(c)(1)(C) draft RA) (Ref. 115) we performed to satisfy this requirement.

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3. Exemptions and Modified Requirements for Certain Facilities

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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 discuss the results of the section 103(c)(1)(C) draft RA. In section VIII.I of this document, we set forth our tentative conclusions regarding combinations of on-farm

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manufacturing, processing, packing, and holding activities and foods determined to be low risk, considering the results of the section 103(c)(1)(C) draft RA. In section VIII.J of this document, we discuss a proposed approach to using the results of the section 103(c)(1)(C) draft RA for the purposes of section 421 of the FD&C Act. In section X.C.6 of this document, we discuss our proposal to exempt low-risk combinations of activities and foods from the requirements of section 418 of the FD&C Act when performed by farm mixed-type facilities that are small or very small businesses as would be defined in proposed § 117.3 (see discussion of the proposed definitions of "small business" and "very small business" in section X.B.4 of this document).

B. The Current Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

As noted in the previous section, 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. Section 1.227 in the section 415 registration regulations includes definitions that are relevant to the scope of those regulations, including definitions for types of establishments ("facility" and "farm") and for types of activities ("holding," "manufacturing/processing," "packaging," and "packing"). In relevant part, these definitions play a role in determining whether an establishment is a facility that must register with FDA and implement a provision (in section 415(b)(1) of the FD&C Act) exempting "farms" from the registration requirement in section 415. We have issued guidance to assist food facilities in complying with the section 415 registration regulations (hereinafter "Food Facility Registration Guidance") (Ref. 116).

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Section 418(n) of the FD&C Act directs the Secretary to establish regulations implementing the requirements of section 418 for hazard analysis and risk-based preventive controls applicable to the owner, operator, or agent in charge of a "facility." Section 418(o)(2) of the FD&C Act defines "facility" for the purpose of section 418 as "a domestic or foreign facility that is required to register under section 415."

Under the framework established by section 415 of the FD&C Act and the section 415 registration regulations, farms are establishments that do conduct activities described in the farm definition in § 1.227(b)(3) but do not conduct other activities (such as manufacturing/processing on food that is not consumed on that farm or another farm under the same ownership) that would trigger the requirements in the section 415 registration regulations. Because establishments that satisfy the definition of "farm" in § 1.227(b)(3) are not required to register under section 415, they do not satisfy the definition of "facility" in section 418(o)(2) of the FD&C Act and, thus, they are not subject to section 418 of the FD&C Act.

The current legal and regulatory framework provided in sections 415 and 418 of the FD&C Act, the section 415 registration regulations, 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 provisions applicable to the current legal and regulatory framework in Table 1.

Table 1. Key Provisions Applicable to the Current Legal and Regulatory Framework under Sections 415 and 418 of the FD&C Act

| Provision of the Section 415 Registration Regulations or the FD&C Act | Definition or Requirement |
|---|---|
| § 1.227(b)(2): Current definition of "facility" | 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. |



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<#>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. ¶

| Provision of the Section 415 Registration Regulations or the FD&C Act | Definition or Requirement |
|---|---|
| § 1.225: Requirement to register | The owner, operator, or agent in charge of either a domestic or foreign facility must register in accordance with the section 415 registration regulations 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. |
| § 1.226(b): Exemption from registration for farms | Farms are not subject to the registration requirement in § 1.225. |
| § 1.227(b)(3): Current definition of "farm" | 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. |
| § 1.227(b)(5): Current definition of "holding" | Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. |
| § 1.227(b)(6): Current definition of "manufacturing/ processing" | 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. |
| § 1.227(b)(8): Current definition of "packaging" | Packaging (when used as a verb) means placing food into a container that directly contacts food and that the consumer receives. |
| § 1.227(b)(9): Current definition of "packing" | Packing means placing food into a container other than packaging the food. |
| Section 418(o)(2) of the FD&C Act | A facility that is subject to the requirements of section 418 of the FD&C Act is a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act. |

Together, the provisions described in Table 1 establish that a business qualifies as a "farm" that is exempt from the section 415 registration regulations 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.

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- 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.

We note that FDA established the same definitions of the terms "facility," "farm," "holding," "manufacturing/processing," "packaging," and "packing" in the section 414 recordkeeping regulations (§ 1.328), because farms are excluded from FDA's authority to establish recordkeeping requirements under section 414(b) of the FD&C Act.

C. Why This Rulemaking Is Needed

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 (34 FR 6977 at 6980, April 26, 1969). The 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. Under that proposed definition, the term "farm" would also have included (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

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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 5378 at 5418, February 3, 2003).

FDA received comments stating that the proposed definition 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 (68 FR 58894 at 58905, October 10, 2003). Accordingly, to reflect the intent of Congress to exempt establishments engaging in activities farms traditionally perform from the section 415 registration regulations, in the final rule 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 (68 FR 58894 at 58905) (emphasis added). FDA also established the same definition of "farm" at § 1.328 for the purpose of exempting farms from the section 414 recordkeeping regulations (69 FR 71652, December 9, 2004). In post-rulemaking guidances implementing the section 415 registration regulations and the section 414 regulations, FDA further addressed and 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 the Food Facility Registration Guidance (Ref. 116) and "Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4), September 2006 (hereinafter "Recordkeeping Guidance" (Ref. 117)).

Farm mixed-type facilities

Consistent with the current legal and regulatory framework under sections 415 and 418 of the FD&C Act and the section 415 registration regulations, activities within the farm definition in § 1.227(b)(3) would not be subject to the requirements of this proposed rule. Activities that

**Deleted:** 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).

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are not within the farm definition and that trigger the section 415 registration regulations would be subject to the requirements of section 418 of the FD&C Act (and therefore to the relevant parts of this proposed rule), except where an exemption applies. (For a discussion of proposed exemptions, see section X.C of this document.)

For the purposes of this document, a "farm mixed-type facility" is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but that also conducts activities that trigger the section 415 registration regulations (see the discussion of our proposed definition of "farm mixed-type facility" in section VIII.E of this document). Section 418 of the FD&C Act does not explicitly address whether a farm mixed-type facility is subject to section 418 with respect to all of its activities or only with respect to its activities that trigger the section 415 registration regulations. Considering the text of section 103 of FSMA and the FD&C Act as a whole, FDA tentatively concludes that a farm mixed-type facility should be subject to section 418 only with respect to its activities that trigger the section 415 registration regulations, and not with respect to its activities that are within the farm definition. Put another way, we would apply section 418 only to the "non-farm" portion of the establishment's activities, and not to the "farm" portion of its 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 section 415 registration regulations, including the farm exemption in § 1.226(b), to be meaningful for the purposes of defining the applicability of section 418. 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

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to take other steps discussed more fully in section XII of 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." Considering the text of FSMA and the FD&C Act as a whole, FDA tentatively concludes that only those manufacturing, processing, packing, or holding activities that trigger registration under the section 415 registration regulations 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 a mixed-type facility should only be subject to section 418 with respect to its activities that actually trigger the section 415 registration regulations, and not with respect to its other activities, at the same location, that would not trigger the section 415 registration regulations. 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 (see the discussion of the exemption provided by section 418(k) of the FD&C Act to such farms in section X.C.5 of this document). 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 conducted by a farm mixed-type facility outside the farm exemption, seems to mean that Congress did not intend the "farm" portion of

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such a facility to be covered by section 418, even though Congress intended the "non-farm" portions of such a facility to be subject to section 418 (including under modified requirements) (provided that FDA concluded that it was appropriate to do so after conducting the science-based risk analysis required by section 103(c)(1)(C) of FSMA). (See section VIII.G for a discussion of the analysis FDA conducted and section VIII.H of this document for a discussion of FDA's proposed actions in light of that analysis.).

Therefore, unless an exemption from section 418 of the FD&C Act applies, FDA tentatively concludes that a facility that is required to register under section 415 of the FD&C Act should be subject to section 418 with respect to all its activities that trigger the section 415 registration regulations, but not with respect to its activities that would not trigger the section 415 registration regulations (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 a farm mixed-type facility must comply with section 418.

Clarification of activities relevant to farm mixed-type facilities

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 section 415 registration regulations and the section 414 recordkeeping regulations. 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 the scope of the

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farm definition, including the classification of manufacturing, processing, packing and holding activities relevant to that definition, and adjust it if necessary and appropriate to enhance implementation of section 418 of the FD&C Act, as well as section 415 of the FD&C Act. Accordingly, in the remainder of this section VIII FDA articulates a comprehensive set of organizing principles that would form the basis for our proposal for classifying activities to more accurately reflect the scope of activities traditionally conducted by farms and to allow for more certainty among industry with regard to how their activities will be regulated. We seek comment on this proposal.

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D. Organizing Principles for How the Status of a Food As a Raw Agricultural Commodity or As a Processed Food Affects the Requirements Applicable to a Farm Under Sections 415 and 418 of the FD&C Act

1. Statutory Framework for Raw Agricultural Commodities and Processed Food

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To clarify the scope of the farm definition, FDA considered how the activities of farms relate to the statutory concepts of "raw agricultural commodity" and "processed food." 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 (which defines pesticide chemicals) contains the following

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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 that applies to RACs but not to processed foods. Under 403(w) of the FD&C Act (21 U.S.C. 343(w)), labeling requirements related to major food allergens apply to processed foods but 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

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CGMP requirements applicable to establishments engaged solely in the harvesting, storage, or distribution of one or more RACs (§ 110.19). (We discuss this exemption in detail in section X.C.9 of this document.)

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.

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## 2. Interpretive Documents and Guidance Regarding Whether an Activity Transforms a Raw Agricultural Commodity Into a Processed Food

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 the "1998 Joint EPA/FDA Policy Interpretation") (63 FR 54532, 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. 118)). 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" (Ref. 118, section 7 and 63 FR 54532 at 54541). 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" (Ref. 118, section 7 and 63 FR 54532 at 54541). In addition, these documents set forth the conclusion of EPA and FDA that drying a RAC causes it to become a processed food, unless the drying is for the purpose of facilitating storage or transportation of the commodity (Ref. 118, section 7 and 63 FR 54532 at 54541-2); 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

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carcasses post-slaughter as "processing" for the purposes of the processed food definition (Ref. 118, section 7 and 63 FR 54532 at 54542). 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

| Activities That Change a RAC into a Processed Food | Activities That Do 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 | |

The summary in Table 2 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" that FDA established in §§ 1.227(b)(6) and 1.328 for the purposes of the section 415 registration regulations and the section 414 recordkeeping regulations, respectively. The definition of "Manufacturing/processing" in those regulations 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,

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transforming a RAC into a processed food seems to require meeting a threshold of altering the general state of the commodity (Ref. 118, section 7 and 63 FR 54532 at 54541), sometimes referred to as transformation of the RAC into a new or distinct commodity (61 FR 2386 at 2388). Because the activities that transform a RAC into a processed food are not coextensive with the definition of "manufacturing/processing" in §§ 1.227(b)(6) and 1.328, 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.

3. The Organizing Principles

The current section 415 registration regulations, section 414 recordkeeping regulations, and related guidances 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. However, "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 rather than manufacturing/processing. To date, FDA has not articulated organizing principles explaining these differences. In this document, we are tentatively articulating the following organizing principles to explain and clarify the basis for our proposed revisions to the definitions that classify activities on-farm and off-farm in the section 415 registration regulations and in the section 414 recordkeeping regulations, and that we interpret in guidances. In section VIII.E of this document, we propose to incorporate these organizing principles into the definitions, previously established in §§ 1.227 and 1.328, that classify activities related to foods on farms and farm mixed-type facilities. FDA tentatively concludes that doing so would more accurately reflect which activities of these establishments should fall within the farm definition.

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a. First organizing principle. The statutes we describe in section VIII.D.1 of this document, and previous interpretations of the concepts of RACs and processed food as set forth in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance, lead FDA to tentatively conclude that the basic purpose of farms is to produce RACS and that RACs are the essential products of farms. This tentative conclusion is the first organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

b. Second organizing principle. In light of the first organizing principle (i.e., that the basic purpose of farms is to produce RACs, and that RACs are the essential products of farms), we also tentatively conclude that activities that involve RACs and 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. Doing so would appropriately implement the intent of Congress (under sections 415(b)(1) and 414(b) of the FD&C Act) that FDA exempt "farms" from the section 415 registration regulations and the section 414 recordkeeping regulations. 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 tentative conclusion regarding a special classification for on-farm activities is the second organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

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c. Third organizing principle. In light of the first organizing principle (i.e., that the basic purpose of farms is to produce RACs, and that RACs --but not processed foods -- are the essential products of farms) FDA tentatively concludes that the second organizing principle (i.e., the special classification of on-farm activities) should only apply to RACs. Thus, the third organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities is that activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food. A farm that chooses to transform its RACs into processed foods should be considered to have chosen to expand its business beyond the traditional business of a farm, thereby opting to become a farm mixed-type facility subject to the section 415 registration regulations, section 414 recordkeeping regulations, and other requirements linked to the registration requirement of section 415 of the FD&C Act by FSMA (such as compliance with section 418 of the FD&C Act).

d. Fourth organizing principle. In light of the first organizing principle (i.e., that the essential purpose of a farm is to produce RACs, and that RACs are the essential products of farms), FDA also tentatively concludes that the second organizing principle (i.e., the 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 refers 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

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to define farms to include typical post-harvesting operations, if all food is grown on the farm (emphasis added) (68 FR 5378 at 5379). 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 (and, thus, becomes 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 manner as for a farm that is not a mixed-type facility, but the activities that are outside the farm definition should be classified in the same manner as for an off-farm food establishment. This is the fourth organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

e. Fifth organizing principle. FDA tentatively concludes that manufacturing/processing, packing, or holding food-- whether 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. This is the fifth organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

f. Summary of organizing principles. For the convenience of the reader, Table 3 summarizes the organizing principles that FDA is articulating in this document to explain and clarify the basis for our proposed revisions to the definitions that classify activities on-farm and off-farm in the section 415 registration regulations and in the section 414 recordkeeping regulations, and that we interpret in guidances.

Table 3. Summary of Organizing Principles Regarding Classification of Activities On-Farm and Off-Farm

| No. | Organizing Principle |
|---|---|

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| No. | Organizing Principle |
|---|---|
| 1 | The basic purpose of farms is to produce RACs and RACs are the essential products of farms. |
| 2 | Activities that involve RACs and 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 and 1.328. |
| 3 | Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food. |
| 4 | 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. |
| 5 | Manufacturing/processing, packing, or holding food-- whether RACs or processed foods, from any source-- for consumption on the farm should remain within the farm definition. |

## E. Proposed Revisions to 21 CFR Part 1

### 1. Proposed Redesignation of the Definitions in § 1.227

FDA is proposing to redesignate all definitions in the section 415 registration regulations (i.e., current § 1.227) to eliminate paragraph designations (such as (a), (b), (1), (2), and (3)). Paragraph designations are not necessary when definitions are presented in alphabetical order. New definitions that FDA is proposing to add to the section 415 registration regulations and the section 414 recordkeeping regulations would be added in alphabetical order.

### 2. Proposed Substantive Revisions to the Definitions in §§ 1.227 and 1.328

FDA is proposing to revise the definitions in the section 415 registration regulations (§ 1.227) and in the section 414 recordkeeping regulations (§1.328), and to add new definitions to those regulations, to reflect the organizing principles articulated in section VIII.D of this document and to clarify how those definitions apply to specific activities depending on where the activities take place, the food used in the activities, where the food comes from, and where the food is consumed.

FDA is proposing 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

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FDA proposes

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 5378 at 5381) and in the interim final rule on food facility registration (68 FR 58894 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 the directives of FSMA section 103(c) 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 section 415, 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 that are outside the farm definition on farms. Accordingly, FDA is proposing to define the term "farm mixed-type facility" to refer to these establishments.

FDA is proposing 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

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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/processing," because it involves preparing, treating, modifying or manipulating food.

FDA is proposing 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 is proposing 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 proposed revision, 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 a farm's own RACs or a farm mixed-type facility's own RACs. Thus, some activities that would otherwise be manufacturing/processing would instead

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FDA proposes

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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 js proposing 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 (which may include packaging) 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 because 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 a 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

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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.

Table 4 provides examples of how we would classify activities conducted off-farm and on-farm (including farm mixed-type facilities) using these proposed revisions to the definitions in the section 415 registration regulations and in the section 414 recordkeeping regulations.

Table 4. Classification of Activities Conducted Off-Farm and On-Farm (Including Farm Mixed-Type Facilities)

| Classification | Off-Farm | On-Farm (Including Farm Mixed-Type Facilities) |
|---|---|---|
| Harvesting | Notes: Not applicable. Harvesting is a classification that only applies on farms and farm mixed-type facilities. | Notes: Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as food. Harvesting is limited to activities performed on RACs on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that change a RAC into processed food. Activities that are harvesting are within the farm definition. |
| Harvesting | Examples: Not applicable. | Examples: Activities that fit this definition when performed on a farm's "own RACs" (a term we use to include RACs grown or raised on that farm or another farm under the same ownership) include gathering, washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, and cooling. These activities, performed on a farm's own RACs, are inside the farm definition. |
| Packing | Notes: Placing food in a container other than packaging the food (where packaging means placing food into a container that directly contacts the food and that the consumer receives). | Notes: Placing food in a container other than packaging the food (using the same definition of packaging), or activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on that farm or another farm under the same ownership for storage or transport. Packing does not include activities that change a RAC into a processed food. Activities that are packing are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition. |

| Classification | Off-Farm | On-Farm (Including Farm Mixed-Type Facilities) |
|---|---|---|
| Packing | Examples: Putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates). | Examples: Activities that fit the definition of packing when performed on a farm's own RACs include packaging, mixing, coating with wax/oil/resin for the purpose of storage or transport, stickering/labeling, drying for the purpose of storage or transport, and sorting/grading/culling. These activities, performed on a farm's own RACs, are inside the farm definition.<br><br>Activities that fit the definition of packing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, include putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates) -- the same activities that fit the definition of packing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm. |
| Holding | Notes: Storage of food. | Notes: Storage of food, or activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on that farm or another farm under the same ownership. Holding does not include activities that change a RAC into a processed food. Activities that are holding are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition. |
| Holding | Example: Storing food, such as in a warehouse. | Examples: activities that fit the definition of holding when performed on a farm's own RACs include fumigating during storage, and storing food, such as in a warehouse. These activities, performed on a farm's own RACs, are inside the farm definition.<br><br>An activity that fits the definition of holding when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, is storing food, such as in a warehouse -- the same activity that fits the definition of holding off farm. This activity, performed on food other than a farm's own RACs, is outside the farm definition unless done on food for consumption on the farm. |
| Manufacturing/ Processing | Notes: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food. Includes packaging (putting food in a container that directly contacts food and that the consumer receives). | Notes: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food; except for things that fall into the categories of harvesting, packing, or holding (see rows above). Activities that are manufacturing/processing are outside the farm definition unless done on food for consumption on the farm. |

| Classification | Off-Farm | On-Farm (Including Farm Mixed-Type Facilities) |
|---|---|---|
| Manufacturing/ Processing | Examples: Activities that fit this definition include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/ slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing. | Examples: Activities that fit the definition of manufacturing/processing when performed on a farm's own RACs include slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, coating with things other than wax/oil/resin, drying that creates a distinct commodity, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing. These activities, performed on a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.<br><br>Activities that fit the definition of manufacturing/processing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing-- the same activities that fit the definition of manufacturing/processing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm. |

3. Proposed Technical Amendments and Conforming Changes

As a technical amendment for clarity and for consistency with our current approach to citing the FD&C Act in new regulations, FDA is proposing to delete the definition of "Act" in current § 1.227 of the section 415 registration regulations and revise all remaining definitions in current § 1.227 to refer to "the Federal Food, Drug, and Cosmetic Act" rather than "the act." As a conforming change, FDA is proposing to revise current § 1.241 in the section 415 registration regulations to refer to "the Federal Food, Drug, and Cosmetic Act" rather than "the act."

Likewise, as a technical amendment for clarity and for consistency with our current approach to citing the FD&C Act in new regulations, FDA is proposing to delete the definition

of "Act" in current § 1.328 of the section 414 recordkeeping regulations and revise all remaining definitions in current § 1.328 to refer to "the Federal Food, Drug, and Cosmetic Act" rather than "the act." As a conforming change, FDA is proposing to revise current §§ 1.361 and 1.363 in the section 414 registration regulations to refer to "the Federal Food, Drug, and Cosmetic Act" rather than "the act."

As a conforming change to the proposed definition of "harvesting," FDA is proposing 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. With the proposed new, separate definition of harvesting, it would be redundant to retain the examples of harvesting within the definition of "Farm."

As a conforming change to the proposed redesignation of § 1.227 to eliminate paragraph designations, FDA is proposing to revise § 1.276(b)(9) in the prior notice regulations to cross-reference § 1.227 (without any paragraph designations) rather than to cross-reference § 1.227(b)(6).

F. Impact of Proposed Revisions to the Definitions in 21 CFR Part 1

1. Approach

FDA has previously addressed whether various activities fall within the farm definition or not and, as discussed more fully in sections VIII.F.2 through VIII.F.5 of this document, has provided guidance on these issues in the rulemakings establishing the section 415 registration regulations and the section 414 recordkeeping regulations and in accompanying guidance (Ref. 116) (Ref. 117). For most of the activities FDA has previously addressed, applying the proposed definitions described in section VIII.E of this document would result in the same classification with respect to whether the activities are within the farm definition or not. However, because we

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have not previously articulated a comprehensive set of organizing principles that form the basis for classification of activities, in some cases the classification of an activity (e.g., packing, holding, or harvesting), or the rationale leading to the classification of an activity, may be different under the proposed revisions to the definitions in part 1 than under the current definitions in part 1.

In sections VIII.F.2 through VIII.F.5 of this document, we discuss several examples of activities that we previously addressed and interpreted during the rulemakings to establish the section 415 registration regulations and the section 414 recordkeeping regulations, or in related guidances. We also explain what, if any, impact our proposed revisions to the definitions in part 1 would have on our interpretation of whether or how an activity conducted on a farm or a farm mixed-type facility would be within the farm definition or would be outside the farm definition (and, thus, trigger the section 415 registration regulations and be within the scope of section 418 of the FD&C Act). We focus on examples of activities where we consider that the proposed revisions to the definitions in part 1 would result in some change in outcome. For the convenience of the reader, in section VIII.F.6 of this document we provide a table summarizing these examples.

In sections VIII.F.2 through VIII.F.5 of this document, for the sake of simplicity, we discuss activities that would be classified as manufacturing/processing outside the farm definition under this proposal, without stating each time that such activities would still be within the farm definition if performed on food for a farm or farm mixed-type facility's own consumption. The discussion below should not be read to suggest that the activities discussed could not be within the farm definition if they were performed on food for a farm or farm mixed-type facility's own consumption.

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**Deleted:** 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 would remain in the proposed revision to that definition. FDA previously 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. 116), and the preamble to the Establishment and Maintenance of Records final rule (69 FR 71562, 71587, December 9, 2004). In those documents, FDA previously 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. For other post-harvest pesticide applications FDA previously concluded that the applications are manufacturing/processing outside the farm definition, because such applications are directed at the food rather than at the entire plant. However, for one specific postharvest pesticide application (i.e., applying wash water containing chlorine), FDA previously concluded both that some uses are washing within the farm definition and that another use is manufacturing/processing outside the farm definition. Specifically, FDA previously concluded that the following two uses of water containing chlorine are washing within the farm definition: (1) the application by a farm of chlorinated water from public or other water supplies that are chlorinated for other purposes and (2) the application by a farm of wash water containing chlorine added by the farm to wash water at levels below 200 parts per million (ppm) total chlorine. FDA also previously concluded that the application by a farm of wash water containing chlorine added by the farm to wash water at levels above 200 ppm is

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manufacturing/processing outside the farm definition because such levels constitute treating the crop against pests rather than washing.

Some but not all of these previous conclusions regarding the application of a pesticide to a farm or farm mixed-type facility's own RACs would change under the proposed revisions to part 1. Under both the current definitions in part 1 and the proposed revisions to those definitions, treatment of food crops against pests before harvest while the crop is still in the growing area has been, and would continue to be, considered an inherent part of the growing process and thus classified within the farm definition. Thus, the classification of such treatments would not be affected by the proposed revisions to part 1.

However, under the proposed revisions to part 1 FDA would now classify pesticide treatments of a farm's own RACs or a farm mixed-type facility's own RACs for the purpose of safe or effective storage to be holding within the farm definition rather than manufacturing/processing outside the farm definition. An example of such activity is fumigating a farm's own raw nuts to prevent insect infestation and damage during the potentially long storage period of the nuts. 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 RACs.

Likewise, under the proposed revisions to part 1 FDA would now classify pesticide treatment of a farm's own RACs or a farm mixed-type facility's own RACs for the purpose of removing the crop from the growing area and preparing it for use as food to be harvesting. An example of such activity is washing a crop in water containing an antimicrobial chemical after

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removing the crop from the growing area. Generally, antimicrobial chemicals are intended only to ensure the safety of the wash water. However, if an antimicrobial chemical was also intended to reduce the microbial load on the crop itself as a safety measure, under the proposed revisions to part 1 addition of that antimicrobial chemical to reduce the microbial load on a farm's own RACs or a farm mixed-type facility's own RACs would now be classified within the farm definition rather than be classified as manufacturing/processing outside the farm definition. For example, the application of wash water containing chlorine added by the farm at levels above 200 ppm to its own RACs would now be classified as washing and/or treating (depending on the circumstances), either of which would be harvesting within the farm definition rather than as manufacturing/processing outside the farm definition. 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. Except for the two examples discussed above where FDA previously concluded that certain applications of water containing chlorine are washing within the farm definition, the classification of washing a crop in water containing an antimicrobial chemical as within the farm definition would represent a change from its previous classification as manufacturing/processing outside the farm definition.

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 the tentative conclusions FDA is reaching in this document. First, the general term "treating" refers broadly to treatments of any kind, and not specifically "treating against pests." Under both the current definitions and the proposed revisions to the definitions, some "treating" (e.g., delivering a heat treatment) has

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been, and would continue to be, classified as manufacturing/processing outside the farm definition. Second, for a farm or farm mixed-type facility conducting operations on its own RACs, only those activities that do not satisfy either the expanded definition of packing or holding, or the new definition of harvesting, would be classified as manufacturing/processing outside the farm definition. Thus, although application of a pesticide treatment to a farm's own RACs would now be classified within the farm definition when such treatment falls within the categories of holding or harvesting, application of a pesticide treatment off-farm has been, and would be continue to be, classified as manufacturing/processing outside the farm definition, because the exclusion applicable to a farm or farm mixed-type facility operating on its 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 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 waxing would remain as an example in the proposed revision to that definition. In addition, FDA has previously 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 71562 at 71587). In those documents, FDA previously concluded that on-farm waxing was manufacturing/processing outside the farm definition.

This previous conclusion that on-farm waxing was manufacturing/processing outside the farm definition would change for certain types of waxing under the proposed revisions to part 1. Under those proposed revisions, applying a coating to a farm or farm mixed-type facility's own

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RACs for the purpose of protecting them during storage or transport, and not to create a distinct commodity, would now be within the expanded definition of packing and thus be classified within the farm definition rather than be classified as manufacturing/processing outside the farm definition. Examples of such coatings are waxes, oils, and resins applied to fresh produce such as cucumbers, apples, and avocados. 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 or a farm mixed-type facility applies a coating to its own RACs in a manner that creates a distinct commodity (e.g., coating nuts in chocolate or coating apples in caramel), that activity would create a processed food and would not fit the expanded definition of packing. Thus, the act of applying the coating would continue to be classified as manufacturing/processing 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 tentative conclusions. As explained with respect to pesticide treatments, activities that are conducted on a farm or farm mixed-type facility and are within the expanded definitions of packing and holding, or the new definition of harvesting, would be classified within the farm definition rather than classified as manufacturing/processing outside the farm definition. The current definition of manufacturing/processing in §§ 1.227(b)(6) and 1.328 and the examples of harvesting within the definition of farm in §§ 1.227(b)(3) 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

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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 previously addressed drying RACs on farms and farm mixed-type facilities in the Food Facility Registration Guidance (Ref. 116) and the Recordkeeping Guidance (Ref. 117). In those documents, FDA previously reached three conclusions relevant to drying: (1) drying peppermint naturally during storage in a barn would not be manufacturing/processing; (2) drying hay naturally or artificially is an essential part of harvesting hay to prevent spontaneous combustion and is therefore not manufacturing/processing; and (3) 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.

One of these previous conclusions regarding drying (i.e., the previous conclusion regarding drying herbs) 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

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the expanded definitions of packing or holding, or the new 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 would be classified as manufacturing/processing outside the farm definition (unless it is done only for consumption on the farm or farm mixed-type facility).

In the Antimicrobial Guidance (Ref. 118), 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 foods 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, under the proposed revisions to part 1 drying hay and alfalfa would now be classified within the expanded definitions of packing or holding, 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 because drying these crops does not create a distinct commodity (so the dried commodity is still a RAC). Drying hay and alfalfa in the manner FDA

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previously discussed would continue to be classified within the farm definition. In contrast, drying herbs such as peppermint would now be classified as manufacturing/processing outside the farm definition, 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.

5. Off-Farm Packaging of Raw Agricultural Commodities

Current §§ 1.227(b)(8) and 1.328 define "packaging" (when used as a verb) as placing food into a container that directly contacts the food and that the consumer receives, and that definition of "packaging" would remain unchanged under the proposed revisions to the definitions in part 1. Packaging is listed as an example of manufacturing/processing in current §§ 1.227(b)(6) and 1.328 (as well as in § 1.226(a)), and would continue to be listed as an example of manufacturing/processing under the proposed revisions to part 1. As discussed in section VIII.E.2 of this document, current §§ 1.227(b)(9) and 1.328 distinguish "packaging" from "packing" and define "packing" as placing food into a container other than packaging the food. Under the proposed revisions to the definitions in part 1, that definition of "packing" would be expanded to 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.

FDA has previously addressed packaging on farms and farm mixed-type facilities, and off-farm, in the Food Facility Registration Guidance (Ref. 116), the preamble to the Establishment and Maintenance of Records final rule (69 FR 71562 at 71587), and the Recordkeeping Guidance (Ref. 117). In those documents, FDA previously reached four

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conclusions relevant to "packaging" and "packing" activities on farms and farm mixed-type facilities: (1) placing RACs into consumer-ready containers (e.g., placing strawberries in clamshell packages, and 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; (2) 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; (3) placing cereal in a plastic cereal box liner is packaging and therefore manufacturing/processing; and (4) placing apples received from elsewhere in bulk into plastic bags is packaging and therefore manufacturing/processing.

Most of these conclusions would remain the same under the proposed revisions to part 1, although the reasoning for those conclusions would instead be based on the organizing principles articulated in the proposed revisions to the definitions in part 1. Specifically, bottling wine and placing cereal in plastic box liners would continue to be classified as 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. Placing apples received from elsewhere in bulk into plastic bags would continue to be classified as packaging and therefore manufacturing/processing, because the activity is conducted on others' RACs.

Under the proposed revisions to the definitions in part 1, a farm or farm mixed-type facility that places its own RACs in consumer containers that contact the food would now be classified as 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

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kind of activity include an egg farm putting its own eggs in cartons, a strawberry farm placing its own strawberries in clamshell packages, or an apple farm placing its own apples into plastic bags. Such packing activities would continue to be classified within the farm definition.

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 a farm or farm mixed-type facility with respect to others' RACs. Off-farm, the expanded definition of packing would not apply, so this activity would be now be classified as packaging (and, therefore, manufacturing/processing). Off-farm, as a practical matter this change should have no practical impact because off-farm establishments that conduct this activity are already required to register under section 415 of the FD&C Act, and therefore already are subject to section 418 of the FD&C Act, whether this activity is classified as packing or manufacturing/processing. However, on a farm or farm mixed-type facility that places others' RACs into consumer containers, this activity would now be classified as packaging and therefore manufacturing/processing, because the expanded definition of packing would only apply to a farm's own RACs. This change in classification would impact a farm or farm mixed-type facility that conducts such activities if it is not currently required to register. This classification result is consistent with the organizing 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 another farm's 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

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**Deleted:** 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.

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activities performed by off-farm distributors of RACs. Therefore FDA tentatively concludes that these activities should now be outside the farm definition. We seek comment on this proposal.

6. Summary of Examples of the Impact of the Proposed Revisions to the Definitions in 21 CFR Part 1 on a Farm or Farm Mixed-Type Facility

For the convenience of the reader, Table 5 summarizes the examples discussed in sections VIII.F.2 through VIII.F.5 of this document.

Table 5. Summary of the Examples of the Impact of the Proposed Revisions to the Definitions in 21 CFR Part 1 on a Farm or Farm Mixed-Type Facility

| Activity | How Does FDA Classify the Activity Under the Current Definitions in §§ 1.227 and 1.328? | Using FDA's Current Classification, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | How Would FDA Classify the Activity Under the Proposed Revisions to the Definitions in §§ 1.227 and 1.328? | Using the Classification Under the Proposed Revised Definitions, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | Would the Classification Under the Proposed Revised Definitions Represent a Change? |
|---|---|---|---|---|---|
| Application of Pesticide | | | | | |
| Applying pesticides to own RACs prior to harvest | Growing within the farm definition (because it is an integral part of growing crops) | No | Growing within the farm definition (because it is an integral part of growing crops) | No | No |
| Fumigating own raw nuts to prevent insect infestation and damage during the potentially long storage period of the nuts | Manufacturing/ processing outside the farm definition (because application of pesticides after harvest is necessarily directed at the food, not the entire plant) | Yes | Holding within the farm definition (for the purpose of safe or effective storage) | No | Yes |

| Activity | How Does FDA Classify the Activity Under the Current Definitions in §§ 1.227 and 1.328? | Using FDA's Current Classification, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | How Would FDA Classify the Activity Under the Proposed Revisions to the Definitions in §§ 1.227 and 1.328? | Using the Classification Under the Proposed Revised Definitions, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | Would the Classification Under the Proposed Revised Definitions Represent a Change? |
|---|---|---|---|---|---|
| Use of pesticides in wash water applied to own RACs | Harvesting within the farm definition if water is from a public or other supply chlorinated for other purposes, or if chlorine is added at 200 ppm or less (washing that does not treat the crop); manufacturing/ processing outside the farm definition if chlorine is added at levels above 200 ppm | Depends on source and level of chlorine in water; FDA has not previously addressed chemicals other than chlorine | Harvesting within the farm definition (washing and/or treating against pests for the purpose of removing the crop from the growing area and preparing it for use as food) | No | Yes |
| Coating | | | | | |
| Applying coatings to own RACs (e.g., applying waxes, oils, and resins to fresh produce; coating raw nuts in chocolate; coating apples in caramel) | Manufacturing/ processing outside the farm definition (waxing generally, not specific to fresh produce) | Yes, for waxing generally; FDA has not previously addressed other coatings | Waxes, oils, and resins on fresh produce: Packing within the farm definition (for the purpose of protecting them during storage or transport, and not to create a distinct commodity);<br><br>Chocolate on nuts or caramel on apples: Manufacturing/ processing outside the farm definition (creates a distinct commodity and thus creates a processed food) | Waxes, oils, and resins on fresh produce: No<br><br>Chocolate on nuts or caramel on apples: Yes | Yes |
| Drying | | | | | |

| Activity | How Does FDA Classify the Activity Under the Current Definitions in §§ 1.227 and 1.328? | Using FDA's Current Classification, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | How Would FDA Classify the Activity Under the Proposed Revisions to the Definitions in §§ 1.227 and 1.328? | Using the Classification Under the Proposed Revised Definitions, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | Would the Classification Under the Proposed Revised Definitions Represent a Change? |
|---|---|---|---|---|---|
| Drying peppermint naturally during storage in a barn | Storage within the farm definition | No | Manufacturing/ processing outside the farm definition (transforms a RAC into a processed food) | Yes | Yes |
| Drying hay naturally or artificially | Harvesting within the farm definition (an essential part of harvesting hay to prevent spontaneous combustion) | No | Packing or holding within the farm definition (depending on whether the drying is before storage or during storage) | No | No |
| Drying alfalfa | Harvesting within the farm definition (traditionally performed during the removing of the crop from the field through the safe storage of the crop) | No | Packing within the farm definition (done before storage to prepare a RAC for storage or transport and does not create a distinct commodity) | No | No |
| Drying grapes to create raisins | FDA has not previously addressed this activity | FDA has not previously addressed this activity | Manufacturing/ processing outside the farm definition (transforms a RAC into a processed food) | Yes | Yes (because FDA is addressing this activity for the first time) |
| Packing/Packaging | | | | | |

| Activity | How Does FDA Classify the Activity Under the Current Definitions in §§ 1.227 and 1.328? | Using FDA's Current Classification, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | How Would FDA Classify the Activity Under the Proposed Revisions to the Definitions in §§ 1.227 and 1.328? | Using the Classification Under the Proposed Revised Definitions, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | Would the Classification Under the Proposed Revised Definitions Represent a Change? |
|---|---|---|---|---|---|
| Bottling wine | Packaging, which is manufacturing/ processing outside the farm definition (because it preserves the manufactured condition of the wine) | Yes | Packaging, which is manufacturing/ processing outside the farm definition (because the food is a processed food so the expanded definition of packing does not apply) | Yes | No |
| Placing cereal in a plastic cereal box liner | Packaging, which is manufacturing/ processing outside the farm definition | Yes | Packaging, which is manufacturing/ processing outside the farm definition (because the food is a processed food so the expanded definition of packing does not apply) | Yes | No |
| Placing a farm's or farm mixed-type facility's own RACs into consumer-ready containers (e.g., placing strawberries in clamshell packages, and placing eggs in a carton) | Packing within the farm definition (because it does not alter the form of the food) | No | Packing within the farm definition (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) | No | No |

| Activity | How Does FDA Classify the Activity Under the Current Definitions in §§ 1.227 and 1.328? | Using FDA's Current Classification, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | How Would FDA Classify the Activity Under the Proposed Revisions to the Definitions in §§ 1.227 and 1.328? | Using the Classification Under the Proposed Revised Definitions, Would Conducting the Activity Trigger the Section 415 Registration Regulations? | Would the Classification Under the Proposed Revised Definitions Represent a Change? |
|---|---|---|---|---|---|
| Placing others' RACs into consumer-ready packages on a farm or farm mixed-type facility (e.g., placing others' apples received in bulk into plastic bags) | Packaging, which is manufacturing/ processing outside the farm definition | Yes | Packaging, which is manufacturing/ processing outside the farm definition (because the activity is conducted on others' RACS) | Yes | No |
| Placing others' RACs into consumer-ready containers off-farm (e.g., placing strawberries in clamshell packages, and placing eggs in a carton at a facility not co-located on a farm or farm mixed-type facility) | Packing (because it does not alter the form of the food), but not within the farm definition because conducted off-farm | Yes | Packaging, which is manufacturing/ processing (because the activity is conducted off-farm, so the expanded definition of packing does not apply) | Yes | Yes, but while the classification of the activity changes from packing to manufacturing/ processing, under both the current and proposed revised definitions, the activity would trigger registration |

G. Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition

As discussed in section VIII.A.2 of this document, 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

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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 used in section 103(c)(1) of FSMA, the term "risk analysis" is ambiguous. One interpretation is that the common meaning of the term is intended – a simple evaluation of whether activity/food combinations are likely to result in the consumer becoming ill. Another interpretation is that the "risk analysis" should be consistent with the formal definition and related terms used by Codex with respect to food safety (Ref. 119):

- Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
- Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication.
- Risk assessment is a scientifically-based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization.
- Risk management is the process, distinct from risk assessment, of weighing policy alternatives, in consultation with interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
- Risk communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

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Because section 103(c)(1)(C) of FSMA calls for a science-based risk analysis, we are applying the Codex definitions to the extent possible. It is not clear whether the requirement of section 103(c)(1)(C) of FSMA to conduct a science-based risk analysis was intended to encompass all three components of risk analysis. Section 103(c)(1)(D) of FSMA requires the Secretary to consider the results of the science-based risk analysis and 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 of section 421, or to modify those requirements for facilities engaged in on-farm manufacturing, processing, packing or holding activities determined to be low risk involving foods determined to be low risk. Thus, section 103(c)(1)(D) of FSMA is focused on ensuring that the agency's risk management decisions with respect to exempting or modifying requirements applicable to low-risk on-farm activity/food combinations under sections 418 and 421 are science-based, as determined by an analysis of the risk of specific types of on-farm activity/food combinations required by section 103(c)(1)(C). We therefore tentatively conclude that the analysis required by section 103(c)(1)(C) should be limited to an assessment of the risk of specific types of on-farm activity/food combinations for the purposes of making the risk management decisions required by section 103(c)(1)(D). The risk communication component of the risk analysis is accomplished through the discussion of that assessment in this document, the opportunities for public comment (on the risk assessment and on this proposed rule), and our evaluation of, and response to, comments in a final rule.

Consistent with this approach, we conducted a qualitative risk assessment (Ref. 115) ("Section 103(c)(1)(C) draft RA") related to activity/food combinations for the purpose of determining which activity/food combinations would be considered low risk. We focused on activity/food combinations that we identified as being conducted on farms (and, thus, might be

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conducted by farm mixed-type facilities), but we did not consider activity/food combinations that would be solely within the farm definition (such as growing fruits and vegetables) and, thus, are not relevant to the requirements of section 103 of FSMA. We focused on considering the risk of activity/food combinations rather than separately considering the risk of specific food categories because doing so better enabled us to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on food by a farm mixed-type facility warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act.

Elsewhere in this issue of the Federal Register, FDA is making the section 103(c)(1)(C) draft RA available for public comment. We will consider comments regarding the section 103(c)(1)(C) draft RA in preparing a final version of the RA and will announce the availability of the final version of the RA when it is available. The final preventive controls rule will take into account the final version of the section 103(c)(1)(C) RA.

H. Results of the Qualitative Risk Assessment

In this section, we report the results of the section 103(c)(1)(C) draft RA, arranged in three lists. References to "farms" in these lists should be understood to include farm mixed-type facilities. The lists are shaped by the proposed definitions for harvesting, manufacturing/processing, packing, or holding in the section 415 registration regulations (discussed in section VIII.E of this document), the organizing principles (discussed in section VIII.D of this document) that form the basis for those proposed definitions, and the examples of activity classifications (discussed in section VIII.F of this document). As 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-

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H. Conclusions

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In this section, FDA states the conclusions of its science-based risk evaluation, as required under

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type facility performing the activity or a farm under the same ownership. We request comment on the lists in sections VIII.H.1 through VIII.H.3.

For the purposes of this document, a fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. For the purposes of this document, a vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Examples of fruits and vegetables are apples, apricots, avocados, bananas, berries, broccoli, cabbage, cantaloupe, carrots, cauliflower, celery, cherries, citrus, cucumbers, garlic, grapes, green beans, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, mushrooms, onions, papaya, peaches, pears, peas, peppers, pineapple, plums, radish, scallions, snow peas, spinach, sprouts, squash, tomatoes, and watermelon. For the purposes of this document, grains means the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.

For the purpose of the section 103(c)(1)(C) draft RA, "intact fruits and vegetables" refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts. Cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree

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nuts can be considered part of "fruits and vegetables" as a general matter, but we addressed those foods separately for the purpose of section 103(c)(1)(C) draft RA 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 specific hazards associated with certain of those foods.

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

The section 103(c)(1)(C) draft RA identified the following 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 - i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

- Hard candy, fudge, taffy, and toffee;
- Cocoa products;
- Cocoa beans and coffee beans (raw or roasted);
- Grains and grain products;
- Honey (raw and pasteurized);
- Intact fruits and vegetables;
- Jams, jellies and preserves;
- Maple sap for syrup and maple syrup;
- Peanuts and tree nuts;
- Soft drinks and carbonated water; and
- Sugar beets, sugarcane, and sugar.

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We note that 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 were outside the scope of the section 103(c)(1)(C) draft RA.

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

The section 103(c)(1)(C) draft RA identified the following low-risk manufacturing/processing activity/food combinations when conducted on a farm on the farm's own RACs for distribution into commerce:

- Artificial ripening of intact fruits and vegetables;
- Boiling/evaporation of maple sap to make maple syrup;
- Chopping raw peanuts and raw tree nuts;
- Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and raw peanuts and raw tree nuts (e.g., adding seasonings);
- Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);
- Extracting oil from grains;
- 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);
- Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- Making sugar from sugarcane and sugar beets; and
- Salting raw peanuts and raw tree nuts.

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<#>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

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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

The section 103(c)(1)(C) draft RA identified the following 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.

- Artificial ripening of intact fruits and vegetables;
- Chopping peanuts and tree nuts;
- Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and peanuts and tree nuts (e.g., adding seasonings);
- Cooling intact fruits and vegetables using cold air;
- Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;
- Extracting oils from grains (e.g., corn, oilseeds, soybeans);
- Fermenting cocoa beans and coffee beans;
- Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);
- Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as

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<#>Making maple syrup (including filtration and boiling/evaporation)¶

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containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;

- Making hard candy, fudge, taffy, and toffee;
- Making cocoa products from roasted cocoa beans;
- Making honey;
- Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- Making maple syrup;
- Making soft drinks and carbonated water;
- Making sugar from sugar beets and sugarcane;
- Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;
- Packaging hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
- Salting peanuts and tree nuts;
- Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;
- Sifting grains and grain products;
- Sorting, culling and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and

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vegetables; grain and grain products; honey; jams, jellies and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets and sugarcane;

- Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation); and
- Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

We note that the list in this section (i.e., section VIII.H.3) for low-risk manufacturing/processing activity/food combinations for foods other than a farm's own RACs is longer than the corresponding list in the previous section (i.e., section VIII.H.2) for low-risk manufacturing/processing activity/food combinations for a farm's own RACs. This relates to the fact that 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. As discussed in sections VIII.E and VIII.F of this document, when some activities are performed on the farm's own RACs, those activities are classified as packing, holding, or harvesting and are within the farm definition, making them outside the scope of the section 103(c)(1)(C) draft RA and resulting in a shorter list of low-risk activity/food combinations for the purpose of the rulemaking required by section 103(c) of FSMA.

I. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Food Combinations Under Section 418 of the FD&C Act

Based on the results of the section 103(c)(1)(C) draft RA regarding on-farm low-risk activity/food combinations, we are proposing in § 117.5(g) and (h) to exempt farm mixed-type facilities that are small or very small businesses (as defined in proposed § 117.3) from

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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 (see the discussion of these proposed exemptions in section X.C.6 of this document). The proposed exemptions would not exempt eligible facilities from the requirement to register under section 415 of the FD&C Act.

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J. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Food Combinations Under Section 421 of the FD&C Act

We tentatively conclude that FDA should consider the low-risk on-farm activity/food combinations identified in the section 103(c)(1)(C) draft RA as a factor in identifying high-risk facilities that are small and very small businesses 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.

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## IX. Proposed General Revisions to Current Part 110

### A. Title

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 proposed part 117 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 proposed part 117 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 proposed part 117. We request comment on the proposed title for part 117.

### B. Proposed Redesignations

FDA is proposing to redesignate the subparts of current part 110 and to include in proposed part 117, 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 as they would be established in proposed part 117. The proposed revisions

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are intended to enhance the clarity of proposed part 117 as a whole. Table 6 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. Provisions that we do not propose to delete or revise would be re-established in part 117 unchanged.

Table 6. 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 § 117.3 | Proposed Subpart A |
| § 110.5--Current good manufacturing practice | Subpart A | Proposed § 117.1 | Proposed Subpart A |
| § 110.10--Personnel | Subpart A | Proposed § 117.10 | Proposed subpart B |
| § 110.19--Exclusions | Subpart A | Proposed § 117.5(k) | Proposed subpart A |
| § 110.20--Plant and grounds | Subpart B | Proposed § 117.20 | Proposed subpart B |
| § 110.35--Sanitary operations | Subpart B | Proposed § 117.35 | Proposed subpart B |
| § 110.37--Sanitary facilities and controls | Subpart B | Proposed § 117.37 | Proposed subpart B |
| § 110.40--Equipment and utensils | Subpart C | Proposed § 117.40 | Proposed subpart B |
| § 110.80--Processes and controls | Subpart E | Proposed § 117.80 | Proposed subpart B |
| § 110.93--Warehousing and distribution | Subpart E | Proposed § 117.93 | Proposed subpart B |
| § 110.110--Natural or unavoidable defects in food for human use that present no health hazard | Subpart G | Proposed § 117.110 | Proposed subpart B |

## C. Proposed Revisions for Consistency of Terms

### 1. Activities Subject to Proposed Part 117

FDA is proposing to revise provisions of current part 110 to make clear that the activities that would be subject to proposed part 117 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 proposed part 117. 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 proposed part 117, 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.

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2. The Term "Facility"

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FDA is proposing to replace the term "facility" or "facilities" in current part 110 with the term "establishment" or "plant" in proposed part 117 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:

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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 § 117.3 would define "facility" to incorporate this statutory definition. Under proposed § 117.3, the term "facility" would have a meaning for the purposes of proposed part 117 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" in proposed part 117 is intended to avoid confusion about the applicability of proposed part 117 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.

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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" as it is used 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 proposed part 117 and, if so, whether the requirements would be clear if we revise the proposed rule to use pronouns (such as "you" and "your") within proposed part 117. Pronouns are commonly used in contemporary regulations and simplify the presentation of the requirements.

4. Food-packaging Materials

Most provisions of current part 110 directed to preventing contamination of food and food-contact substances also are directed to preventing contamination of food-packaging materials. Because food-packaging materials come in contact with food, if they become contaminated this could lead to contamination of the food. FDA is proposing that provisions of current part 110 directed to preventing contamination of food and food-contact substances consistently be directed to preventing contamination of food-packaging materials as well. We

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describe each of these proposed revisions elsewhere in this document, in an order consistent with the placement of the current or revised provision.

D. Proposed Additions Regarding Cross-Contact

Proposed § 117.3 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.B.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. 1). 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. 1). 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

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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. 120). In the past, inadvertent incorporation of an allergen into a food was referred to as "contamination" or "cross contamination" (Ref. 121), and in many instances these terms are still used (Ref. 122). More recently, the term "cross-contact" (rather than "contamination" or "cross contamination") has been applied with respect to unintentional transfer of allergenic proteins from a food containing the proteins to one that does not (Ref. 123) (Ref. 124), 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" and "cross 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 current part 110 to explicitly address cross-contact in proposed part 117.

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.

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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,

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thus, the manufacture of a food additive is subject to current 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) (which would be proposed § 117.80(b)) 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 current § 110.80 that refer to both raw materials and ingredients. We do not list every instance where this proposed revision would apply in proposed § 110.80.

F. Proposed Revisions to Address Guidance in 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. 1). Consistent with these comments and with 21 CFR 10.115, we are proposing to delete some non-binding provisions of current part 110 (e.g., provisions using "should" or "compliance may be achieved by"). We request comment on this proposal. In section XI.M of this document, we request comment on whether to revise other non-binding provisions to establish new requirements in proposed part 117 or to simply retain them as useful provisions of a comprehensive CGMP. We describe each of these in more detail elsewhere in this document.

G. Proposed Editorial Changes

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

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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 34752 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).
- Replace the term "whenever" with "when" for grammatical simplicity.

X. Proposed Revisions to General Provisions of Part 110 (Proposed Part 117, Subpart A)

A. Proposed § 117.1 - Applicability and Status

FDA is proposing to redesignate current § 110.5(a) as proposed § 117.1(a) with associated editorial changes described in section IX.G 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

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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 § 117.1(a). The provisions of current § 110.5(a) as re-established in proposed § 117.1(a) would continue to apply to all provisions that currently are established in part 110 and would be re-established in proposed part 117. Under this proposed rule, proposed § 117.1 also would apply to new provisions of proposed part 117, 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 117 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.

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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 § 117.1(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 117 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 § 117.1(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

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current good manufacturing practice requirements that are currently established in part 110 and would be re-established in part 117. 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 within the framework of current part 110, as would be re-established in proposed part 117. As discussed in section IX.A of this document, we are proposing that the title of proposed part 117 reflect the addition of these new requirements. As discussed more fully in section X.C 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 § 117.5(b) would provide that proposed subpart C of proposed part 117 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 § 117.1(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. The same would be true for establishments and facilities that are

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subject to other food safety regulations, consistent with the exemptions that would be established in proposed § 117.5.

B. Proposed § 117.3 - Definitions

1. Redesignation

FDA is proposing to redesignate all definitions in current § 110.3(a) through (r) as proposed § 117.3, 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 § 117.3 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.

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. 34), the Codex HACCP Annex (Ref. 35), and Federal HACCP regulations for seafood (part 123), juice (part 120), and meat and poultry (9 CFR 417). Proposed § 117.3 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 § 117.3 would

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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 § 117.3 and the definition of CCP in § 120.3(d) is that proposed § 117.3 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 § 117.3 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 proposed part 117 (see the discussion of our definition of the term “hazard” in section X.B.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. Part 123 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

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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 § 117.3 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 § 117.3 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 § 117.3 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

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operations. Proposed § 117.3 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 § 117.3 would define "microorganisms" to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. Proposed § 117.3 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.

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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 proposed part 117. 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 § 117.3 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.

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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 § 117.3 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 § 117.3 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. 125). Proposed § 117.3 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

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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 "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.

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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 proposed part 117 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 proposed part 117.

FDA is proposing to define the term "FDA" to mean the Food and Drug Administration. Defining this term within the definitions applicable to part 117 would eliminate the need to define the term within each distinct section of the regulation and would provide for the substitution of "Food and Drug Administration" with "FDA" each time "Food and Drug Administration appears in current 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

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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. 34) 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

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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. 35). 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.

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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 "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."

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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

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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. 34). 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. 35). 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 § 117.3 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

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"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 § 117.155 (see section XII.H 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 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. 52), 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

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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. 126), 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 before it is eaten. 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 § 117.130(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.7 of this document, under proposed § 117.135(d)(3) preventive controls must include, as appropriate and 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 that include procedures for the (A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; and (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.

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. 77). 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 spp. from an ingredient (hydrolyzed vegetable protein) (Ref. 24).

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

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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 "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. 34). 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. 35). 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).

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FDA is proposing to define the term "small business" to mean, for the purposes of part 117, a business employing fewer than 500 persons. See section X.B.5 for additional discussion of the definition of small business.

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 "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. 34) 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. 35). 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. 127). 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 § 117.150(a)), and their relationship to HACCP systems, in section XII.G.2.a of this document.

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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. 34), 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. 35). 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. 127). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry, do not define the term "verification."

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FDA is proposing to define the term "very small business" to mean, for the purposes of proposed part 117, a business that has less than $250,000 in total annual sales of foods, adjusted for inflation (Option 1 of co-proposal). As one co-proposal, we are proposing to define the term "very small business" to mean a business that has less than $500,000 in total annual sales of foods, adjusted for inflation (Option 2). As another co-proposal, we are proposing to define the term "very small business" to mean a business that has less than $1,000,000 in total annual sales of foods, adjusted for inflation (Option 3). See section X.B.5 for additional discussion of the definition of very small business.

5. Food Processing Sector Study and the Definitions of "Small Business" and "Very Small Business"

FDA conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 32) . The purpose of that study was to make determinations in five areas as required by section 418(l)(5)(A) of the FD&C Act and to use the results of the study in defining the terms "small business" and "very small business." 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. The Food Processing Sector Study provides information on the number of establishments and average sales per establishment by industry and size of operation. FDA's proposed definitions are informed by that study. The food processing sector study is available in the docket established for this proposed rule (Ref. 32). We request comment on that study. We will consider comments regarding the study, as well as comments regarding our proposed definitions "small business" and "very small business," in any final rule based on this proposed rule.

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Section 418(l)(5)(B) of the FD&C Act required consideration of harvestable acres, income, the number of employees, and the volume of product in defining the terms "small business" and "very small business." The Food Processing Sector Study (Ref. 32) concluded that there was no consistent pattern across food categories in terms of which sizes of establishments contribute most to foodborne illness risk. "Harvestable acres," "income," "the number of employees," and "the volume of food harvested" are all ways to measure the size of an operation. Income does not appear to be the most relevant measure, since facility income may

be derived from multiple sources, many of which are not food-related. "Harvestable acres" and "volume of food harvested" are similar measures that appear primarily relevant to the growing and harvesting of crops, which are activities not subject to this regulation. Harvestable acres and volume of food harvested do not provide a meaningful measure with respect to the risk from food produced by a farm mixed-type facility (a food facility co-located on a farm subject to this regulation); our qualitative risk assessment of manufacturing, processing, packing and holding activities conducted in a facility co-located on a farm showed that risk was related to activity/food combinations; these foods could be harvested from large or small farms (see section VIII.G of this document for a discussion of that qualitative risk assessment). A high risk activity/food combination could be conducted on a farm with many harvestable acres or very few harvestable acres. For example, an on-farm facility producing bagged salads (which would not be considered a low-risk activity/food combination) could be one that has very few acres, or the bagged salads production could be a small component of a large vegetable growing farm. FDA has previously used both number of employees and annual sales as criteria for defining small and very small businesses, e.g., in 21 CFR 120.1(b)(1) and (b)(2). We have limited data on number of employees, income, and annual sales upon which to base our definitions of small and very small business, but no data for "harvestable acres" or "the volume of food harvested."

a. Definition of "Small Business." FDA is proposing to define the term "small business" to mean, for the purposes of part 117, 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

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for small business as we used to define a small business in our juice HACCP regulation (§ 120.1(b)(1)). The definition of small business is relevant to two provisions in the proposed rule. It would affect which facilities qualify for the exemption in § 117.5(g) for on-farm packing or holding, and the exemption in § 117.5((h) for on-farm manufacturing/processing, of food by a small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/food combinations listed in those sections. It would also affect what the compliance date is for such facilities.

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Effect on proposed § 117.5(g) and proposed § 117.5(h).

Under proposed § 117.5(g) a farm mixed-type facility that meets the definition of a small business and only conducts specific packing or holding activity/food combinations would be eligible for an exemption from subpart C. Similarly, under proposed § 117.5(h) a farm mixed-type facility that meets the definition of a small business and only conducts specific manufacturing/processing activity/food combinations would be eligible for an exemption from subpart C. Based on the Food Processing Sector Study, we estimate that approximately 97,169 facilities would be part of a small business under the proposed definition and thus satisfy the size requirement of the exemption in proposed § 117.5(g) and proposed § 117.5(h). Of those facilities, we estimate that approximately 1,661 would be co-located on farms. A subset of those facilities would qualify for the exemption from Subpart C based on their manufacturing/processing and packing and holding activities.

Other Effects.

Based on the Food Processing Sector Study we estimate that businesses employing fewer than 500 employees produce approximately 18 percent (based on sales) of all manufactured food produced in the United States. As discussed in section VII of this document, the compliance date

for a small business would be 2 years after the date of publication of the final rule. Under our proposed definition, 97,169 facilities would be subject to this compliance date.

b. Definition of "Very Small Business." In addition to defining "small business," FDA is required to define "very small business." FDA has not reached a tentative conclusion on how best to define "very small business" for the purposes of this rule. Consequently, we are proposing three possible definitions based on annual sales of $250,000, $500,000, or $1,000,000 and requesting comment on which of these three options to include in a final rule. All three proposed definitions are informed by the findings of the Food Processing Sector Study (Ref. 32). We request comment on whether a dollar amount of sales that is more than, or less than, the $250,000, $500,000, or $1,000,000 dollar amounts we are proposing would be appropriate. We also request comment on how a particular dollar amount of sales would be in keeping with Congressional intent - i.e., in light of the provisions in section 418(l) regarding qualified facilities, including the statutory limitations on sales to qualified end-users.

The definition of very small business is relevant to 3 provisions of the proposed rule. It would affect which facilities qualify for the exemption in § 117.5(g) for on-farm packing or holding, and the exemption in § 117.5((h) for on-farm manufacturing/processing, of food by a very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/food combinations listed in those sections. It would also affect which facilities are automatically "qualified" facilities subject to the modified requirements in § 117.201 and what the compliance date is for such facilities.

i. Effect on proposed § 117.5(g) and proposed § 117.5(h). The definition of very small business affects which facilities qualify for the exemption in § 117.5(g) for on-farm packing or holding, and the exemption in § 117.5((h) for on-farm manufacturing/processing, of food by a

very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/food combinations listed in those sections,

ii. Other Effects. The definition of very small business affects which facilities are automatically "qualified" facilities subject to the modified requirements in §117.201, and the applicable compliance dates for such facilities. There are two ways a facility may be "qualified" and thus subject to the modified requirements in proposed § 117.201. The first, limited annual monetary value of sales, is based on fixed criteria set out in FSMA § 418(l)(1)(C). The second, as provided by § 418(l)(1)(B), is to be a very small business as defined by FDA. Therefore, we discuss the affect of the proposed definitions for very small business in relation to the existing requirements for qualified facilities in § 418(l)(1)(C).

Less than $250,000 in Total Annual Sales - Effect on proposed § 117.5(g) and proposed § 117.5(h).

One possible definition of the term "very small business," for the purposes of proposed part 117, would be a business that has less than $250,000 in total annual sales of foods, adjusted for inflation (Option 1 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 736 facilities would meet the size requirement for the exemptions in proposed § 117.5(g) and proposed § 117.5(h). A subset of those facilities would then qualify for the exemption from Subpart C based on their manufacturing/processing, packing or holding activities.

Less than $250,000 in Total Annual Sales - Effect on number of qualified facilities.

The proposed definition of $250,000 uses a dollar amount for sales that is, essentially, the same as the maximum dollar amount of sales by a qualified facility to end-users other than those

that would satisfy the definition of "qualified end-users," except unlike with § 418(l)(1)(C), there would be no requirement that more than half of sales must be to qualified end-users. The $250,000 definition of very small business would add approximately 34,600 domestic facilities to the number of qualified facilities beyond the approximately 11,500 domestic facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 46,100 domestic qualified facilities. These 46,100 domestic qualified facilities would have a 3 year compliance date. 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.

Less than $500,000 in Total Annual Sales - Effect on proposed § 117.5(g) and proposed § 117.5(h).

One possible definition of the term "very small business," for the purposes of proposed part 117, would be a business that has less than $500,000 in total annual sales of foods, adjusted for inflation (Option 2 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 903 facilities would meet the size requirement for the exemptions in proposed § 117.5(g) and proposed § 117.5(h). A subset of those facilities would then qualify for the exemption from Subpart C based on their manufacturing/processing, packing or holding activities.

Less than $500,000 in Total Annual Sales - Effect on number of qualified facilities.

Defining very small business to mean a business that has less than $500,000 in total annual sales of foods would add approximately 45,900 domestic facilities to the number of qualified facilities beyond the approximately 11,500 domestic facilities that are qualified

facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 57,400 domestic qualified facilities. These 57,400 domestic qualified facilities would have a 3 year compliance date. As a group, businesses with less than $500,000 in total annual sales of foods produce less than one percent of all food produced in the United States when measured by dollar value

Less than $1,000,000 in Total Annual Sales - Effect on proposed § 117.5(g) and proposed § 117.5(h).

One possible definition of the term "very small business," for the purposes of proposed part 117, would be a business that has less than $1,000,000 in total annual sales of foods, adjusted for inflation (Option 3 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 1,227 facilities would meet the size requirement for the exemption in proposed § 117.5(g) and proposed § 117.5(h). A subset of those facilities would then qualify for the exemption from Subpart C based on their manufacturing/processing, packing or holding activities.

Less than $1,000,000 in Total Annual Sales - Effect on number of qualified facilities.

As compared to option two, defining very small business to mean a business that has less than $1,000,000 in total annual sales of foods would add approximately 63,500 domestic facilities to the number of qualified facilities beyond the approximately 11,500 domestic facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 75,000 domestic qualified facilities. These 75,000 domestic qualified facilities would have 3 year compliance date. As a group, businesses with less than $1,000,000 in total annual sales of foods produce less than two percent of all food produced in the United States when measured by dollar value.

## C. Proposed § 117.5 - Exemptions

For a summary list of the exemptions in proposed § 117.5, see the table in the Executive Summary of this document.

### 1. Proposed § 117.5(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 § 117.201). We also define the term "qualified facility" in proposed § 117.3 (see the discussion of definitions in section X.B.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 § 117.5(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 § 117.201.

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2. Proposed § 117.5(b) and (c)--Exemptions Applicable to Food Subject to HACCP Requirements for Fish and Fishery Products or for Juice

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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.)

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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 § 117.5(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 § 117.5(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

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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 § 117.5(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 § 117.5(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

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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 § 117.5(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 § 117.5(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

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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 § 117.5(d)(2) would establish that the exemption in proposed § 117.5(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 (Ref. 128) (Ref. 129).

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

4. Proposed § 117.5(e)--Exemption Applicable to a Facility That Manufactures, Processes, Packs, or Holds a Dietary Supplement

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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

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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. 130).

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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 proposed part 117. 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 § 117.5(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).

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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 § 117.5(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]." Elsewhere in this issue of the Federal Register, FDA is issuing a proposed rule to implement section 419. That proposed rule would apply section 419 to (1) "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; and to (2) 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

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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 § 117.5(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.C.6 of this document, proposed § 117.5(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 § 117.5(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.1 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

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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.2 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, consistent with the requirements of section 103(c)(1)(C) of FSMA we have conducted a qualitative risk assessment related to activity/food combinations for the purpose of determining which activity/food combinations would be considered low risk.

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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.

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c. Proposed § 117.5(g)--Exemptions for on-farm low-risk packing or holding activity/food combinations. Proposed § 117.5(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

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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 - i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(1) Hard candy, fudge, taffy, and toffee;

(2) Cocoa beans and coffee beans (raw and roasted);

(3) Cocoa products.

(4) Grains and grain products;

(5) Honey (raw and pasteurized);

(6) Intact fruits and vegetables (for purposes of proposed §§ 117.5(g) and (h) only, "intact fruits and vegetables" refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts);

(7) Jams, jellies and preserves;

(8) Maple sap for syrup and maple syrup;

(9) Peanuts and tree nuts;

(10) Sugar beets, sugarcane, and sugar; and

(11) Soft drinks and carbonated water.

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 analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VIII.G and VIII.H of this document. For purposes of proposed §§ 117.5(g) and (h) only, "intact fruits and vegetables" refers only to fruits and

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(iv) Peanuts and tree nuts; ¶
(v) Honey (raw and pasteurized); ¶
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<#>(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; ¶
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<#> (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. ¶

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vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts. Cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts can be considered part of "fruits and vegetables" as a general matter, but FDA has addressed those foods separately for the purpose of the analysis required by section 103(c)(1)(C) of FSMA and the proposed §§ 117.5(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 § 117.5(h)--Exemptions for on-farm low-risk manufacturing/processing activity/food combinations. Proposed § 117.5(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) Chopping peanuts and tree nuts;

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

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(v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);

(vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans);

(vii) 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);

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

(ix) Making sugar from sugar beets and sugarcane; and

(x) Salting 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) Artificial ripening of intact fruits and vegetables;

(ii) Chopping peanuts and tree nuts;

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

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

(v) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;

(vi) Extracting oils from grains (e.g., corn, soybeans, oilseeds);

(vii) Fermenting cocoa beans and coffee beans;

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(ii) Making maple syrup (including filtration and boiling/evaporation);¶
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(viii) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);

(ix) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate)coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;

(x) Making hard candy, fudge, taffy, and toffee;

(xi) Making cocoa products from roasted cocoa beans;

(xii) Making honey;

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

(xiv) Making maple syrup;

(xv) Making soft drinks and carbonated water;

(xvi) Making sugar from sugar beets and sugarcane;

(xvii) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;

(xviii) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; and maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xix) Salting peanuts and tree nuts;

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(xx) Shelling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;

(xxi) Sifting grains and grain products;

(xxii) Sorting, culling and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies, and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xxiii) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);

(xxiv) 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 analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VIII.G and VIII.H of this document.

7. Proposed § 117.5(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

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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 § 117.5(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.

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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 § 117.5(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.

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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. 131 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

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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 § 117.5(i)(1) would provide that subpart C would not apply with respect to alcoholic beverages at facilities meeting the criteria in proposed § 117.5(i)(1)(i) and (ii). Proposed § 117.5(i)(2) would provide that subpart C would not apply with respect to food other than alcoholic beverages at facilities described in proposed § 117.5(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.

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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 § 117.5(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 § 117.5(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. 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.C.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

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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 § 117.5(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 § 117.5(k) and revise the newly established provision as follows:

- Delete current § 110.19(b);
- Make clear that the exemption from requirements in proposed part 117 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 part 117, 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.

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Proposed § 117.5(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 § 117.5(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 remains limited to the requirements in current part 110 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 § 117.5(a) through (j)).

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

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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 those in the proposed 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. 132) 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. 133). 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

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117. 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 the proposed rule to establish produce safety standards under section 419 of the FD&C Act.

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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 sections VIII.C and VIII.E 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

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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 § 117.7, exemption for small or very small businesses performing only on-farm low-risk activity/food combinations under proposed § 117.5(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 § 117.5(j)).

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By removing the term "distribution" from current § 110.19(a), FDA proposes to exclude packing of RACs that does not fall within the farm definition 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. 1). 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. 1). 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

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contamination in multi-state foodborne illness outbreaks associated with RACs (Ref. 134) (Ref. 135) (Ref. 136).

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. We seek comment on this proposal. 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 proposed rule to establish 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 further 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, April 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

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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 it 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.C.2 and X.C.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

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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.

D. Proposed §

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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. ¶

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1. Redesignation¶
FDA is proposing to redesignate all definitions in current § 110.3(a) through (r) as proposed § 110

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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

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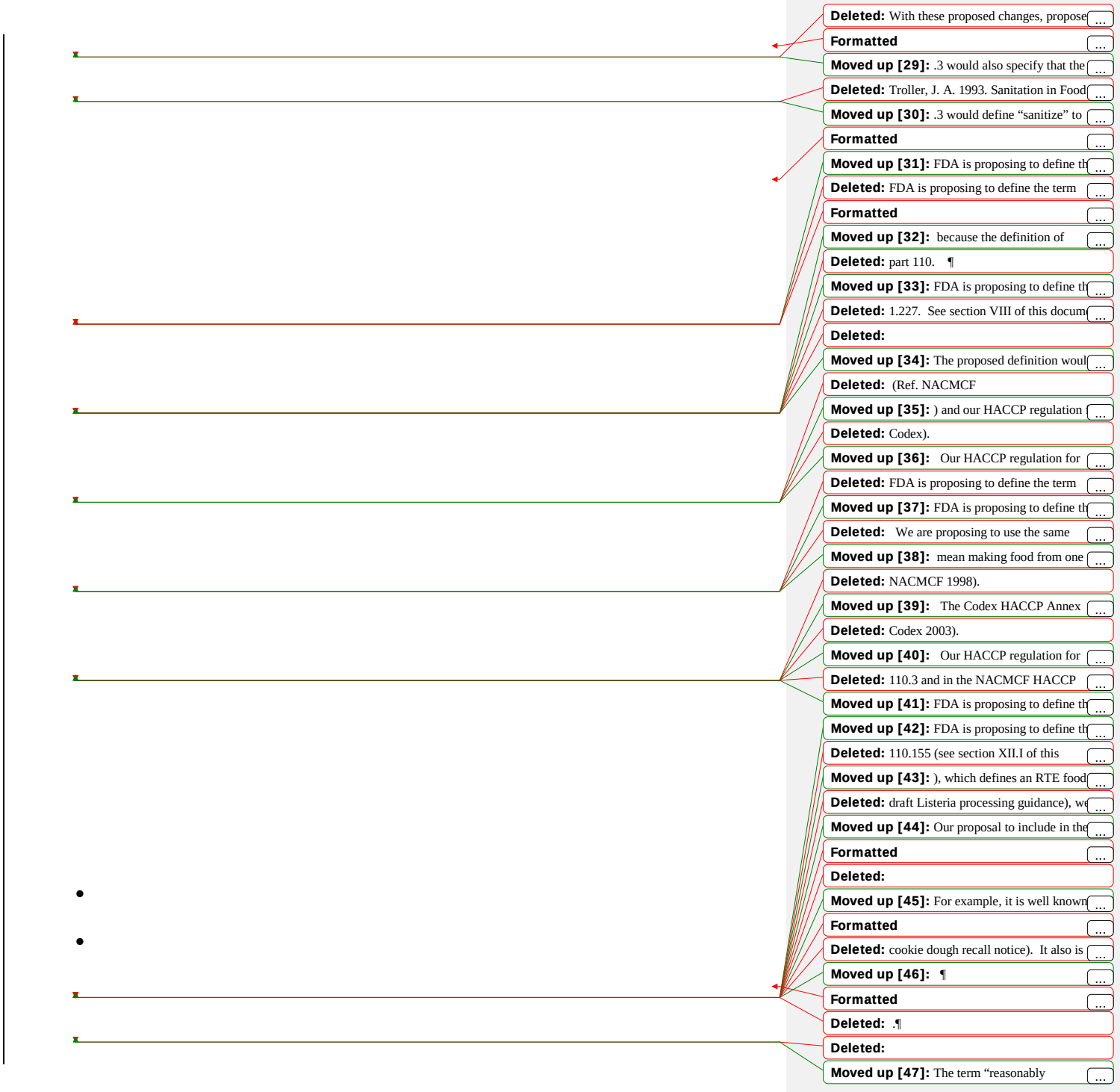
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117. 7--Applicability of Part 117 to a Facility Solely Engaged in the Storage of Packaged Food That is Not Exposed to the Environment

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

**Moved up [48]:** 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.

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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. 137) (Ref. 138) (Ref. 139) (Ref. 140). 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. 137). 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

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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 current § 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 proposed § 117.93, along with other applicable provisions of proposed part 117, subpart B, such as pest control in proposed § 117.35, do adequately address most safety-related issues that may arise in facilities solely engaged in the storage of unexposed packaged food. We disagree that current § 110.93 or other provisions in proposed part 117, 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.

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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 § 117.3, "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 § 117.7). 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 § 117.206). See the discussion of proposed § 117.7 in the next section of this document and the discussion of proposed § 117.206 in section XIII.B of this document.

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4. Proposed § 117.7--Applicability of Part 117 to a Facility Solely Engaged in the Storage of Packaged Food that is Not Exposed to the Environment

Proposed § 117.7(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 § 117.7(b) would establish that unexposed packaged food at such facilities is subject to modified requirements that would be established in proposed § 117.206. 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 part 117, subpart B (e.g., proposed §§ 117.20, 117.35, 117.37, and 117.93) 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

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establishment solely engaged in storing RACs is exempt from CGMPs in current part 110; under proposed § 117.5(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 § 117.135(d)(1));
- Food allergen controls (proposed § 117.135(d)(2));
- Sanitation controls (proposed § 117.135(d)(3));
- Monitoring of process controls, food allergen controls, and sanitation controls (proposed § 117.140);
- Corrective actions (proposed § 117.145);
- Verification (including initial validation) of process controls (proposed § 117.150); and
- A recall plan (proposed § 117.137) (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

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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 § 117.126(c)); developing the hazard analysis (proposed § 117.130(a)(3)); validating the preventive controls (proposed § 117.150(a)(1)); reviewing records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (proposed § 117.150(d)(2)); or performing reanalysis of the food safety plan (proposed § 117.150(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.

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The purpose of proposed § 117.7(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 § 117.206. 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.

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## XI. Proposed Revisions to Current Good Manufacturing Practice Requirements of Part 110 (Proposed Part 117, Subpart B)

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A. Proposed Deletion of Guidance from Current Part 110

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As discussed in section IX.F of this document, FDA is proposing a number of revisions to delete some guidance currently established in part 110 (e.g., provisions using "should" or "compliance may be achieved by"). Table 8 identifies each of the proposed deletions and either explains the deletion or, for deletions with longer explanations, refers to the section of the preamble where the deletion is explained.

Table 8. Proposed Deletion of Guidance Currently Established in Part 110

| Current Designation of Provision That Includes Guidance | Guidance that FDA is Proposing to Delete | Explanation |
|---|---|---|
| § 110.10(b)(5) (Cleanliness) | Gloves should be of an impermeable material. | We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117. 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. |
| § 110.35(b)(2) (Substances used in cleaning and sanitizing) | Follow 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. | Although such a recommendation may be helpful and could be included in future guidance, FDA tentatively concludes that it is more properly addressed by the applicable Federal, State, and local government agencies and is outside the scope of proposed part 117. |
| § 110.37(d) (Toilet facilities) | Compliance with the requirements for toilet facilities may be accomplished by four specified mechanisms. | See explanation in section XI.H.2 of this document |
| § 110.37(e) (Hand-washing facilities) | Compliance with the requirements for hand-washing facilities may be accomplished by six specified mechanisms. | See explanation in section XI.H.3 of this document |

| Current Designation of Provision That Includes Guidance | Guidance that FDA is Proposing to Delete | Explanation |
|---|---|---|
| § 110.40(e) (Equipment and utensils) | 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. | It is now very common for freezer and cold storage compartments to be fitted with an automatic control for regulating temperature. 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. |
| § 110.80(a)(2) (Processes and controls - raw materials and ingredients) | Compliance with the requirements for the safety of raw materials and ingredients may be achieved by purchasing raw materials and ingredients under a supplier's guarantee or certification. | We tentatively conclude that there are more mechanisms for achieving compliance than the single mechanism identified in current § 110.80(a)(2) – 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. |
| § 110.80(a)(3) (Processes and controls - raw materials and ingredients) | Compliance with action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. | See explanation in section XI.J.2 of this document. |
| § 110.80(a)(3) (Processes and controls - raw materials and ingredients) | Compliance with the requirement for raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins to comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food 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 tentatively conclude that there may be more mechanisms for achieving compliance than those mechanisms 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. |

| Current Designation of Provision That Includes Guidance | Guidance that FDA is Proposing to Delete | Explanation |
|---|---|---|
| § 110.80(a)(4) (Processes and controls - raw materials and ingredients) | Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. | See explanation in section XI.J.2 of this document. |
| § 110.80(a)(4) (Processes and controls - raw materials and ingredients) | The requirement for raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material to comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food 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. | We tentatively conclude that there may be more mechanisms for achieving compliance than those mechanisms identified in current § 110.80(a)(4). 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. |
| § 110.80(b)(2) (Manufacturing operations) | One way to comply with the requirement for all food manufacturing, including packaging and storage, to 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 is careful monitoring of physical factors such as time, temperature, humidity, water activity, 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. | We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117 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. |

| Current Designation of Provision That Includes Guidance | Guidance that FDA is Proposing to Delete | Explanation |
|---|---|---|
| § 110.80(b)(3) (Manufacturing operations) | Compliance with the requirement for food that can support the rapid growth of undesirable microorganisms to be held in a manner that prevents the food from becoming adulterated within the meaning of the FD&C Act 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, maintaining frozen foods in a frozen state, maintaining hot foods at 140°F (60°C) or above, and heat treating acid or acidified foods. | We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117, 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). |
| § 110.80(b)(8) (Manufacturing operations) | Compliance with the requirement for effective measures to be taken to protect against the inclusion of metal or other extraneous material in food be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means. | We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117 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. |
| § 110.80(b)(10) (Manufacturing operations) | Protection may be provided during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming by 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 § 117.35(d), which 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, and in proposed § 117.80(c)(1), which would require, in relevant part, that equipment and utensils be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. |

| Current Designation of Provision That Includes Guidance | Guidance that FDA is Proposing to Delete | Explanation |
|---|---|---|
| § 110.80(b)(10) (Manufacturing operations) | Protection may be provided during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming by using time and temperature controls at and between each manufacturing step. | We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117 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. |
| § 110.80(b)(12) (Manufacturing operations) | Recommendations for how to comply with requirements for batters, breading, sauces, gravies, dressings, and other similar preparations to be treated or maintained in such a manner that they are protected against contamination. | Recommendations to comply by using ingredients free of contamination, employing adequate heat processes where applicable, and providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them, would already be addressed in proposed §§ 117.80(b)(2), 117.80(c)(2), 117.80(c)(4) and 117.80(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. |

| Current Designation of Provision That Includes Guidance | Guidance that FDA is Proposing to Delete | Explanation |
|---|---|---|
| **§ 110.80(b)(13) (Manufacturing operations)** | **Compliance with the requirement for filling, assembling, packaging, and other operations to be performed in such a way that the food is protected against contamination 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); (iv) providing physical protection from contamination, particularly airborne contamination; and (v) using sanitary handling procedures.** | **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.** |
| **§ 110.80(b)(14) (Manufacturing operations)** | **Mechanisms for compliance with the requirement for food (such as dry mixes, nuts, intermediate moisture food, and dehydrated food) that relies on the control of water activity for preventing the growth of undesirable microorganisms to be processed to and maintained at a safe moisture level.** | **We considered that the listed mechanisms are not the only possible mechanisms for achieving compliance. FDA tentatively concludes that it would not be appropriate to establish these recommendations as requirements and that such recommendations would be more appropriate in a guidance document.** |
| § 110.80(b)(15) (Manufacturing operations) | Compliance with the requirement for food (such as acid and acidified food) that relies principally on the control of pH for preventing the growth of undesirable microorganisms to be monitored and maintained at a pH of 4.6 or below may be accomplished by any effective means, including employment of one or more of the following practices: (i) monitoring the pH of raw materials, food in process, and finished food and (ii) controlling the amount of acid or acidified food added to low-acid food. | We considered that the listed mechanisms are not the only possible mechanisms for achieving compliance. FDA tentatively concludes that it would not be appropriate to establish these recommendations as requirements and that such recommendations would be more appropriate in a guidance document. |

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| § 110.80(b)(17) (Processes and controls - manufacturing operations) | Food-manufacturing areas and equipment used for manufacturing human food should 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 tentatively concludes that this recommendation would be more appropriate in a guidance document, which could include examples of situations where there is no reasonable possibility for the contamination of the human food. |
| § 110.110(e) | Information 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 and FDA no longer has printed copies of the compilation of defect action levels. An electronic compilation of such current defect action levels is available on the internet (Ref. 141) |

### B. Other Potential Revisions to Current Guidance

As discussed in sections IX.F and XI.A of this document, FDA is proposing a number of revisions to delete some guidance currently established in part 110 (e.g., provisions using "should" or "compliance may be achieved by"). In section XI.M of this document, FDA requests comment on whether to revise other non-binding provisions to establish new requirements in proposed part 117 or retain them as useful recommended provisions of a comprehensive CGMP provision.

### C. Proposed Revisions for Consistency of Terms

As discussed in section IX.C of this document, FDA is proposing revisions to use terms consistently throughout proposed part 117. Table 9 identifies and explains each of these proposed revisions. Because other revisions also may be proposed for certain sections included in Table 9 (e.g., if FDA also is proposing a revision to address cross-contact), Table 9 does not state the proposed requirement and instead refers to the section of this document containing the complete proposed requirement, including all proposed revisions

Table 9. Proposed Revisions for Consistency of Terms

| Current Designation | Proposed Revision and Explanation |
|---|---|
| § 110.20(b) (Plant Construction and Design) | (1) Replace the phrase "food-manufacturing purposes" with the phrase "food-production purposes (i.e., manufacturing, processing, packing, and holding) to consistently use the same group of terms in proposed part 117.<br>(2) Replace the phrase "plant and facilities" with the single term "plant" as would be defined in proposed § 117.3. The requirement would be clear using the single term "plant" and, thus, the term "facilities" is unnecessary. In addition, under proposed § 117.3 (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).<br>See section XI.F for the proposed requirement. |
| § 110.20(b)(4) (Plant Construction and Design) | (3) Add "food-packaging materials" to the requirement that aisles or working spaces be provided between equipment and walls and be 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. Contamination of food-packaging materials could lead to contamination of the food. See section XI.F for the proposed requirement. |
| § 110.35(c) (Pest control) | Replace the phrase "processing area" with the phrase "manufacturing, processing, packing and holding areas" to consistently use the same group of terms in proposed part 117 and to provide for internal consistency between the requirements in current § 110.35(c) to not allow pests in "any area of a food plant" and 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. See section XI.G.3 for the proposed requirement. |
| § 110.35(d)(1) (Food-contact surfaces) | Replace the term "manufacturing" with "manufacturing/processing" in light of our proposed definition of manufacturing/processing (see discussion of the definition of manufacturing/processing in section X.B of this document). See section XI.G.4 for the proposed requirement. |
| § 110.35(d)(3) (Non-food-contact surfaces) | Add "food-packaging materials" to the recommendation that non-food-contact surfaces of equipment used in the operation of food plants be cleaned as frequently as necessary to protect against contamination of food. Contamination of food-packaging materials could lead to contamination of the food. See section XI.G.5 for the proposed provision. |
| § 110.35(d)(4) (Food-contact surfaces) | Add "food-packaging materials" to the requirement that single-service articles be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces. Contamination of food-packaging materials could lead to contamination of the food. See section XI.G.4 for the proposed requirement. |
| § 110.37(a) (Water supply) | Add "food-packaging materials" to the requirement that any water that contacts food, food-contact surfaces, or food-packaging materials be safe and of adequate sanitary quality. Contamination of food-packaging materials could lead to contamination of the food. See section XI.H.1 for the proposed requirement. |
| § 110.37(f) (Rubbish and offal disposal) | Add "food-packaging materials" to the requirement that rubbish and any offal be so conveyed, stored, and disposed of as to protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces. Contamination of food-packaging materials could lead to contamination of the food. See section XI.H.4 for the proposed requirement. |
| § 110.80(b)(7) (Manufacturing operations) | (1) Replace the term "storage" with the term "holding" for consistency with use of the term "holding" throughout proposed part 117.<br>(2) Add "processing" and "packing" as activities where protection is needed against contamination (and against cross-contact) because contamination and cross-contact can occur during any activities subject to proposed part 117.<br>(3) Inserting an "and," rather than an "or," between the cited activities to make clear that the requirements for protection against cross-contact and contamination apply to all activities at a plant.<br>See section XI.J.3 for the proposed requirement. |

| Current Designation | Proposed Revision and Explanation |
|---|---|
| § 110.110(c) (Defect action levels) | 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 for consistency with terminology used throughout proposed part 117. See section XI.L for the proposed requirement. |

* New designation relative to current designation.

## D. Proposed Revisions to Address Cross-Contact

As discussed in section IX.D 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. Table 10 identifies and explains each of these proposed revisions addressing cross-contact. Table 10 does not state the proposed requirement and instead refers to the section of this document containing the complete proposed requirement, including all proposed revisions.

Table 10. Proposed Revisions Regarding Cross-Contact

| Current Designation | Nature of Proposed Change and Explanation |
|---|---|
| § 110.10(b) (Cleanliness) | Clarification. 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. See section XI.E.1 for the proposed requirement. |
| § 110.10(b)(1) (Cleanliness) | Clarification. Appropriate use of outer garments protects against the transfer of food allergens from food to person to food. See section XI.E.1 for the proposed requirement. |
| § 110.10(b)(9) (Cleanliness) | Clarification. 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. See section XI.E.1 for the proposed requirement. |
| § 110.20(b)(2) (Plant construction and design) | Clarification. Inadequate construction and design of a plant can result in the transfer of food allergens to food. Separation of operations is a key means of preventing cross-contact. See section XI.F for the proposed requirement. |
| § 110.20(b)(6) (Plant construction and design) | Clarification. Inadequate construction and design of a plant can result in the transfer of food allergens to food. 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. See section XI.F for the proposed requirement. |
| § 110.35(a) (General maintenance) | Clarification. 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. See section XI.G.1 for the proposed requirement. |

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Deleted: 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. ¶
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| Current Designation | Nature of Proposed Change and Explanation |
|---|---|
| § 110.35(d) (Sanitation of food-contact surfaces) | Clarification. 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. See section XI.G.4 for the proposed requirement. |
| § 110.35(d)(2) (Sanitation of food-contact surfaces) | Clarification. 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. See section XI.G.4 for the proposed requirement. |
| § 110.35(d)(3) (Sanitation of non-food-contact surfaces) | Clarification. Inadequate sanitation of non-food contact surfaces may leave residues of food containing allergens on the surfaces and result in the transfer of food allergens from such surfaces to food-contact surfaces or food. See section XI.G.5 for the proposed requirement. |
| § 110.35(d)(4) (Sanitation of food-contact surfaces) | Clarification. Failure to properly store single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) could lead to cross-contact. See section XI.G.4 for the proposed requirement. |
| § 110.35(e) (Storage and handling of cleaned portable equipment and utensils) | Clarification. Failure to properly store and handle cleaned portable equipment and utensils could lead to cross-contact of the equipment and utensils and then to cross-contact of food if the equipment and utensils come in contact with food. See section XI.G.6 for the proposed requirement. |
| § 110.40(a) (Equipment and utensils) | Clarification. Equipment and utensils that are improperly designed, cleaned and maintained may result in the transfer of food allergens from equipment and utensils to food. See section XI.I for the proposed requirement. |
| § 110.40(b) (Equipment and utensils) | Clarification. Equipment and utensils that are improperly designed, cleaned and maintained may result in the transfer of food allergens from equipment and utensils to food. See section XI.I for the proposed requirement. |
| § 110.80 (Processes and controls) | Clarification. Inadequate processes and controls practices may result in the transfer of food allergens to food. See section XI.J.1 for the proposed requirement. |
| § 110.80 (Processes and controls - General) | Clarification. Inadequate processes and controls practices may result in the transfer of food allergens to food. See section XI.J.1 for the proposed requirement. |
| § 110.80(a)(1) (Processes and controls - raw materials and ingredients.) | Clarification. 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. See section XI.J.2 for the proposed requirement. |
| § 110.80(a)(5) (Processes and controls - raw materials and ingredients.) | Clarification. Improper handling of raw materials and ingredients may result in the transfer of food allergens to food. See section XI.J.2 for the proposed requirement. |
| § 110.80(a)(7) (Processes and controls - raw materials and ingredients.) | Clarification. Improper handling of raw materials and ingredients may result in the transfer of food allergens to food. See section XI.J.2 for the proposed requirement. |

| Current Designation | Nature of Proposed Change and Explanation |
|---|---|
| N/A | 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. See section XI.J.2 for the proposed requirement. |
| § 110.80(b)(5) (Processes and controls - manufacturing operations) | Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement. |
| § 110.80(b)(6) (Processes and controls - manufacturing operations) | Clarification. Manufacturing operations may result in the transfer of food allergens to food. Allergens may be transferred from one food to another when raw materials or ingredients are unprotected and allergens in unprotected refuse could contaminate food. Cross-contact can occur when food is conveyed unprotected. See section XI.J.3 for the proposed requirement. |
| § 110.80(b)(7) (Processes and controls - manufacturing operations) | Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement. |
| § 110.80(b)(10) (Processes and controls - manufacturing operations) | Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement. |
| § 110.80(b)(12) (Processes and controls - manufacturing operations) | Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement. |
| § 110.80(b)(13) (Processes and controls - manufacturing operations) | Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement. |
| § 110.93 (Warehousing and distribution) | Clarification. Inadequate storage and transportation conditions may result in the transfer of food allergens to food. See section XI.K for the proposed requirement. |

We seek comment on these proposed changes.

E. Proposed and Potential Revisions to Current § 110.10--Personnel (Proposed § 117.10)

1. Proposed Revisions to Current § 110.10(b)--Cleanliness

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.10(b) (Cleanliness), (b)(1) and (b)(9) to make clear that certain provisions involving

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hygienic practices protect against cross-contact. Proposed § 117.10(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 § 117.10(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 contamination of food, food-contact surfaces, or food-packaging materials, and to protect against the cross-contact of food (emphasis added). Proposed § 117.10(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).

As discussed in section XI.A of this document, FDA is proposing to revise current § 110.10(b)(5) to remove the recommendation that gloves be of an impermeable material. Proposed § 117.10(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. Potential 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.

**Deleted:** (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

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**Deleted:** 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

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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. 1). 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 (Ref. 58); deficiencies in training were identified as a contributing factor in 24 percent of CGMP-related primary recalls in the 2008-2009 analysis (Ref. 59). In addition, as discussed with respect to the proposed definition of preventive controls (see section X.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 proposing to re-establish current § 110.10(c) as proposed § 117.10(c). In addition, as discussed in section XI.M of this document, FDA is requesting comment on how best to revise current § 110.10(c) to implement section 418(o)(3) of the FD&C Act and the recommendations of the CGMP Working Group with respect to training.

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

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**Deleted:** 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 ...

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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 part 117, subpart B rather than with all of proposed part 117. 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 part 117, subpart C. Proposed § 117.10(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).

F. Proposed Revisions to Current § 110.20--Plant and Grounds (Proposed § 117.20)

As discussed in section XI.C of this document, FDA is proposing to revise current § 110.20(b) (Plant Construction and Design) to make two changes for consistency with terms used throughout proposed part 117. Proposed § 117.20(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 require that specific construction and design requirements apply to the "plant" rather than the "plant and facilities" (emphasis added).

As discussed in section XI.D of this document, 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. Proposed § 117.20(b)(2) would require that the plant take proper precautions to reduce the potential for

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**Deleted:** § 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

**Deleted:** 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

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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 § 117.20(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.

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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 § 117.20(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

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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 § 117.20(b)(3).

In addition, as discussed in section XI.C of this document, FDA is proposing to revise current § 110.20(b)(4) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.20(b)(4) would require that the plant 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, food-contact surfaces, or food-packaging materials with clothing or personal contact (emphasis added).

G. Proposed Revisions to Current § 110.35--Sanitary Operations (Proposed § 117.35)

1. Proposed Revisions to Current § 110.35(a)--General Maintenance

As discussed in section XI.D of this document, 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. Proposed § 117.35(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).

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**Deleted:** 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

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 § 117.35(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.

As discussed in section XI.A of this document, 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 and could be included in future guidance, it is more properly addressed by the applicable Federal, State, and local government agencies and is outside the scope of proposed part 117.

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

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the FD&C Act. Proposed § 117.35(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 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" (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 § 117.35(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 current § 110.35(d), which addresses sanitation of food-contact surfaces. As a conforming editorial change, current § 110.35(e) would become proposed § 117.35(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. As discussed in section XI.C of this document, the proposed revision would apply to "manufacturing/processing" rather than only to "manufacturing." Proposed § 117.35(d)(1) would require that food-contact surfaces used for

**Deleted:** (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

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manufacturing/processing or holding low-moisture food be in a clean, dry, sanitary condition at the time of use (emphasis added).

Third, as discussed in section XI.D of this document, 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. Proposed § 117.35(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 § 117.35(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, as discussed in section XI.C of this document, FDA also is proposing to revise current § 110.35(d)(4) (proposed § 117.35(d)(3)) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. As discussed in section XI.D of this document, FDA also is proposing to revise current § 110.35(d)(4) (proposed § 117.35(d)(3)) to address cross-contact and clarify that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact of food. In addition, in section XI.M of this document, we are requesting comment on whether 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, food-contact surfaces, or food-packaging materials. Proposed § 117.35(d)(3) would provide that single-service articles (such as utensils intended for one-time use, paper cups, and

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paper towels) should 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, food-contact surfaces, or food-packaging materials (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 § 117.35(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

As discussed in sections XI.C and XI.D of this document, FDA is proposing to revise current § 110.35(d)(3) (proposed § 117.35(e); sanitation of non-food-contact surfaces) to recommend that such cleaning of non-food contact surfaces protect against cross-contact as well as against contamination and to recommend that such cleaning protect against contamination of food-packaging materials as well as protect against contamination of food and food-contact surfaces. Proposed § 117.35(e) would 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 cross-contact and contamination of food, food-contact surfaces, and food-packaging materials (emphasis added). In addition, as discussed in section XI.M of this document, FDA also is requesting comment on whether to revise current § 110.35(d)(3) (proposed § 117.35(e)) 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 cross-contact and contamination of food, food-contact surfaces, and food-packaging materials.

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6. Proposed Revisions to Current § 110.35(e)--Storage and Handling of Cleaned Portable Equipment and Utensils

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.35(e) (proposed § 117.35(f); storage and handling of cleaned portable equipment and utensils) to address cross-contact and to recommend 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 as well as from contamination. Proposed § 117.35(f) would recommend 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 (emphasis added). In addition, as discussed in section XI.M of this document, FDA also is requesting comment on whether to revise current § 110.35(e) (proposed § 117.35(f)) to require, rather than recommend, 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.

H. Proposed Revisions to Current § 110.37--Sanitary Facilities and Controls (Proposed § 117.37)

1. Proposed Revisions to Current § 110.37(a)--Water Supply

As discussed in section XI.C of this document, FDA is proposing to revise current § 110.37(a) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(a) would require that the water supply be sufficient for the operations intended and be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality (emphasis added). 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

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cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

2. 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 12158 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

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mandating the recommendations in current § 110.37(d). Consistent with the discussion in section XI.C of this document, the proposed performance standard would be directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(d) would maintain the current requirement that each plant provide its employees with adequate, readily accessible toilet facilities. In addition, proposed § 117.37(d) would require that toilet facilities be kept clean and not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

3. 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 12158 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

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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). Consistent with the discussion in section XI.C of this document, the proposed performance standard would be directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(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, food-contact surfaces, or food-packaging materials by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

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4. Proposed Revisions to Current § 110.37(f)-- Rubbish and Offal Disposal.

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As discussed in section XI.C of this document, FDA is proposing to revise current § 110.37(f) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(f) would require that rubbish and any offal 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, food-packaging materials, water supplies, and ground surfaces (emphasis added).

I. Proposed Revisions to Current § 110.40--Equipment and Utensils (Proposed § 117.40)

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. As discussed in section XI.M of this document, FDA also is requesting comment on whether 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 § 117.40(a)(3)).

As discussed in section XI.D of this document, FDA is proposing to (1) revise current § 110.40(a) (in proposed § 117.40(a)(5)) to clarify that all plant equipment and utensils must protect against cross-contact in addition to the contamination of food and (2) revise current § 110.40(b) to clarify that seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize the opportunity for cross-contact. Proposed § 117.40(a)(5) would require that 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 § 117.40(b) would require that 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).

As discussed in section XI.A of this document, FDA 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 be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant

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temperature change in a manual operation. Proposed § 117.40(e) 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 § 117.40(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).

J. Proposed Revisions to Current § 110.80--Processes and Controls (Proposed § 117.80)

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

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changes, including the title "General" for new paragraph (a) of proposed § 117.80. 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 become proposed § 117.80(b) and current § 110.80(b) would become proposed § 117.80(c).

As discussed in section XI.D of this document, FDA is proposing to revise two provisions to current § 110.80 to clarify that certain practices involving processes and controls must protect against cross-contact. Proposed § 117.80(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 § 117.80(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 XI.D of this document, 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. As discussed in section XI.D of this document, FDA also is proposing to clarify that three of the five separate statements within current § 110.80(a)(1) address cross-contact as well as contamination. Proposed § 117.80(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 (emphasis added). Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination

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**Deleted:** 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. ¶

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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.

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of the food or cause cross-contact (emphasis added). Proposed § 117.80(b)(1) would continue to recommend that containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food (emphasis added). As discussed in section XI.M of this document, FDA also is requesting comment on whether 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 cross-contact, contamination or deterioration of food.

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. As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(a)(2). Proposed § 117.80(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

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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 current § 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. As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(a)(3). Proposed § 117.80(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. 141). FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend

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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

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regulatory action (Ref. 141). 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). As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(a)(4). Proposed § 117.80(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.

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.80(a)(5) to clarify that raw materials, ingredients, and rework be held in bulk, or in containers designed and constructed so as to protect against cross-contact as well as against contamination. Proposed § 117.80(b)(5) would require 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 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. (Emphasis added.)

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.80(a)(7) to clarify that liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact as well as contamination. Proposed § 117.80(b)(7) would require that liquid or dry raw materials and ingredients received

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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

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and stored in bulk form be held in a manner that protects against cross-contact and contamination (emphasis added).

As discussed in section XI.D of this document, FDA is proposing to establish a new requirement in current § 110.80(a) regarding cross-contact. Proposed § 117.80(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. We seek comment on this proposal.

3. Proposed Revisions to Current § 110.80(b)--Manufacturing Operations

As discussed in section XI.C of this document, 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." As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(b)(2). Proposed § 117.80(c)(2) would require that all food manufacturing, processing, packing and holding, 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 FD&C Act and provides recommendations for complying with this requirement. 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.,

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**Deleted:** 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 ...

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**Deleted:** 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.

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through temperature control. Temperature control is generally recognized as essential to food safety for foods that can support the rapid growth of microorganisms (Ref. 137) (Ref. 138) (Ref. 139) (Ref. 140).

- 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). (See the discussion of the proposed deletion in section XI.A of this document.)

With these changes, proposed § 117.80(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 (emphasis added).

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. 142). 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 § 117.3), which identifies microorganisms of public health significance as a type of undesirable microorganism, and therefore is unnecessary. Proposed § 117.80(c)(4) would require measures such as sterilizing, irradiating, pasteurizing,

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cooking, 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. As discussed in section XI.D of this document, FDA also is proposing to clarify that work-in-process must be handled in a manner to protect against cross-contact. In addition we are proposing to revise current § 110.80(b)(5) to broaden the provision to include "rework." The term "rework" would be defined in proposed § 117.3 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 § 117.80(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).

As discussed in section XI.D of this document, FDA is proposing to clarify that three provisions in current § 110.80(b)(6) require that effective measures be taken to protect finished food from cross-contact as well as from contamination. Proposed § 117.80(c)(6) would require that effective measures be taken to protect finished food from cross-contact and contamination

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**Deleted:** 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

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).

As discussed in section XI.D of this document, FDA is proposing to clarify that 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 cross-contact as well as against contamination. As discussed in section XI.C of this document, FDA also is proposing to replace the term "storage" with the term "holding" for consistency with use of the term "holding" throughout proposed part 117 and to add processing and packing as activities where protection is needed against contamination and cross-contact. Proposed § 117.80(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).

As discussed in section XI.A of this document, FDA is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(b)(8). Proposed § 117.80(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

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**Deleted:** 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

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 § 117.80(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. 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 three recommendations. As discussed in section XI.A of this document, FDA is proposing to delete two of these recommendations (regarding adequate cleaning and sanitizing of all food-contact surfaces and regarding the use of time and

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**Deleted:** 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.

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**Deleted:** 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

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temperature controls). As discussed in section XI.D of this document, FDA also is proposing to clarify that steps identified in current § 110.80(b)(10) require protection against cross-contact. Proposed § 117.80(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 continue to recommend that food should be protected from contaminants that may drip, drain, or be drawn into the food (emphasis added). As discussed in section XI.M of this document, FDA is requesting comment on whether to establish the third recommendation (regarding physical protection of food from contaminants that may drip, drain, or be drawn into the food) as a requirement.

Current § 110.80(b)(11) requires, in relevant part, that where a blanched food is washed prior to filling, water used be safe and of adequate sanitary quality. FDA is proposing to delete this requirement because water quality would already be addressed in proposed § 117.37(a) and would be redundant in proposed § 117.80(c)(11). Current § 110.80(b)(11) also recommends that heat blanching, when required in the preparation of food, 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. As discussed in section XI.M, of this document, FDA is requesting comment on whether to establish this recommendation as a requirement. Current § 110.80(b)(11) also recommends that thermophilic growth and contamination in blanchers be minimized by the use of adequate operating temperatures and by periodic cleaning. As discussed in section XI.M of this document, FDA is requesting comment on whether to establish this recommendation as a requirement. Proposed § 117.80(c)(11) would continue to recommend that heat blanching, when required in the

**Deleted:** , 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.

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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 (emphasis added). Proposed § 117.80(c)(11) also would continue to recommend that thermophilic growth and contamination in blanchers should 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 and provides several recommendations for how to comply with this requirement. As discussed in section XI.A of this document, FDA is proposing to delete these recommendations. As discussed in section XI.D of this document, FDA also is proposing to clarify that steps identified in current § 110.80(b)(12) require protection against cross-contact. Proposed § 117.80(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. 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. As discussed in section XI.A of this document, FDA is proposing to delete these

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**Deleted:** 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.

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recommendations. As discussed in section XI.D of this document, FDA also is proposing to require protection against cross-contact. Proposed § 117.80(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 recommendations for accomplishing compliance with this requirement. As discussed in section XI.A of this document, FDA is proposing to delete these recommendations. Proposed § 117.80(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 and includes two recommendations for how to comply with the requirement. As discussed in section XI.A of this document, FDA is proposing to delete these recommendations. Proposed § 117.80(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.

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K. Proposed Revisions to Current § 110.93--Warehousing and Distribution (Proposed § 117.93)

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.

As discussed in section XI.D of this document, 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.

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.

**Deleted:** 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). ¶
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**Deleted:** 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 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 proposed part 117. In section XII.B.3 of this document, we discuss a requirement, which would be established in proposed § 117.130(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 § 117.130(b).

Proposed § 117.93 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 (emphasis added).

L. Proposed Revisions to Current § 110.110--Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard (Proposed § 117.110)

As discussed in section XI.C of this document, 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. 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 § 117.110(c) would specify that compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the

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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 part 117 that food manufacturers, processors, packers, and holders must observe current good manufacturing practice (emphasis added). 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. 141). 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 § 117.110(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 (emphasis added).

As discussed in section XI.A of this document, FDA is proposing to delete current § 110.110(e), which provides that a compilation of the current defect action levels for natural or

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unavoidable defects in food for human use that present no health hazard may be obtained upon request.

M. Potential Revisions to Establish Requirements in Place of Current Guidance

1. Overview

In sections IX.F and XI.A of this document, we discuss our intent to delete some non-binding provisions of current part 110 (e.g., provisions using "should" or "compliance may be achieved by"). In this section of this document, we request comment on whether to revise other non-binding provisions to establish new requirements in proposed part 117 or retain them as useful recommendations of a comprehensive CGMP provision. We discuss each of these immediately below.

We believe that these CGMP provisions are science-based and an important part of a modern food safety system. Because these non-binding provisions have been in place for decades, they are widely used and commonly accepted in many sectors of the food industry. In addition, under section 418(o)(3) of the FD&C Act, the procedures, practices, and processes described in the definition of preventive controls may include sanitation procedures for food contact surfaces of utensils and equipment; supervisor, manager, and employee hygiene training; and CGMPs under part 110 of title 21 (or any successor regulations).

The vast majority of the costs related to a revised mandatory sanitary operations, process and controls program would be for the time that workers are in training for the alternative requirements rather than in production. We estimate that this alternative, when implemented as part of a preventive approach, could impose an incremental annual cost of $560 – $28,000 per facility based on size (number of employees) to facilities that do not already comply with this alternative. This would result in an estimated aggregate cost of $16 million for domestic

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facilities and an estimated aggregate cost of $17,400,000 for foreign facilities. This estimate assumes that about half of the qualified facilities would need to review their operations and perform the training. Most non-qualified facilities would have met the requirements by following the requirements for sanitation controls in subpart C but for those that do not have hazards that are reasonably likely to occur or for those with sanitation controls that do not fully address the requirements of the sanitary operations, they would need to review their operations and perform the training. Further details are provided in the "Consideration of Other Provisions" section of the RIA.

2. Summary of Potential Revisions to Establish Requirements in Place of Current Guidance

Table 11 identifies each of the potential revisions to establish new requirements and either explains the reason for establishing the requirement or, for such revisions with longer explanations, refers to the section of this document where the potential requirement is explained.

Table 11. Potential Revisions to Establish Requirements in Place of Current Guidance

| Designation of Proposed Provision | Potential Additional Revision to Establish a Requirement in Place of a Recommendation (Emphasis Added) | Basis for Potential Revision |
|---|---|---|
| § 117.10(c) | Personnel responsible for identifying sanitation failures or food contamination must 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. Food handlers and supervisors must 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. | See explanation and questions about whether more detail would be appropriate in section XI.M.3 of this document. |

| Designation of Proposed Provision | Potential Additional Revision to Establish a Requirement in Place of a Recommendation (Emphasis Added) | Basis for Potential Revision |
|---|---|---|
| § 117.35(d)(3) (Sanitation of food-contact substances) | 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, food-contact surfaces, or food-packaging materials. | 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. |
| § 117.35(e) (Sanitation of non-food-contact substances) | 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. | 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, cleaning non-food-contact surfaces is essential to prevent contamination of food from environmental pathogens such as L. monocytogenes and Salmonella spp. |
| § 117.35(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 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. |
| § 117.40(a)(1) (Equipment and utensils) | All equipment must be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. | 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. |
| § 117.80(b)(1) (Processes and controls - raw materials and ingredients) | Containers and carriers of raw materials must 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. |
| § 117.80(c)(10) (Manufacturing operations) | ... Food must be protected from contaminants that may drip, drain, or be drawn into the food during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming. | 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. |

| Designation of Proposed Provision | Potential Additional Revision to Establish a Requirement in Place of a Recommendation (Emphasis Added) | Basis for Potential Revision |
|---|---|---|
| § 117.80(c)(11) (Manufacturing operations) | 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. | 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. |
| § 117.80(c)(11) (Manufacturing operations) | Thermophilic growth and contamination in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning. | 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. |

3. Potential Revisions to Establish Requirements in Place of Current Guidance for 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. 1). 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

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**Deleted:** 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).

analysis (Ref. 58); deficiencies in training were identified as a contributing factor in 24 percent of CGMP-related primary recalls in the 2008-2009 analysis (Ref. 59). In addition, as discussed with respect to the proposed definition of preventive controls (see section X.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.

The vast majority of costs related to a mandatory education and training program would be for the time that workers would be training rather than in production. We estimate that a requirement for education and training, when implemented as part of a preventive approach, could impose an incremental annual cost of $1,000 – $25,000 per facility based on size (number of employees) to facilities that do not already conduct training. This would result in an estimated aggregate cost of $93 million for domestic facilities and an estimated aggregate cost of $101,300,000 for foreign facilities. This estimate assumes that both qualified and nonqualified facilities would be required to perform the training. Further details are provided in the "Consideration of Other Provisions" section of the RIA.

We request comment on how best to revise current § 110.10(c) in light of section 418(o)(3) of the FD&C Act and the recommendations of the CGMP Working Group with respect to training. Should we replace the current recommendations for personnel education and experience with requirements? Doing so would be consistent with the emphasis in section 418(o)(3) of the FD&C Act on the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls and with the

**Deleted:** 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.¶

recommendation in the CGMP Working Group Report. If so, what is the appropriate level of specificity? For example, should we simply replace the "shoulds" in current § 110.10(c) with "musts"? This would provide flexibility for each establishment to determine the type and frequency of education and training appropriate for its personnel.

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying that each person engaged in food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) receive training as appropriate to the person's duties;
- Specifying the frequency of training (e.g., upon hiring and periodically thereafter);
- Specifying that training include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility; and
- Specifying that records document required training of personnel and, if so, specifying minimum requirements for the documentation (e.g., the date of the training, the type of training, and the person(s) trained).

We also request comment on whether to establish some or all of the potential requirements for education and training in subpart B, subpart C, or both. If we establish a requirement for education and training in subpart B, that requirement would apply to all persons who manufacture, process, pack or hold food, with the exceptions of persons who would be exempt from subpart B (i.e., under proposed § 117.5(k), a requirement in subpart B would not apply to "farms", activities of "farm mixed-type facilities" that fall within the definition of "farm," or the holding or transportation of one or more RACs). On the other hand, if we

establish a requirement for education and training in subpart C, that requirement would not apply to persons who would be exempt from the requirements of proposed subpart C (e.g., qualified facilities and persons conducting activities subject to HACCP regulations for juice or seafood).

N. Request for Comment on Additional CGMP Requirements

We request comment on any additional proposed revisions or clarifications to our CGMP regulations that should be included in subpart B, including whether to further implement the "opportunities" for CGMP modernization identified by the CGMP Working Group or to enhance the CGMP regulations in some other way. For example, we request comment on whether a final rule based on this proposed rule should include CGMP requirements for environmental monitoring for L. monocytogenes, and whether such requirements should include other environmental pathogens such as Salmonella spp. If so, we also request comment on what such requirements should be. For additional information on environmental monitoring for L. monocytogenes and Salmonella spp., see sections I.D and I.E of the Appendix to this document.