List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 110

Food packaging, Foods.

21 CFR Part 114

Food packaging, Foods, Reporting and recordkeeping requirements.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 120

Foods, Fruit juices, Imports, Reporting and recordkeeping requirements, Vegetable juices.

21 CFR Part 123

Fish, Fishery products, Imports, Reporting and recordkeeping requirements, Seafood.

21 CFR Part 129

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

21 CFR Part 179

Formatted: Right

Style Definition: Normal Dble Sp Flush Left Underline: Left

Style Definition: FR Codified Indent 36 pt: Indent: First line: 0"

Formatted: Level 1

Formatted

Formatted: FR Codified Indent 36 pt, Indent: First line: 0.5", Line spacing: single

Formatted: Level 1

Formatted: FR Codified Indent 36 pt, Indent: First line: 0.5", Line spacing: single

Formatted: Level 1

Formatted: FR Codified Indent 36 pt, Indent: First line: 0.5"

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter 1 be amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Section 1.227 is revised to read as follows:

§ 1.227 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Calendar day means every day shown on the calendar.

Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: is

Formatted: Normal Double space, Level 1

Deleted: –

Formatted: Level 1, Indent: First line: 0.5"

Formatted: Underline

Formatted: Indent: First line: 0.5"

Formatted: Level 1, Indent: First line: 0.5"

Formatted: Underline

Formatted: Indent: First line: 0.5"

facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) Domestic facility means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) Foreign facility means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)),

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(6)), or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

Formatted: Right

Formatted: Underline

Formatted: Underline

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Formatted: Right

Formatted: No underline

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging)

Formatted: Right

Formatted: Indent: First line: 0.5"

Formatted: Underline

Formatted: Right

traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ``Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations.

Trade name means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between the Food and Drug Administration (FDA) and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies under § 1.233(e) another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

3. Section 1.241 is amended by revising paragraph (a) to read as follows:

§ 1.241 What are the consequences of failing to register, update, or cancel your registration?

Formatted: Right

Formatted: Underline

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

4. Section 1.276 is amended by revising paragraph (b)(9) to read as follows:

§ 1.276 What definitions apply to this subpart?

* * * * *

(b) * * *

(9) Manufacturer means the last facility, as that word is defined in § 1.227, that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a de minimis nature. If the food undergoes further manufacturing/processing that exceeds an activity of a de minimis nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: it's

Formatted: Indent: First line: 0.5"

Formatted: Underline

Deleted: * * *

Formatted: Indent: First line: 0.5"

Formatted: No underline

Formatted: No underline

* * * * *

5. Section 1.328 is amended by removing the definition for “Act” and by alphabetically adding definitions for "Harvesting", "Mixed-type facility", and “Packing”, and revising the definitions for “Farm”, “Food”, “Holding”, “Manufacturing/processing”, and “Packaging” to read as follows:

§ 1.328 What definitions apply to this subpart?

* * * * *

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

* * * * *

Formatted: Right

Deleted: * * *

Formatted: Indent: First line: 0.5"

Deleted: "

Deleted: ,"

Deleted: "

Deleted: "

Deleted: "

Deleted: ," "

Deleted: ," and "

Deleted: "

Formatted: Underline

Formatted: Indent: First line: 0.5"

Deleted: * * * *

Formatted: FR Codified Indent 36 pt

Formatted: Right

Formatted: Indent: First line: 0.5"

Formatted: No underline

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Holding means storage of food. Holding facilities include: Warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling,

labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

* * * * *

Packaging (when used as a noun) means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(6)).

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

6. Section 1.361 is revised to read as follows:

Formatted: Right

Formatted: No underline

Deleted: * * * * *¶

Formatted: No underline

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

7. Section 1.363 is revised to read as follows:

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the Federal Food, Drug, and Cosmetic Act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(e) to establish, maintain, or establish and maintain, records required under § 1.352(a), (b), (c), or (d), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

Formatted: Right

Moved (insertion) [1]

Deleted: * * * * *¶

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act and this regulation is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

8. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

9. Section 16.1 is amended by numerically adding the following entry in paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 117.251 through 117.284 (part 117, subpart E), relating to withdrawal of an exemption applicable to a qualified facility.

* * * * *

PART 106--INFANT FORMULA QUALITY CONTROL PROCEDURES

10. The authority citation for 21 CFR part 106 continues to read as follows:

Authority: 21 U.S.C. 321,350a, 371.

11. Section 106.100 is amended by revising the fourth sentence of paragraph (j) and paragraph (n) to read as follows:

§ 106.100 Records.

Formatted: Right

Deleted: –

Formatted: No underline

Formatted: No underline

Deleted: 6

Formatted: Indent: First line: 0.5"

Formatted: Underline

Moved up [1]: 7.

Deleted: In §

Deleted: , in paragraph (b)(2) , add

Deleted: numerical order to read

Deleted:)*

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 8. Revise

Formatted: Normal Double space

Deleted: 110

Formatted: Right

* * * * *

(j) * * * Records of audits shall include the information and data necessary for a determination as to whether the manufacturer complies with the current good manufacturing practices and quality procedures identified in parts 106, 107, 109, 110, 113, and 117 of this chapter. * * *

* * * * *

(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with parts 106, 107, 109, 110, 113, and 117 of this chapter, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is greater.

* * * * *

PART 110 -- [Removed and Reserved]

Formatted: No underline

12. Part 110 is removed and reserved [A DATE WILL BE ADDED 3 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

PART 114--ACIDIFIED FOODS

13. The authority citation for 21 CFR part 114 continues to read as follows:

Authority: 21 U.S.C. 342, 371,374; 42 U.S.C. 264.

14. Revise § 114.5 to read as follows:

§ 114.5 Current good manufacturing practice.

The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in parts 110 and 117 of this chapter, apply in determining whether an article of acidified food is adulterated:

(1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that it has been manufactured under such conditions that it is unfit for food, or

(2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)) in that 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.

15. Add part 117 to read as follows:

PART 117—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart A—General Provisions

Sec.

Subpart B—Current Good Manufacturing Practice

Formatted: Right

Formatted: No underline

Formatted: Level 1

Deleted: 110

Deleted: 110.2 Exemptions.¶ 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

117.80 Processes and controls.

117.93 Warehousing and distribution.

117.110 Defect Action Levels

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

117.126 Requirement for a food safety plan.

117.130 Hazard analysis.

117.135 Preventive controls for hazards that are reasonably likely to occur.

117.137 Recall plan for food with a hazard that is reasonably likely to occur.

117.140 Monitoring.

117.145 Corrective actions.

117.150 Verification.

117.155 Requirements applicable to a qualified individual.

117.175 Records required for subpart C.

Subpart D—Modified Requirements

117.201 Modified requirements that apply to a qualified facility.

117.206 Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility

117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

Formatted: Right

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110.120 Records for subpart B.¶

Deleted: 110

Deleted: Requirements

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: in which there is

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110.152 Supplier approval and verification program.¶
110

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: Level 1

Deleted: 110

Deleted: 110

Deleted: 110

117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

117.264 Procedure for submitting an appeal.

117.267 Procedure for requesting an informal hearing.

117.270 Requirements applicable to an informal hearing.

117.274 Presiding officer for an appeal and for an informal hearing.

117.277 Time frame for issuing a decision on an appeal.

117.280 Revocation of an order to withdraw an exemption applicable to a qualified facility.

117.284 Final agency action.

Subpart F—Requirements Applying to Records That Must be Established and Maintained

117.301 Records subject to the requirements of this subpart F.

117.305 General requirements applying to records.

117.310 Additional requirements applying to the food safety plan.

117.315 Requirements for record retention.

117.320 Requirements for official review.

117.325 Public disclosure.

Subpart G—[Reserved]

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 117.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether a food is adulterated;

Formatted: Right

Deleted: 110

Deleted: to, the

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: Be

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: --[

Formatted: No underline

Deleted: 110

Deleted:

(1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of part 117 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(uu)).

(c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 117

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: 110

Deleted: § 110.2

Moved down [2]: Exemptions.¶
(a) Except as provided by subpart E of this part, subpart C of this part does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in §

Moved down [3]: (b) Subpart C of this part does not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 of this chapter with respect to such activities.¶
(c) Subpart C of this part does not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 of this chapter with respect to such activities.¶
(d)(1) Subpart C of this part does not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 113 of this chapter with respect to such activities.¶
(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.¶
(e) Subpart C does not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements). ¶
(f) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).¶ ...

Formatted: Indent: First line: 0.5"

Deleted: 110.201.¶

Formatted: Indent: First line: 0.5"

Deleted: :¶
(1) Packing or re-packing (including weighing or conveying incidental to packing or re-packing) of:¶
(i) Intact fruits and vegetables (for purposes of paragraph (g) and paragraph (h) of this section on ...

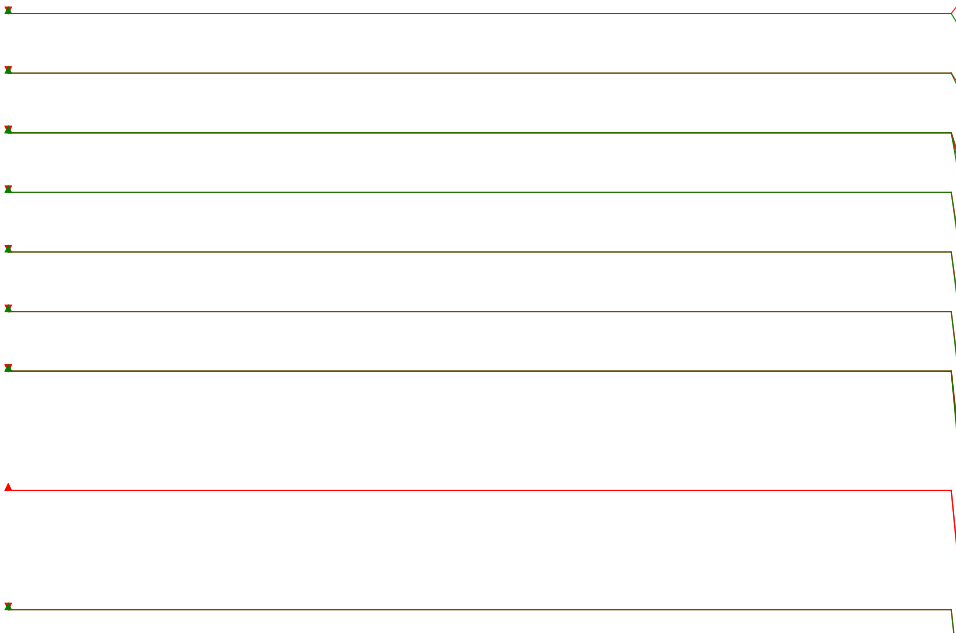
Moved down [4]: (h) Subpart C of this part does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to ...

.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.



Formatted: Right

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

Moved down [5]: where the drying creates a distinct commodity (e.g., drying fruits or herbs);¶

Deleted: (vi

Moved down [6]:)
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); ¶

Deleted: (vii

Moved down [7]:) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

Deleted: and¶
(viii) Salting seeds for consumption, raw peanuts, and raw tree nuts.¶

Moved down [8]: (2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce: ¶

Deleted: (i) Making honey (including extraction and filtration);¶ ...

Moved down [9]: (iv) Cooling intact fruits and vegetables using cold air;¶

Deleted: (v) Coating (with coatings other than wax, oil, or resin used for the purpose of storage ... ...

Moved down [10]: grains (e.g., making grain products such as corn meal), and peanuts and tree ...

Deleted: (ix) Labeling (including stickering) intact fruits and vegetables, grain and grain products, se ...

Moved down [11]: Making jams, jellies and preserves from acid foods (e.g., acid fruits);¶

Deleted: (xi) Mixing/blending intact fruits and vegetables, grain and grain products, seeds for ...

Moved down [12]: e.g., fumigation);

Deleted: and¶
(xix

Moved down [13]:) Waxing (wax, oil, or resin used for the purpose of storage or transportation) ...

Formatted: Underline

Formatted: Underline

Deleted: (i)(1), provided such food:¶

Moved down [14]: (i) Is in prepackaged form that prevents any direct human contact with such ...

Deleted: § 110

Formatted: Indent: First line: 0.5"

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Cross-contact means the unintentional incorporation of a food allergen into a food.

Environmental pathogen means a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in § 1.227 of this chapter.

FDA means the Food and Drug Administration.

Formatted: Right

Deleted: Designated food safety regulation means a regulation contained in part 106 of this chapter (Infant Formula Quality Control Procedures), part 107 of this chapter (Infant Formula), subpart B of this part (Current Good Manufacturing Practice) or subpart C of this part (Hazard Analysis and Risk-Based Preventive Controls) of part 110, part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements), part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers), part 114 of this chapter (Acidified Foods), part 118 of this chapter (Production, Storage, and Transportation Of Shell Eggs), part 120 of this chapter (Hazard Analysis and Critical Control Point Systems), part 123 of this chapter (Fish and Fishery Products), or part 129 of this chapter (Processing and Bottling of Bottled Drinking Water).¶

Formatted: Right

Formatted: Indent: First line: 0.5"

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Hazard means any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a

reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Lot means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Formatted: Right

Deleted: Hazard reasonably likely to occur, in the context of supplier controls, means a hazard for which a prudent owner, operator, or agent in charge of a receiving facility would establish controls or verify that the supplier has controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being received in the absence of those controls.¶

Formatted: No underline

Formatted: Right

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Formatted: No underline

Formatted: Right

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located;

(i) In the same State as the qualified facility that sold the food to such restaurant or establishment; or

Deleted: a

(ii) Not more than 275 miles from such facility; and

Deleted: b

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

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

Deleted: as

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable that the food would be eaten without further processing that will significantly minimize biological hazards.

Reasonably foreseeable hazard means a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Formatted: Right

Deleted: the

Deleted: the food is normally eaten, or

Deleted: ,

Deleted: Receiving facility means, for an article of food, a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier. ¶

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Should is used to state recommended or advisory procedures or identify recommended equipment.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part 117, a business employing fewer than 500 persons.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

Option 1 for definition of "Very small business"

Very small business means, for purposes of this part 117, a business that has less than $250,000 in total annual sales of food, adjusted for inflation.

Option 2 for definition of "Very small business"

Very small business means, for purposes of this part 117, a business that has less than $500,000 in total annual sales of food, adjusted for inflation.

Option 3 for definition of "Very small business"

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: 110

Deleted: Supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food (other than a farm that harvests a raw agricultural commodity that is a fruit or vegetable) that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.¶

Formatted: Indent: First line: 0.5"

Deleted: 110

Very small business means, for purposes of this part 117, a business that has less than $1,000,000 in total annual sales of food, adjusted for inflation.

Water activity (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 117.5 Exemptions.

(a) Except as provided by subpart E of this part, subpart C of this part does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in § 117.201.

(b) Subpart C of this part does not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 of this chapter with respect to such activities.

(c) Subpart C of this part does not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 of this chapter with respect to such activities.

(d)(1) Subpart C of this part does not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 113 of this chapter with respect to such activities.

(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.

Formatted: Right

Formatted: Indent: First line: 0.5"

Moved (insertion) [2]

Deleted: 110

Moved (insertion) [3]

Formatted: Indent: First line: 0.5"

Formatted: Indent: First line: 0.5"

Formatted: Right

(e) Subpart C does not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).

(f) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(g) Subpart C of this part does not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership--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 paragraph (g) and paragraph (h) of this section 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) Soft drinks and carbonated water;

(11) Sugar beets, sugarcane, and sugar;

(h) Subpart C of this part does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following:

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

(i) Artificial ripening of intact fruits and vegetables;

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

(iii) Chopping raw peanuts and raw 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 raw peanuts and raw tree nuts (e.g., adding seasonings);

(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);

Formatted: Right

Moved (insertion) [4]

Formatted: Indent: First line: 0.5"

Formatted: Indent: First line: 0.5"

Moved (insertion) [5]

(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 coating 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, oilseeds, and soybeans);

(vii) Fermenting cocoa beans and coffee beans;

(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

Formatted: Right

Formatted: Indent: First line: 0.5"

Moved (insertion) [6]

Moved (insertion) [7]

Moved (insertion) [8]

Formatted: Indent: First line: 0.5"

Moved (insertion) [9]

Formatted: Indent: First line: 0.5"

Formatted: Indent: First line: 0.5"

Moved (insertion) [10]

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; 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;

(xx) Shelling/hulling 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

Formatted: Right

Formatted: Indent: First line: 0.5"

Moved (insertion) [11]

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.

(i)(1) Subpart C of this part does not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) Subpart C of this part does not apply with respect to food other than alcoholic beverages at a facility described in paragraph (i)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

Formatted: Right

Moved (insertion) [12]

Moved (insertion) [13]

Formatted: Indent: First line: 0.5"

Formatted: Underline

Formatted: Underline

Moved (insertion) [14]

Formatted: Indent: First line: 0.5"

(j) Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k) Subpart B of this part does not apply to "farms" (as defined in § 1.227 of this chapter), activities of "farm mixed-type facilities" (as defined in § 1.227) that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

§ 117.7 Applicability of subparts C and D to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(a) Subpart C of this part does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(b) A facility solely engaged in the storage of packaged food that is not exposed to the environment is subject to the modified requirements in § 117.206 of subpart D of this part.

Subpart B—Current Good Manufacturing Practice

§ 117.10 Personnel.

The plant management must take all reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: 110

Deleted: 110

Formatted: Indent: First line: 0.5"

until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

Formatted: Right

Formatted: No underline

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against cross-contact of food.

(c) Education and training. 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. Food handlers and supervisors should 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.

(d) Supervision. Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 117.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

Formatted: Right

Deleted: chewing gum,

Deleted: (1) Each person engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof, must receive training, as appropriate to the person's duties upon hiring and periodically thereafter. The training must include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility.¶
(2) Each person engaged in manufacturing, processing, packing or holding food (including temporary and seasonal personnel), or in the supervision thereof, must have the training, in combination with education or experience, to perform the person's assigned duties. ¶
(3) Plant management must establish and maintain records that document required training of personnel, including the date of the training, the type of training, and the person(s) trained.¶

Deleted: 110

Formatted: Indent: First line: 0.5"

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to reduce the potential for cross-contact. The potential for cross-contact and contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which cross-contact and

Formatted: Right

Deleted: paragraph

Deleted:) (

Deleted: must

contamination are likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and

Formatted: Right

Deleted: or

operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for cross-contact.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 117.35 Sanitary operations.

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

Formatted: Right

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: ¶

Deleted: must

(c) Pest control. Pests must not be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.

(1) Food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) 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.

Formatted: Right

Deleted: must

Deleted: or

(e) Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant should 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.

(f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination.

§ 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) Water supply. The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

Formatted: Right

Deleted: must

Deleted: and

Deleted: must

Deleted: 110

Formatted: Indent: First line: 0.5"

Formatted: No underline

Deleted: or

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal must be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) Rubbish and offal disposal. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

§ 117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils must be so designed and of such material and workmanship as to be adequately cleanable, and must be properly maintained.

Formatted: Right

Deleted: and

Deleted:

Deleted: or

Deleted: 110

Formatted: Indent: First line: 0.5"

(2) The design, construction, and use of equipment and utensils must preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents.

(6) Food-contact surfaces must be maintained to protect food from cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and cross-contact.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food must be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

Formatted: Right

Deleted: 1

Deleted: 2

Deleted: must

Deleted: 3

Deleted: 4

Deleted: 5

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§ 117.80 Processes and controls.

(a) General. (1) All operations in the manufacturing, processing, packing and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) All reasonable precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if permissible, treated or processed to eliminate the contamination.

(b) Raw materials and ingredients. (1) Raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for

Formatted: Right

Deleted: 110

Formatted: Indent: First line: 0.5"

processing into food and must be stored under conditions that will protect against cross-contact and contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross-contact. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food.

(2) Raw materials and ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.

(4) Raw materials, ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against cross-contact and contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

Formatted: Right

Deleted: must

Deleted: Food and Drug Administration

Deleted: Food and Drug Administration

(6) Frozen raw materials and ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated.

(7) Liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact and contamination.

(8) Raw materials and ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents cross-contact.

(c) Manufacturing operations. (1) Equipment and utensils and finished food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against cross-contact, contamination, and growth of undesirable microorganisms.

Formatted: Right

Deleted: ,

(6) Effective measures must be taken to protect finished food from cross-contact and contamination by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in cross-contact or contaminated food. Food transported by conveyor must be protected against cross-contact and contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food must be constructed, handled, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination.

(8) Effective measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food or, if the adulterated food is capable of being reconditioned, it must be reconditioned using a method that has been proven to be effective.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against cross-contact and contamination. Food should be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay.

Formatted: Right

Deleted: must

Deleted: must

Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against cross-contact and contamination.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, including acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container.

§ 117.110 Defect action levels.

Natural or unavoidable defects in food for human use that present no health hazard:

Formatted: Right

Deleted: must

Deleted: (17) Food-manufacturing areas and equipment used for manufacturing human food must not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for cross-contact or contamination of the human food.¶
§ 110

Formatted: Indent: First line: 0.5"

Deleted: 110

Deleted: Action Levels

Formatted: Indent: First line: 0.5"

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods when it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food not be prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, or the requirements in this part that food manufacturers, processors, packers, and holders must observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 Requirement for a food safety plan.

Formatted: Right

Deleted: The Food and Drug Administration

Deleted: § 110.120 Records required for subpart B.¶
(a) Plant management must establish and maintain records that document required training of personnel.¶
(b) The records that plant management must establish and maintain are subject to the requirements of subpart F of this part.¶

Deleted: 110

(a) Food safety plan. The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan.

(b) Contents of a Food Safety Plan. The food safety plan must include:

(1) The written hazard analysis as required by § 117.130(a)(2);

(2) The written preventive controls as required by § 117.135(b);

(3) The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by § 117.140(a);

(4) The written corrective action procedures as required by § 117.145(a)(1);

(5) The written verification procedures as required by § 117.150(e); and

(6) The written recall plan as required by § 117.137(a).

(c) Qualified individual. The food safety plan must be prepared by (or its preparation overseen by) a qualified individual.

§ 117.130 Hazard analysis.

(a) Requirement for a hazard analysis. (1) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur.

(2) The hazard analysis must be written.

(b) Hazard identification. The hazard identification must consider hazards that may occur naturally or may be unintentionally introduced, including:

(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance;

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: , and the frequency with which they are to be performed

Deleted: 110

Deleted:)(1);

Deleted: 110

Deleted:); and

Deleted: (7) The written list of approved suppliers and the written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient as required by § 110.152(a)(3)(i) and (ii).¶

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: ¶

(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens;

(3) Physical hazards; and

(4) Radiological hazards.

(c) Hazard evaluation. (1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

(2) The hazard analysis must include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging.

(3) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the facility and equipment;

(iii) Raw materials and ingredients;

(iv) Transportation practices;

(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;

(vii) Storage, and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors.

Formatted: Right

Deleted: ¶

§ 117.135 Preventive controls for hazards that are reasonably likely to occur.

For hazards indentified in the hazard analysis as reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Preventive controls must be written.

(c) Preventive controls must include, as appropriate to the facility and the food:

(1) Parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, and refrigerating foods, and

(2) The maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

(d) Preventive controls must include, as appropriate:

(1) Process controls. Process controls must include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur.

(2) Food allergen controls. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from cross-contact, including during storage and use; and

Formatted: Right

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: parameters

Deleted: the

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) Sanitation controls. (i) Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls must include procedures for the:

(A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

(B) Prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(ii) The owner, operator or agent in charge of a facility must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

(iii) The owner, operator, or agent in charge of a facility is not required to follow the corrective actions established in § 117.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(3)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

Formatted: Right

Deleted: ¶

Deleted:

Deleted:

Deleted: paragraph

Deleted: 110

Deleted: paragraph

(iv) All corrective actions taken in accordance with paragraph (d)(3)(ii) of this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

(4) Recall plan. Recall plan as required by § 117.137.

(5) Other controls. Preventive controls must include any other controls necessary to satisfy the requirements of paragraph (a) of this section.

(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:

(i) Monitoring as required by § 117.140;

(ii) Corrective actions as required by § 117.145; and

(iii) Verification as required by § 117.150.

(2) The recall plan established in § 117.137 is not subject to the requirements of paragraph (e)(1) of this section.

§ 117.137 Recall plan for food with a hazard that is reasonably likely to occur.

For food with a hazard that is reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must establish a written recall plan for the food.

(b) The recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

Formatted: Right

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: (5) Supplier program. Supplier approval and verification program as required by § 110.152.¶ (6)

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: , and the supplier approval and verification program established in § 110.152, are

Deleted: 110

Deleted: in which there is

Formatted: Indent: First line: 0.5"

Deleted: in which there is

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food--e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

§ 117.140 Monitoring.

(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.

(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed.

(c) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(b) and records review in accordance with § 117.150(d)(5)(i).

§ 117.145 Corrective actions.

(a) Corrective action procedures. (1) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;

(ii) All affected food is evaluated for safety; and

(iii) All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under

Formatted: Right

Deleted: –

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110

Deleted: 110

Formatted: No underline

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: ¶

section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Corrective action in the event of an unanticipated problem. If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:

(1) Take corrective action to identify and correct the problem to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (a)(2)(iii) of this section; and

(2) Reanalyze the food safety plan in accordance with § 117.150(f) to determine whether modification of the food safety plan is required.

(c) Documentation. All corrective actions taken in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

§ 117.150 Verification.

(a) Validation. Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(1) Must be performed by (or overseen by) a qualified individual:

Formatted: Right

Deleted: 110

Deleted: (c) Corrective actions for environmental monitoring. If environmental monitoring in accordance with § 110.150(d)(4) identifies the presence of an environmental pathogen or appropriate indicator organism, the owner, operator, or agent in charge of a facility must take corrective actions that include:¶
(1) Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;¶
(2) Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;¶
(3) Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated;¶
(4) Conducting finished product testing when appropriate; and¶
(5) Performing any other corrective actions necessary to prevent reoccurrence of the contamination.¶
(d

Formatted: No underline

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and

(3) Need not address:

(i) The food allergen controls in § 117.135(d)(2);

(ii) The sanitation controls in § 117.135(d)(3); and

(iii) The recall plan in § 117.137.

(b) Monitoring. The owner, operator, or agent in charge of a facility must verify that monitoring is being conducted, as required by § 117.140.

(c) Corrective actions. The owner, operator, or agent in charge of a facility must verify that appropriate decisions about corrective actions are being made, as required by § 117.145 and § 117.135(d)(3)(ii).

(d) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the following activities, as appropriate to the facility and the food:

(1) Calibration of process monitoring instruments and verification instruments; and

(2) Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities

Formatted: Right

Deleted: six

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: ; and

Deleted: (iv) The supplier approval and verification program in § 110.152.¶

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: iv

Deleted: , by conducting activities that

Deleted: (1) Review of any consumer, customer, or other complaints to determine whether a complaint relates to the effectiveness of the food safety plan;¶
(2

Deleted: ¶
(3) Performance of finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur;¶
(4) Performance of environmental monitoring, for a microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur, by collecting environmental samples at locations within the facility at a frequency of not less than monthly,

Deleted: testing the samples to assess whether the preventive controls significantly minimize or prevent the potential for an environmental pathogen to contaminate food;

Deleted: (5

reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within a week after the records are made.

(ii) Records of calibration within a reasonable time after the records are made.

(e) Written procedures for verification activities. As appropriate to the facility and the food, the owner, operator, or agent in charge of a facility must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.

(f) Reanalysis. (1) The owner, operator, or agent in charge of a facility must:

(i) Conduct a reanalysis of the food safety plan;

(A) At least once every 3 years;

(B) Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;

(C) Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food;

(D) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and

(E) Whenever a preventive control is found to be ineffective.

(ii) Complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production; and

Formatted: Right

Deleted: consumer, customer, or other complaints,

Deleted: , finished product testing, environmental monitoring, and supplier verification activities

Deleted:)(1

Deleted: The

Deleted: :

Deleted: (i) Conducting finished product testing. Procedures for finished product testing must be scientifically valid and must include the procedures for sampling and the sampling frequency; and¶
(ii) Conducting environmental monitoring. Procedures for environmental monitoring must:¶
(A) Be scientifically valid; ¶
(B) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be sufficient to determine whether preventive controls are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces within the manufacturing, processing, packing and holding environment; and¶
(C) Identify the test microorganism(s);¶
(iii) The frequency of calibrating process monitoring instruments and verification instruments.¶
(2) Written procedures must identify or include the analytical methods used to test finished product or environmental samples.¶

Deleted: ¶

(iii) Revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

(2) The reanalysis must be performed (or overseen) by a qualified individual.

(3) FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

(g) Documentation. All verification activities taken in accordance with this section must be documented in records.

§ 117.155 Requirements applicable to a qualified individual.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(c));

(2) Validation of the preventive controls (§ 117.150(a)(1));

(3) Review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 117.150(d)(2)); and

(4) Reanalysis of the food safety plan (§ 117.150(f)(2)).

(b) To be qualified, an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(c) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

Formatted: Right

Formatted: Underline

Deleted: 110.152 Supplier approval and verification program.¶
(a) Supplier approval and verification program. (1) Except as provided in paragraph (a)(6) of this section, the owner, operator, or agent in charge of a receiving facility must establish and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur.¶
(2) The supplier approval and verification program must provide adequate assurances that the hazards identified as reasonably likely to occur by the receiving facility are significantly minimized or prevented. ¶
(3) The supplier approval and verification program must include:¶
(i) A written list of approved suppliers; ¶
(ii) For each raw material and ingredient, a written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient. If the owner, operator, or agent in charge of a receiving facility determines that a supplier is not subject to part 110, subpart C because the supplier is a qualified facility, then the owner, operator, or agent in charge of the receiving facility must obtain written assurance that the supplier meets the conditions for exemption as a qualified facility under § 110.2(a) and that FDA has not withdrawn such exemption for the supplier under subpart E of this part; and ¶
(iii) Verification activities as required by paragraphs (b) and (c) of this section.¶
(4) When supplier verification activities are required under paragraph (b) or (c) of this section for more than one type of hazard, the owner, operator ...

Formatted: Indent: First line: 0.5"

Deleted: A

Deleted: individual

Deleted: Prepare

Deleted: 110

Deleted:)).

Deleted:

Deleted: Validate

Deleted: 110

Deleted:)).

Deleted: 110

Deleted: 5)).

Deleted: Perform reanalysis

Deleted: 110

Deleted: (5) Perform an onsite audit (§ 110.152(e)(1).¶

Deleted: A

Deleted: the

§ 117.175 Records required for subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan.

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation,

(ii) Monitoring,

(iii) Corrective actions,

(iv) Calibration of process monitoring and verification instruments,

(v) Records review, and

(vi) Reanalysis; and

(5) Records that document applicable training for the qualified individual.

(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Modified Requirements

§ 117.201 Modified requirements that apply to a qualified facility.

(a) Documentation to be submitted. A qualified facility must submit the following documentation to the FDA:

Formatted: Right

Deleted: 110

Formatted: Level 1, Indent: First line: 0.5"

Formatted: Indent: First line: 0.5"

Deleted: recall plan, written list of approved suppliers, and the written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient

Deleted: including corrective actions for environmental monitoring,

Deleted: (iv) Review of consumer, customer or other complaints,¶
(v

Deleted: (vi) Finished product testing,¶
(vii) Environmental monitoring,¶
(viii)

Deleted: ix

Deleted: ¶
(5) Records that document the supplier approval

Deleted: verification program; and

Deleted: 6

Formatted: Level 1, Indent: First line: 0.5"

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: Food and Drug Administration (FDA):

(1) Documentation that the facility is a qualified facility as defined in § 117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) Documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) Documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(b) Procedure for submission. The documentation required by paragraph (a) of this section must be submitted to FDA by one of the following means:

(1) Electronic submission. To submit electronically, go to http://www.access.fda.gov and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) Submission by mail. To submit documents in a paper format or in an electronic format on a CD-ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. We recommend that an owner, operator or agent in charge of a facility submit by mail only if the facility does not have reasonable access to the Internet.

Formatted: Right

Deleted: 110

Deleted: http://www.access.fda.gov

Deleted: website

(c) Frequency of submission. The documentation required by paragraph (a) of this section must be:

(1) Submitted to FDA initially within 90 days of the applicable compliance date of this part; and

(2) Resubmitted at least every 2 years, or whenever there is a material change to the information described in paragraph (a) of this section. For the purpose of this section, a material change is one that changes whether or not a facility is a "qualified facility."

(d) Notification to consumers. A qualified facility that does not submit documentation under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities), as follows:

(1) If a food packaging label is required, the notification required by paragraph (c)(1) of this section must appear prominently and conspicuously on the label of the food.

(2) If a food packaging label is not required, the notification required by paragraph (c)(1) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(e) Records. (1) A qualified facility must maintain those records relied upon to support the documentation required by § 117.201(a).

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

Formatted: Right

Deleted: ¶

Deleted: 110

§ 117.206 Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) If there is a problem with the temperature controls for such refrigerated packaged food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected food for safety; and

(iii) Prevent the food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

Formatted: Right

Deleted: 110

Formatted: Indent: First line: 0.5"

(jii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged food; and

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility

§ 117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(b) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

§ 117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

Formatted: Right

Deleted: ii

Deleted: 110

Formatted: Underline

Formatted: Indent: First line: 0.5"

Deleted: 110.2

Deleted: 110

(a) If FDA determines that an exemption applicable to a qualified facility under § 117.5(a) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.

(b) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 117.5(a) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: 110.2

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110.2

(d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.270;

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(h) The name and the title of the FDA representative who approved the order.

§ 117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) The owner, operator, or agent in charge of a qualified facility that receives an order under § 117.251 to withdraw an exemption applicable to that facility under § 117.5(a) must either:

(1) Comply with applicable requirements of this part within 60 calendar days of the date of the order; or

(2) Appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 117.264.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA,

Formatted: Right

Deleted: 110

Deleted: e-mail

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110.2

Deleted: 110

unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order.

§ 117.264 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 117.5(a), the owner, operator, or agent in charge of the facility must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 117.5(a), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 117.267.

§ 117.267 Procedure for requesting an informal hearing.

(a) If the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility:

(1) May request an informal hearing; and

Formatted: Right

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110.2

Deleted: e-mail

Deleted: 110.2

Deleted: 110

Deleted: 110

Formatted: Indent: First line: 0.5"

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 117.264 within 10 calendar days of the date of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial.

§ 117.270 Requirements applicable to an informal hearing.

If the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 117.254 and 117.257, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the

Formatted: Right

Deleted: 110

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: Except as provided by paragraph (b) of this section, the

Deleted:

Deleted: 110

Deleted: 110

Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 117.274, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 117.270(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 117.270(c)(5) constitutes

Formatted: Right

Deleted: 110

Deleted: Sections

Deleted: 110

Deleted: pursuant to

Deleted: 110

the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 117.274 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 117.277 Time frame for issuing a decision on an appeal.

(a) If the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.270(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 117.280 Revocation of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 117.5(a) is revoked if:

Formatted: Right

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: tenth

Deleted: 110

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110.2

(a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 117.284 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 117.301 Records subject to the requirements of this subpart F.

(a) Except as provided by paragraphs (b) and (c) of this section, all records required by this part are subject to all requirements of this subpart F.

(b) The requirements of § 117.310 apply only to the written food safety plan.

(c) The requirements of § 117.305(b), (d), (e), and (f) do not apply to the records required by § 117.201(e).

§ 117.305 General requirements applying to records.

Records must:

Formatted: Right

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110

Formatted: Indent: First line: 0.5"

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(b) Contain the actual values and observations obtained during monitoring;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§ 117.310 Additional requirements applying to the food safety plan.

The food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility:

(a) Upon initial completion; and

(b) Upon any modification.

§ 117.315 Requirements for record retention.

(a) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated

Formatted: Right

Formatted: Indent: First line: 0.5"

Deleted: 110

Formatted: Indent: First line: 0.5"

Formatted: No underline

Deleted: 110

Formatted: Indent: First line: 0.5"

the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.150(a));

(c) Except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 117.320 Requirements for official review.

All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request.

§ 117.325 Public disclosure.

Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart G—[Reserved]

PART 120--HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

16. The authority citation for 21 CFR part 120 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241.

17. Amend § 120.3 by revising the first sentence of the introductory text to read as follows:

§ 120.3 Definitions.

Formatted: Right
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: Indent: First line: 0.5"
Deleted: FDA
Formatted: No underline
Deleted: 110
Formatted: Indent: First line: 0.5"
Formatted: No underline
Deleted: –
Formatted: No underline
Formatted: No underline

Formatted: Right

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part.

* * *

* * * * *

18. Revise § 120.5 to read as follows:

§ 120.5 Current good manufacturing practice.

Except as provided by § 117.5(c), parts 110 and 117 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

19. Amend § 120.6 by revising the first sentence of paragraph (b) to read as follows:

§ 120.6 Sanitation standard operating procedures.

* * * * *

(b) Monitoring. The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 and in subpart B of part 117 of this chapter that are appropriate both to the plant and to the food being processed. * * *

* * * * *

PART 123--FISH AND FISHERY PRODUCTS

20. The authority citation for 21 CFR part 123 continues to read as follows:

Formatted: Right

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 241l, 264.

21. Revise the first sentence of the introductory text in § 123.3 to read as follows:

§ 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part.

* * *

* * * * *

22. Revise paragraph (a) of § 123.5 to read as follows:

§ 123.5 Current good manufacturing practice.

(a) Except as provided by § 117.5(b), parts 110 and 117 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

* * * * *

23. .Amend § 123.11 by revising the introductory text of paragraph (b) to read as follows:

§ 123.11 Sanitation control procedures.

* * * * *

(b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those

Formatted: Right

conditions and practices specified in part 110 and in subpart B of part 117 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

* * * * *

PART 129--PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

24. The authority citation for 21 CFR part 129 continues to read as follows:

Authority: 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

25. Revise § 129.1 to read as follows:

§ 129.1 Current good manufacturing practice.

The applicable criteria in parts 110 and 117 of this chapter, as well as the criteria in §§ 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

PART 179--IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

26. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

27. Revise paragraph (a) of § 179.25 to read as follows:

§ 179.25 General provisions for food irradiation.

* * * * *

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of parts 110 and 117 of this chapter and other applicable regulations.

* * * * *

PART 211--CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

28. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

29. Amend § 211.1 by revising the last sentence in paragraph (c) to read as follows:

§ 211.1 Scope.

* * * * *

(c) * * * Therefore, until further notice, regulations under parts 110 and 117 of this chapter, and where applicable, parts 113 to 129 of this chapter, shall be applied in determining whether these OTC drug products that are also foods are manufactured, processed, packed, or held under current good manufacturing practice.

Dated: January 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

Although the proposed rule that is the subject of this document does not include provisions for environmental monitoring or finished product testing, we believe that these regimes can play a critical role in a modern food safety system. In sections XII.J.2 and XII.J.3 of

Formatted: Right

Deleted: :_____.

Deleted: ¶
¶
_____¶

Formatted: Right

the preamble of this document, we request comment on when and how these types of testing are an appropriate means of implementing the statutory directives set out in section 418 of the FD&C Act. In this Appendix, we provide background material on these testing measures.

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

A. Verification of Preventive Controls

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. 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. Although testing may be conducted for biological, chemical, physical or radiological hazards, the most common testing is for microbiological hazards. Thus, much of the testing described below focuses on microbial testing, but many of the issues discussed apply to testing for other hazards as well. We focus more of our discussion below on verification testing of the environment because of the increasing recognition of the benefits of such testing in identifying conditions that could result in environmental pathogens contaminating food; thus such verification testing is important in preventing contamination in food, whereas verification

Formatted: Right

testing of raw materials, ingredients, and finished products is used to detect contamination that has already occurred.

As discussed in sections I.C, I.E, and I.F of this 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.

Each type of testing provides information applicable to managing hazards in foods, depending on the food and process. For example, a dry blending operation, e.g., for spices and seasonings, often verifies its supplier controls by testing incoming ingredients before use (as discussed in section I.C of this Appendix) and periodically sampling and testing finished products. If all the ingredients being blended had been treated to adequately reduce hazards such as Salmonella spp., a dry blending operation generally does less testing to verify supplier controls than if this were not the case. (We use the term "adequately reduce" (which is a term used in some of our guidance documents) (Ref. 6) (Ref. 156) to mean the same as "significantly minimize or prevent" as described in section 418 of the FD&C Act or "prevent, eliminate or reduce to an acceptable level" as used in our seafood and juice HACCP regulations. All these terms mean to reduce a hazard to an extent that it is not reasonably likely to cause illness or injury.) A dry blending operation generally does not test incoming ingredients if the facility treats the blended materials to ensure adequate reduction of pathogens but sometimes tests finished product to verify preventive controls have been effective. A dry blending operation also

Formatted: Right

sometimes uses environmental monitoring to verify that sanitation controls to significantly minimize or prevent the potential for environmental pathogens to contaminate the blended materials have been effective.

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

B. Scientifically Valid Sampling and Testing

Consistent with our previous discussion of the term "scientifically valid" in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements (68 FR 12158 at 12198), we use the term "scientifically valid" with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12158 at 12198). Sampling and testing used for verification in a food safety system must be scientifically valid if they are to provide assurance that preventive controls are effective.

C. Verification Testing of Raw Materials and Ingredients

Raw materials and ingredients are often tested as part of a supplier approval and verification program, as one of the verification activities when a preventive control that is adequate to significantly minimize or prevent the hazard is not applied at the receiving facility.

Formatted: Right

The utility and frequency of raw material and ingredient testing for verification of supplier controls depend on many factors, including:

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

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

Testing a raw material or ingredient is more useful, and a facility generally tests a raw material or ingredient more frequently, when the raw material or ingredient contains a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. However, when a hazard that the receiving facility has identified as reasonably likely to occur in a raw material or ingredient is one for which the receiving facility has preventive controls that significantly minimize or prevent the hazard, testing generally is less frequent. An exception to this general paradigm is when the process control depends on the amount of the hazard present in the raw material or ingredient (e.g., when the process control is effective at eliminating 100 microorganisms per gram of ingredient, but not 1000 microorganisms per gram of ingredient) and there is a need to verify that

Formatted: Right

the hazard is not present in amounts that would render the process control ineffective. A receiving facility often finds that testing of raw materials or ingredients is most useful, and generally tests more frequently, when the receiving facility does not have a process that would significantly minimize the hazard and is relying on preventive controls earlier in the supply chain to significantly minimize or prevent the hazard in the raw material or ingredient, as in a bagged salad facility or a dry-mix operation producing, for example, spice blends or trail mix. In such situations, the testing is conducted to verify the preventive controls used to ensure that hazards in the raw material or ingredient have been significantly minimized or prevented.

The frequency of the testing conducted by a facility generally depends in part on the likelihood and severity of illness to the consumer if the hazard were present, the ability of supplier controls to significantly minimize or prevent the hazard in the raw material or ingredient, the practicality of testing to detect the hazard, and other factors. For example, a facility generally tests a raw material or ingredient more frequently from a supplier that does not have a kill step for Salmonella spp. in shelled nutmeats compared to a supplier that steam treats the nuts to kill Salmonella spp. As another example, if a facility tests a raw material or ingredient as part of its food safety program for salad greens, the facility is more likely to test more frequently for E. coli O157:H7 than for other Shiga-toxin producing E. coli (pathogenic E. coli that produce the same toxin as E. coli O157:H7 but are less likely to cause severe illness (Ref. 195)), based on both the severity of the illness to the consumer and practical problems with testing fresh produce for pathogenic strains of Shiga-toxin producing E. coli. Where a raw material or ingredient could introduce an environmental pathogen such as Salmonella spp. or L. monocytogenes to the facility (e.g., raw nuts or soy powder for Salmonella spp.; chopped celery to be used in a salad for L. monocytogenes), a facility generally tests the raw material or

Formatted: Right

ingredient more frequently to verify that supplier controls for the raw material or ingredient minimize to the extent possible the potential for a contaminated raw material or ingredient to introduce the environmental pathogen to the facility's environment.

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

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

1. Environmental Pathogens in Food

As discussed in section II.D of the preamble of this document, food can become contaminated with pathogenic microorganisms at many different steps in the farm-to-table continuum. Any time a food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated with pathogenic microorganisms. As discussed in section X.B of the preamble of this document, proposed § 117.3 would define the term "environmental pathogen" to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. The environmental pathogens most frequently involved in the contamination of foods leading to foodborne illness are Salmonella spp. and L. monocytogenes.

2. Salmonella spp. as an Environmental Pathogen.

We discuss Salmonella spp. in section II.D.2.a of the preamble of this document. Salmonella has been isolated from a variety of foods and it can get into food by a variety of mechanisms (see section II.D of the preamble of this document). Our focus here is on Salmonella

Formatted: Right

contamination from the environment (discussed further in section I.D.2 of this Appendix), particularly as a hazard associated with low-moisture foods (Ref. 145) (Ref. 179) . Low-moisture foods include cereal, peanuts, nuts, nut butters (including peanut butter), spices, dried herbs, milk powder, chocolate and many other foods. Although Salmonella outbreaks from low-moisture foods are less common than from foods such as eggs and produce, several such outbreaks in the last decade have involved hundreds of illnesses (Ref. 145). The low-moisture foods causing outbreaks included cereal, raw almonds, dried snacks, spices, and peanut butter (Ref. 145) (Ref. 196). Chocolate also has been a source of outbreaks from Salmonella spp., although none in the U.S. in recent years (Ref. 145). Dried dairy products, such as milk and whey, also present a risk of contamination with Salmonella spp. from the environment (Ref. 197). A review of FDA recall data from 1970 to 2003 showed there were 21 recalls of spices and herbs contaminated with Salmonella spp. (Ref. 198). Almost half of the 86 primary RFR entries reported in the first RFR Annual Report due to finding Salmonella spp. were from low-moisture foods (Ref. 60).

3. Listeria monocytogenes as an environmental pathogen.

We discuss L. monocytogenes in section II.D.2.a of the preamble of this document. As discussed in that section, the FDA/FSIS Lm RA shows that the risk of illness from L. monocytogenes increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of L. monocytogenes than from those that do not (Ref. 56). A key finding of the risk assessment released by FAO in 2004 was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (Ref. 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

Formatted: Right

does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with L. monocytogenes is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from L. monocytogenes in that food increases. As discussed in section II.D.1 of the preamble of this document, contamination of RTE food with L. monocytogenes from the environment is common and, thus, targeted preventive controls to significantly minimize or prevent L. monocytogenes contamination of RTE foods are warranted.

4. Environmental pathogens in the plant environment.

Environmental pathogens may be introduced into a facility through raw materials or ingredients, people, or objects (Ref. 145) (Ref. 179) (Ref. 199) (Ref. 144) (Ref. 185). Once in the facility, environmental pathogens can be a source of contamination of food. Environmental pathogens may be transient strains or resident strains (Ref. 145) (Ref. 179) (Ref. 199). Transient strains are environmental pathogens that contaminate a site in the facility where they can be eliminated by normal cleaning and sanitizing (Ref. 199). Transient strains tend to vary over time within a facility, e.g., they will be found in different areas and the specific strain will differ. Resident strains are environmental pathogens that contaminate a site in the facility that is difficult to clean and sanitize with normal cleaning and sanitizing procedures and, thus, these strains become established in what is referred to as a "niche" or harborage site (Ref. 145) (Ref. 179) (Ref. 199) (Ref. 144) (Ref. 185) (Ref. 200). The finding of the same specific strain multiple times in a facility often indicates a resident strain.

If a harborage site contains nutrients (i.e., food) and water and is exposed to a temperature that falls within the growth range of the environmental pathogen, the pathogen can multiply, which increases the chance that it will be transferred to other sites (including food-contact surfaces) and to food. Transfer can occur by people (e.g., if a person touches the

Formatted: Right

contaminated site and then touches other objects, or tracks the pathogen from the contamination site to other sites on shoes), by equipment (e.g., if the pathogen is picked up by the wheels of a cart or forklift and is transferred to other locations), by water (e.g., water that contacts the harborage site is splashed onto other areas, including equipment, or aerosols containing the pathogen transfer it to other areas) or by air (dissemination of contaminated dust particles by air handling systems) (Ref. 145) (Ref. 179) (Ref. 200) (Ref. 144). Such transfer mechanisms from harborage sites can result in intermittent contamination of food-contact surfaces and food over long periods of time, often with the same strain of the pathogen (Ref. 145) (Ref. 199) (Ref. 200) (Ref. 201).

5. Contamination of food with Salmonella spp. from the plant environment.

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

In 1998, a breakfast cereal product was implicated in an outbreak, due to Salmonella Agona, that caused 409 illnesses and one death in 23 states (Ref. 201) (Ref. 202) (Ref. 203). During the outbreak investigation, Salmonella was isolated from various locations in the plant, including the floor, processing equipment, and the exhaust system of the implicated processing line (Ref. 201). In 2008, the same Salmonella Agona strain was again implicated in an outbreak linked to a similar cereal product from the same manufacturing facility (Ref. 204). In the 2008 outbreak, the same strain was isolated from patients, cereal and the plant environment (Ref. 204).

In 2006-2007, a commercial brand peanut butter contaminated with Salmonella Tennessee caused 715 illnesses and 129 hospitalizations (Ref. 62). FDA isolated Salmonella

Formatted: Right

Tennessee from 13 unopened jars of peanut butter with production dates ranging from August 2006 to January 2007 and from two plant environmental samples (Ref. 63).

During the years 2008 through 2010, there were three large recalls of foods containing ingredients contaminated with Salmonella spp. where FDA's investigation identified insanitary conditions at the facility that manufactured the ingredient and detected Salmonella spp. in the plant environment (Ref. 19) (Ref. 23) (Ref. 66) (Ref. 67) (Ref. 68) (Ref. 69) (Ref. 205) (Ref. 155) (Ref. 206). In 2008-2009, an outbreak was linked to Salmonella Typhimurium in peanut butter and peanut paste (Ref. 66) (Ref. 67) (Ref. 205). This outbreak resulted in an estimated 714 illnesses, 166 hospitalizations, and 9 deaths (Ref. 67). Implicated foods included contaminated peanut butter consumed at institutional settings and crackers made with the contaminated peanut butter as an ingredient (Ref. 66) (Ref. 67). Inspections conducted by FDA at the two implicated ingredient manufacturing facilities (which shared ingredients) revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Ref. 19) (Ref. 68) (Ref. 69). Several strains of Salmonella spp. were found in multiple products and in the plant environment (Ref. 68). This outbreak led to the recall of more than 3900 products containing peanut-derived ingredients (Ref. 20).

In 2009, USDA detected Salmonella spp. in a powdered dairy shake and FDA began an investigation of the suppliers of ingredients used to manufacture the product. The inspection of the supplier of one of the ingredients uncovered insanitary conditions that resulted in the recall of multiple ingredients manufactured by that supplier, including instant nonfat dried milk and whey proteins, produced over a 2-year period (Ref. 155). During its investigation of the supplier's facility, FDA identified several strains of Salmonella spp. on food-contact and non-food-contact

Formatted: Right

surfaces and in other areas of the plant environment, as well as a number of sanitation deficiencies (Ref. 206).

In 2010, FDA received a report through the RFR of Salmonella contamination of hydrolyzed vegetable proteins that a company purchased as an ingredient. Both the company that submitted the report and FDA found multiple Salmonella-positive samples collected from the plant environment, including food-contact surfaces. FDA found numerous sanitation deficiencies during its inspection of the production facility. There were no reports of illness associated with the contamination, but multiple product recalls resulted (Ref. 23).

6. Contamination of food with L. monocytogenes from the plant environment.

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

Between October 2008 and March 2009, eight cases of listeriosis from five states were linked to Mexican-style cheese that was likely contaminated post-pasteurization (Ref. 72). The outbreak strain was isolated from product and from a vat gasket in a post-pasteurization section of the processing line.

In October 2010, the Texas Department of State Health Services ordered a fresh-cut produce facility to stop processing after laboratory tests of chopped celery indicated the presence of L. monocytogenes (Ref. 207). The testing was done as part of an investigation of 10 cases of listeriosis, six of which were linked to chopped celery from the facility. Texas Department of State Health Services and FDA inspectors found sanitation deficiencies at the plant (Ref. 207) (Ref. 208) and suggested that the L. monocytogenes in the chopped celery may have

Formatted: Right

contaminated other produce. FDA laboratory testing found L. monocytogenes in multiple locations in the plant environment, including on food-contact surfaces; the DNA fingerprint of the L. monocytogenes in the FDA samples matched the DNA fingerprint of the clinical cases reported by the Texas Department of State Health Services (Ref. 209).

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).

There have been several outbreaks in which meat or poultry products produced in FSIS-inspected establishments were contaminated with L. monocytogenes from the plant environment (Ref. 210), and much of our understanding of sources of L. monocytogenes in the plant environment, as well as appropriate ways to control this organism, has come from the efforts of FSIS and the meat and poultry industry to control this hazard in FSIS-inspected establishments (Ref. 185). For example, harborage sites such as hollow rollers, rubber seals, close-fitting metal-to-metal spaces in equipment such as slicers, and on-off switches of equipment were identified in meat and poultry establishments. The increased risk of contamination resulting from construction, and the importance of control of traffic and water in the RTE area also became widely known as a result of investigations at meat and poultry establishments (Ref. 144) (Ref. 185).

Formatted: Right

Outbreaks of listeriosis resulting from environmental contamination have also occurred in other countries. For example, an outbreak of listeriosis in Finland in 1999 was associated with butter (Ref. 211). The outbreak strain was isolated from the manufacturing facility, including from the packaging machine and the floor (Ref. 211). An outbreak of listeriosis in 2009 in Austria and Germany was associated with acid curd cheese; the outbreak strain was found in the production facility (Ref. 212).

Many foods without a known association with illnesses have been recalled due to the presence of L. monocytogenes (Ref. 188) (Ref. 189) (Ref. 190) (Ref. 213). There is also an extensive body of literature on isolation of L. monocytogenes in the food processing environment. Information on the environment as a source of Listeria has been available for many years. For example, in a 1989 study involving 6 different types of food plants (frozen food, fluid dairy, cheese, ice cream, potato processing, and dry food), drains, floors, standing water, food residues, and food-contact surfaces were found to be positive (Ref. 214). No finished foods were tested, but the authors concluded that food production environments could be the source of contamination for foods that have received listericidal treatments and that measures should be taken to prevent survival and growth of these organisms in food environments (Ref. 214).

Listeria testing in 62 dairy facilities during 1987-1988 (including facilities producing fluid milk, frozen product, butter, processed cheese, natural cheese and dry products) found Listeria in a variety of locations, including packaging equipment, conveyors, coolers, drains and floors (Ref. 215). Listeria was detected more frequently in wet locations, including drains, conveyors and floors (Ref. 215). Pritchard and co-workers also examined 21 dairy processing environments for Listeria and found 80 of 378 sites positive for Listeria spp. (Ref. 216). Sites

Formatted: Right

positive for L. monocytogenes included holding tanks, table tops, conveyor/chain systems, a milk filler and a brine pre-filter machine (Ref. 216).

The packaging machine was found to be the main problem with L. monocytogenes that persisted in an ice cream plant in Finland for several years and occasionally contaminated finished product (Ref. 217). A volumetric doser was found to be the source of L. monocytogenes in sauces produced in a fresh sauce production plant in Italy (Ref. 218), and slicers and conveyor belts were found to contribute to contamination of sandwiches in a Swiss sandwich producing plant (Ref. 219). L. monocytogenes also has been found on tables, water hoses, air guns, floors, gloves, drains and a bread-feeding machine (Ref. 219).

Some of the available data and information about the potential presence of the environmental pathogen L. monocytogenes comes from studies conducted to detect the presence of Listeria spp. in lieu of L. monocytogenes. Listeria spp. are "indicators" of the potential presence of L. monocytogenes. (See section I.E of this Appendix for a discussion of indicator organisms). A study conducted over a 4-year time period on the prevalence of L. monocytogenes on produce and in the plant environment in a large produce processing plant in Poland demonstrated that the indicator organism Listeria spp., and the environmental pathogen L. monocytogenes, could be isolated from conveyor belts after blanching and from freezing tunnels (Ref. 220). Studies in a vegetable processing plant in Spain found the indicator organism L. innocua (commonly found when the species of Listeria spp. are determined) in frozen RTE vegetables and in the plant environment, e.g., washing tunnels, conveyor belts and floors (Ref. 221). L. innocua was more prevalent than L. monocytogenes in the frozen RTE vegetables and in the plant environment. In both of these examples, the presence of an "indicator organism"

Formatted: Right

(either Listeria spp. or L. innocua) demonstrated that insanitary conditions existed that were conducive to the presence and harborage of L. monocytogenes.

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

1. Purpose of Environmental Monitoring

Appropriate sanitation controls can minimize the presence of environmental pathogens in the plant and the transfer of environmental pathogens to food-contact surfaces and to food (Ref. 199). The purpose of monitoring for environmental pathogens in facilities where food is manufactured, processed, packed or held is to verify the implementation and effectiveness of sanitation controls intended to significantly minimize or prevent the potential for an environmental pathogen to contaminate food. In so doing, environmental monitoring can find sources of environmental pathogens that remain in the facility after routine cleaning and sanitizing (particularly strains that may have become established in the facility as resident strains) so that the environmental pathogens can be eliminated by appropriate corrective actions (e.g., intensified cleaning and sanitizing, sometimes involving equipment disassembly). Pritchard et al. noted that daily cleaning and sanitizing appeared to be effective in eliminating transient contaminants from equipment and concluded that greater emphasis needs to be placed on cleaning and sanitizing the plant environment (Ref. 216). A robust environmental monitoring program for environmental pathogens can detect these strains and enables the facility to eliminate them from the environment which can prevent contamination of food with these pathogens and, thus, prevent foodborne illnesses (Ref. 52) (Ref. 144) (Ref. 185) (Ref. 186) (Ref. 184). In the situations described in sections I.D.5 and I.D.6 of this Appendix, such a program for

Formatted: Right

the environmental pathogens Salmonella spp. and L. monocytogenes might have allowed the facility to detect a problem before product contamination occurred, thereby preventing an outbreak, recall, or both, or minimizing the amount of product affected by a recall. Studies of environmental pathogens have clearly demonstrated that environmental monitoring can identify the presence of situations that can lead to contamination of food and allow actions to be taken to prevent such contamination (Ref. 216) (Ref. 187).

2. Indicator Organisms.

The term "indicator organism" can have different meanings, depending on the purpose of using an indicator organism. As discussed in the scientific literature, the term "indicator organism" means a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. 222). This definition in the scientific literature is consistent with a definition of indicator organism established by NACMCF as one that indicates a state or condition and an index organism as one for which the concentration or frequency correlates with the concentration or frequency of another microorganism of concern (Ref. 223). FDA considers the NACMCF definition of an indicator organism to be an appropriate working definition for the purpose of this document.

The use of "indicator organisms" as a verification of hygiene measures in facilities is common practice (Ref. 224). For example, it is common practice to use the presence of generic (nonpathogenic) E. coli in a food processing plant as an indication of whether food was prepared, packed, or held under insanitary conditions, without considering whether the insanitary conditions reflect a specific pathogen, such as E. coli O157:H7 or Salmonella spp. However,

Formatted: Right

such use of an indicator organism is distinct from the use of indicator organisms as discussed in the remainder of this document – i.e., for the specific purpose of monitoring for the presence of environmental pathogens.

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

- Similar survival and growth characteristics;
- A shared common source for both organisms; and
- A direct relationship between the state or condition that contributes to the presence of pathogen and the indicator organism (Ref. 223).

The presence of an indicator organism in the plant environment, including on a food-contact surface, does not necessarily mean that an environmental pathogen is in the plant or in a food produced using that food-contact surface – the indicator may be present but the pathogen may be absent. Pritchard et al., in their study on the presence of Listeria in dairy plant environments, concluded that, because the level of contamination was higher in environmental samples than in equipment samples, environmental contamination with Listeria does not necessarily translate into contamination of equipment in the plant (Ref. 216).

Formatted: Right

Typically, a facility that finds an indicator organism during environmental monitoring conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the indicator organism is found on retest, the facility generally takes more aggressive corrective actions (e.g., more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts) (Ref. 144). In general, whether a facility takes subsequent steps to determine an indicator organism detected on a food-contact surface is actually the environmental pathogen depends, in part, on the risk of foodborne illness if the food being produced on a food-contact surface that has tested positive for an indicator organism were to be contaminated. For example, the risk of listeriosis is greater if the food supports growth of L. monocytogenes. In some cases, a facility simply assumes that a food produced using a food-contact surface that is contaminated with an indicator organism is contaminated with the environmental pathogen and takes corrective action to either reprocess it or divert it to a use that would not present a food safety concern.

3. Environmental Monitoring for L. monocytogenes and the Use of an Indicator Organism.

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

Formatted: Right

FSIS has issued guidelines (FSIS Compliance Guideline for Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products) (hereinafter the FSIS Listeria Compliance Guideline) to help FSIS-regulated establishments that produce RTE meat or poultry products exposed to the processing environment after a lethality procedure comply with the requirements of 9 CFR part 430 (Ref. 225). Under the FSIS Listeria Compliance Guideline, FSIS-regulated establishments may establish an environmental monitoring program for Listeria spp. rather than for the pathogen, L. monocytogenes.

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

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

Some segments of the food industry subject to regulation by FDA have adopted the principles, described in the FSIS Listeria Compliance Guideline, for corrective actions after a finding of Listeria spp. on food-contact surfaces in the plant. For example, in response to a request for comments on a draft guidance document directed to control of L. monocytogenes in refrigerated or frozen ready-to-eat foods, we received letters describing programs similar to the program in the FSIS Listeria Compliance Guideline, using Listeria spp. as an indicator organism during environmental monitoring for L. monocytogenes (Ref. 226) (Ref. 227) (Ref. 228) (Ref.

Formatted: Right

229). In addition, as discussed in section II.A.1 of the preamble of this document, a key finding of the CGMP Working Group Report was the importance of updating CGMP requirements to require a written environmental pathogen control program for food processors that produce RTE foods that support the growth of L. monocytogenes. Written comments from the food industry supported such a control program (Ref. 230). Thus, the importance of controlling L. monocytogenes in the environment of RTE food production facilities and using environmental monitoring to detect the presence of L. monocytogenes or Listeria spp. (as an indicator organism for L. monocytogenes) has been well-established.

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

4. Environmental Monitoring for Salmonella spp. and the Use of an Indicator Organism.

Salmonella spp. is a member of the family Enterobacteriaceae, and thus there is some relationship between the presence of Salmonella spp. and the presence of Enterobacteriaceae. There are few studies that have investigated the use of organisms such as Enterobacteriaceae or other members of the family Enterobacteriaceae, such as E. coli, to serve as an indicator organism for Salmonella spp. in the environment. The European Food Safety Agency (EFSA) evaluated whether environmental monitoring for Enterobacteriaceae as an indicator organism for Salmonella spp. (or for Cronobacter spp.) could be useful. Although EFSA's focus was on the utility of Enterobacteriaceae as an indicator organism in the production of a single product – i.e., powdered infant formula – their analysis may be relevant to the utility of Enterobacteriaceae as

Formatted: Right

an indicator organism in other dried foods. EFSA concluded that, although there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and Salmonella spp. in powdered infant formula because Salmonella spp. is so rarely present, monitoring for Enterobacteriaceae in the product environment can be used to confirm the application of GMPs (Ref. 231). ICMSF also considered the utility of environmental monitoring for Enterobacteriaceae as an indicator organism for Salmonella spp. ICMSF indicates that, for powdered infant formula manufacturing, low levels of Enterobacteriaceae do not guarantee the absence of Salmonella spp. (Ref. 232) and recommends testing directly for the pathogen, as well as for Enterobacteriaceae. FDA agrees with EFSA and ICMSF that there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and Salmonella spp. during the production of powdered infant formula; FDA is not aware of any information supporting the use of an indicator organism for the purpose of environmental monitoring for Salmonella spp. during the production of other foods, particularly dried foods.

ICMSF recommends testing for Salmonella spp. in the environment for a number of other products, e.g., baked dough products (Ref. 233), dry spices receiving a kill step (Ref. 234), dried cereal products (Ref. 235), nuts (Ref. 236), cocoa powder, chocolate and confectionary (Ref. 237), and dried dairy products (Ref. 238). For most of these products ICMSF also recommends testing the environment for Enterobacteriaceae as a hygiene indicator, but not in lieu of the environmental pathogen Salmonella spp. Likewise, food industry guidance for low-moisture foods recommends testing for Salmonella spp. in the environment (Ref. 184). FDA's current thinking is that there is no currently available indicator organism for Salmonella spp. We request data, information, and other comment bearing on whether there is a currently available indicator organism for Salmonella spp. that could be used for environmental monitoring.

Formatted: Right

5. Environmental Monitoring Procedures.

The procedures associated with an environmental monitoring program generally include the collection of environmental samples at locations within the facility and testing the samples for the presence of an environmental pathogen or indicator organism. One approach to defining sampling locations is to divide the facility into zones based on the risk with respect to contamination of product. A common industry practice is to use four zones (Ref. 199) (Ref. 184):

- Zone 1 consists of food-contact surfaces;
- Zone 2 consists of non-food-contact surfaces in close proximity to food and food-contact surfaces;
- Zone 3 consists of more remote non-food-contact surfaces that are in the process area and could lead to contamination of zones 1 and 2; and
- Zone 4 consists of non-food-contact surfaces, outside of the processing area, from which environmental pathogens can be introduced into the processing environment.

Generally the number of samples and frequency of testing is higher in zones 1 and 2 because of the greater risk of food contamination if the environmental pathogen is detected in these zones. Information on appropriate locations for sampling within these zones can be found in the literature (Ref. 197) (Ref. 144) (Ref. 215) (Ref. 216) (Ref. 184). Facilities should become familiar with locations in which environmental pathogens have been found in other facilities and use this information in selecting sites to sample.

Examples of appropriate food-contact surfaces that could be monitored include hoppers, bins, conveyors, tables, slicers, blenders, knives and scrapers. Testing food-contact surfaces for Listeria spp. is a commonly recommended verification measure for facilities producing

Formatted: Right

refrigerated RTE foods (Ref. 52) (Ref. 199) (Ref. 144). Although some literature suggests that routine environmental monitoring for Salmonella spp. in low-moisture food environments would not normally target food-contact surfaces (Ref. 184), the data (discussed in the preamble of this document) available from investigations of food facilities following outbreaks, recalls, or reports to the RFR warrant including food-contact surfaces in a routine environmental testing program for Salmonella spp. However, a routine environmental monitoring program for Salmonella spp. may not contain the same level of food-contact surface testing (including the frequency of testing and number of samples collected) as a routine environmental monitoring program for Listeria, because the same benefits may not be achieved. For example:

- L. monocytogenes is usually the environmental pathogen of concern for most wet RTE food production environments. It is important to sample areas where the organisms are likely to be present in relatively high numbers. L. monocytogenes frequently establishes itself in a harborage site on equipment and grows (increases in number) there, where both food and moisture are available. L. monocytogenes organisms work their way out of the harborage site during production and contaminate food.
- Salmonella spp. is usually the environmental pathogen of concern for most dry (e.g., low-moisture) RTE food environments. Equipment used in the production of dry products is rarely wet and, thus, there is no moisture to allow growth of Salmonella spp. As a result, Salmonella harborage sites are less likely to be found on equipment and are more likely to be found in the environment in locations where food particles lodge and escape a dry cleaning process. When these locations get wet, the Salmonella spp. grows and contaminates other areas of the facility, eventually contaminating food-contact surfaces and food. Nevertheless, sampling

Formatted: Right

food-contact surfaces (e.g., filler hoppers, conveyors, valves, sifter cuffs) can be useful, as can sampling residues such as sifter tailings and product scrapings.

Examples of appropriate non-food-contact surfaces that could be monitored include exteriors of equipment, equipment supports, control panels, door handles, floors, drains, refrigeration units, ducts, overhead structures, cleaning tools, motor housings and vacuum canisters. Standing water in production areas and areas that have become wet and then have dried are also appropriate places to monitor. Testing non-food-contact surfaces for L. monocytogenes or Listeria spp. is a commonly recommended verification measure for facilities producing refrigerated or frozen RTE foods (Ref. 52) (Ref. 199) (Ref. 144) and can detect L. monocytogenes that is brought into the plant by people or objects. Corrective actions can prevent transferring the organisms to a food-contact surface (where they can contaminate food) or from establishing a harborage that can serve as a source of contamination. Recommendations for routine environmental monitoring for Salmonella spp. in low moisture food environments generally target non-food-contact surfaces because equipment used in the production of low-moisture foods where Salmonella spp. is the environmental pathogen of concern does not have the moisture to allow Salmonella spp. to grow and, thus, sampling non-food-contact surfaces for Salmonella spp. may be more effective in finding the organism than sampling food-contact surfaces. Scrapings or residues that accumulate under or above equipment are more useful samples than sponges or swabs of food-contact surfaces (Ref. 237).

As discussed in section I.E.2 of this Appendix with respect to indicator organisms, a facility that finds an indicator organism or an environmental pathogen during environmental monitoring typically conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and

areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the organism is found on retest, the facility generally takes more aggressive corrective actions (e.g., more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts) (Ref. 144).

The adequacy of a corrective action in response to environmental monitoring depends in part on the following factors related to the risk presented in a particular situation:

- Whether the environmental contamination is on a food-contact surface or a non-food-contact surface;
- The proximity of a contaminated non- food-contact surface to one or more food-contact surfaces;
- Whether there have been previous positives on the specific food-contact surface or non- food-contact surface or in the same area; and
- The environmental monitoring strategy for the type of food, and whether the food supports growth of the environmental pathogen (see the discussion of the relevance of whether a food supports the growth of an environmental pathogen in section I.D.4 of this Appendix).

If an environmental pathogen or an appropriate indicator organism (the test organism) is detected in the environment, corrective actions are taken to eliminate the organism, including finding a harborage site if one exists (Ref. 144) (Ref. 185) (Ref. 184). Otherwise, the presence of the environmental pathogen could result in contamination of food-contact surfaces or food. The presence of the indicator organism suggests that conditions exist in which the environmental pathogen may be present and could result in contamination of food-contact surfaces or food. Corrective actions are taken for every finding of an environmental pathogen or indicator organism in the environment to prevent contamination of food-contact surfaces or food.

Formatted: Right

Formatted: Right

Sampling and microbial testing from surfaces surrounding the area where the test organism was found are necessary to determine whether the test organism is more widely distributed than on the original surface where it was found and to help find the source of contamination if other sites are involved. Cleaning and sanitizing the contaminated surfaces and surrounding areas are necessary to eliminate the test organism that was found there. Additional sampling and microbial testing are necessary to determine the efficacy of cleaning and sanitizing. For example, detection of the test organism after cleaning and sanitizing indicates that the initial cleaning was not effective, and additional, more intensified cleaning and sanitizing, or other actions may be needed, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts (Ref. 144). Examples of additional corrective actions that could be taken include reinforcing employee hygiene practices and traffic patterns; repairing damaged floors; eliminating damp insulation, water leaks, and sources of standing water; replacing equipment parts that can become harborage sites (e.g., hollow conveyor rollers and equipment framework), and repairing roof leaks (Ref. 144) (Ref. 184). The types of corrective actions would depend on the type of food, the facility and the environmental pathogen.

The finding of a test organism on a food-contact surface usually represents transient contamination rather than a harborage site (Ref. 185). However, finding the test organism on multiple surfaces in the same area, or continuing to find the test organism after cleaning and sanitizing the surfaces where it was found, suggests a harborage site for the test organism. Mapping the location of contamination sites, whether the harborage site is on equipment or in the environment, can help locate the source of the harborage site or identify additional locations to sample (Ref. 184).

Formatted: Right

The types of facilities that may conduct environmental monitoring and that could implement corrective actions on finding the test organism in the facility are quite diverse, and include facilities producing low-moisture products such as cereals, chocolate and dried milk powders and facilities producing a variety of RTE refrigerated products such as deli salads, cheeses and bagged salads. The number of sites appropriate for testing and the applicable cleaning and sanitizing procedures would depend on the facility and the equipment.

Corrective actions may involve investigative procedures when the initial corrective actions have not been successful in eliminating the environmental pathogen or indicator organism. One example of an investigative procedure is taking samples from food-contact surfaces and/or product from the processing line at multiple times during the day while the equipment is operating and producing product (Ref. 144). Another example of an investigative procedure is conducting molecular strain typing such as pulsed-field gel electrophoresis (PFGE), ribotyping, or polymerase chain reaction (PCR) analysis to determine if particular strains are persistent in the environment (Ref. 200) (Ref. 239) (Ref. 219) (Ref. 217) (Ref. 218) (Ref. 240). Molecular strain typing can indicate that strains isolated at different points in time have the same molecular "fingerprint," suggesting a common source, and perhaps a harborage site, that has not been detected based on the results of routine environmental monitoring (Ref. 217) (Ref. 218). Molecular strain typing can also be used when trying to determine if a specific ingredient is the source of contamination (Ref. 239).

If environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the facility may conduct finished product testing. As discussed in section I.F of this Appendix, there are shortcomings for microbiological testing of food for process control purposes. Testing cannot ensure the absence of a hazard, particularly when the

Formatted: Right

hazard is present at very low levels and is not uniformly distributed. If an environmental pathogen is detected on a food-contact surface, finished product testing would be appropriate only to confirm actual contamination or assess the extent of contamination, because negative findings from product testing could not adequately assure that the environmental pathogen is not present in food exposed to the food-contact surface. If a facility detects an environmental pathogen on a food-contact surface, the facility should presume that the environmental pathogen is in the food.

Finished product testing could be appropriate if an environmental pathogen is detected on a non-food-contact surface, such as on the exterior of equipment, on a floor or in a drain. The potential for food to be contaminated directly from contamination in or on a non-food-contact surface is generally low, but transfer from non-food-contact surfaces to food-contact surfaces can occur. Finished product testing can provide useful information on the overall risk of a food when pathogens have been detected in the environment. In general, finished product testing is most appropriate when an indicator organism, rather than an environmental pathogen, is detected on a food-contact surface.

The results of finished product testing can be used in combination with the results of environmental monitoring and corrective actions to help ensure that the food released into commerce is not adulterated. For example, if a facility with an aggressive environmental monitoring program detects an indicator organism on a food-contact surface, it may use information such as the following in determining whether to release product into commerce:

- The number and location of positive sample findings, including from the original sampling and from additional/follow-up testing of areas surrounding the site of the original finding;

Formatted: Right

- The root cause analysis of the source of the contamination;
- Information on the efficacy of the facility's corrective actions (including the results of additional follow-up sampling);
- Information obtained from any finished product testing, taking into consideration the statistical confidence associated with the results.

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

Although FDA is not including a provision for finished product testing in this proposed rule, here we set out some considerations regarding the appropriate use of such testing. The utility of finished product testing for verification depends on many factors that industry currently considers in determining whether finished product testing is an appropriate approach to reducing the risk that contaminated food would reach the consumer and cause foodborne illness. The first such consideration is the nature of the hazard and whether there is evidence of adverse health consequences from that hazard in the food being produced or in a similar food. If the hazard were to be present in the food, how likely is it that illness will occur and how serious would the consequences be? The more likely and severe the illness, the greater the frequency of conducting verification testing. For example, Salmonella spp. is a hazard that if consumed could cause serious illness, particularly in children and the elderly. In contrast, in situations where unlawful pesticide residues are considered reasonably likely to occur, the presence of a pesticide residue that is not approved for a specific commodity but that is within the tolerance approved for other commodities, while deemed unsafe as a matter of law, may not actually result in illness. Thus, a firm is more likely to conduct finished product testing to verify Salmonella spp. control than to verify control of pesticides.

Formatted: Right

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

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

Another consideration in determining whether finished product testing is appropriate is the intended use of the food. For example, consumers cook many foods, e.g., dried pasta, cake mixes, and most frozen vegetables, thereby reducing pathogens. A facility should not rely on the consumer to eliminate hazards that can be prevented. However, there is little benefit in testing a food that is normally consumed following a step that can be relied on to inactivate the hazard. It is important to validate that the instructions provided to the consumer adequately reduce the pathogen of concern. It is also important to understand the customary use of the food, which

Formatted: Right

may include uses that do not include the hazard reduction step. For example, dried soup mixes may be mixed with sour cream to make a dip, without the pathogen inactivation step that occurs when boiling the soup mix with water. If Salmonella spp. may be present in an ingredient for the soup mix, e.g., dried parsley or black pepper, and neither the supplier nor the facility treats the ingredient or the soup mix in a way that significantly reduces Salmonella spp., then finished product testing for Salmonella spp. would be warranted. Likewise, frozen peas and corn may be added to fresh salads, deli-type salads, or salsas without a pathogen inactivation step; finished product testing for L. monocytogenes could be warranted for these foods where this is a likely use.

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

Formatted: Right

the receiving facility will not significantly minimize it, or if a facility is using a new supplier, the frequency of finished product verification testing increases.

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

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

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

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

Formatted: Right

Formatted: Right

There are well-known shortcomings of product testing, especially microbiological testing, for process control purposes, and it is generally recognized that testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed (Ref. 222) (Ref. 241)). Moreover, the number of samples used for routine testing often is statistically inadequate to provide confidence in the safety of an individual lot in the absence of additional information about adherence to validated control measures. This is illustrated below for Salmonella spp.

FDA's Investigations Operations Manual (IOM) (Ref. 242) and Bacteriological Analytical Manual, BAM, (Ref. 243) provide sampling plans to determine the presence of Salmonella in processed foods intended for human consumption. The stringency of the sampling plan is based on the category of the food. Category III foods are those that would normally be subject to a process lethal to Salmonella spp. between the time of sampling and consumption (e.g., macaroni and noodle products, frozen and dried vegetables, frozen dinners, food chemicals). Category II foods are those that would not normally be subject to a process lethal to Salmonella spp. between the time of sampling and consumption (e.g., fluid milk products, cheeses, nut products, spices, chocolate, prepared salads, ready-to-eat sandwiches). Category I foods are Category II foods intended for consumption by the aged, the infirm, and infants (e.g., foods produced for a hospital). FDA takes 15 samples for Category III foods, 30 for Category II foods, and 60 for Category I foods and tests a 25 g subsample (analytical unit) from each sample. To reduce the analytical workload, the analytical units may be composited (Ref. 244), with the maximum size of a composite unit being 375 g (15 analytical units). This composite is tested in its entirety for Salmonella spp. The probability of detecting Salmonella spp. for various

Formatted: Right

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

Table 1. Probability of Detecting Salmonella spp. in Lots at Various Contamination Rates under the Three Different IOM Salmonella Sampling Plans (left) and the Expected Number of Positive Composite Samples Using Weekly Testing for 1 Year under the IOM Salmonella Sampling Plans (right).

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

* In the table, "n" is the number of subsamples (which are composited in groups of 15 for analysis).

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

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

Formatted: Right

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

Periodic testing for trend analysis and statistical process control, however, does provide information to assess whether processes (or the food safety system) are under control over time. Data collected from multiple lots of product produced over days, months or years are used to establish a baseline for the level of control that can be attained under a functioning food safety system and to verify the system is in control or to indicate loss of control. In addition to showing the probability of detecting contamination in a lot of product for a given contamination rate, Table 1 also shows the value of periodic testing when contamination levels are low. Even though a product with 1 in 300 contaminated units is unlikely to be rejected when sampling a single lot at the Category III sampling schedule (i.e., 4.9 percent of the time), testing of finished products with this level of contamination on a weekly basis would be expected to find 2.5 positive composite samples per year. Similarly, if the background contamination rate is thought to be near 1 in 1000 but periodic testing using the Category III schedule has found 3 positives in the last year, then it seems clear that the actual frequency of contaminated units is closer to 1 in 300. Periodic testing according to the Category I Salmonella plan has the potential to detect situations where the contamination rates are as low as 1 in 1000. If 60 samples of a food are collected weekly, then 3,120 samples would be collected over the course of a year. Compositing these 3,120 samples into 375g analytical units would reduce the number of analytical tests to 208 (4 tests per week). If 30 samples are collected weekly, and composited, there would be 104 tests annually, or two each week. At the 1 in 1000 contamination rate there would be a greater than 95

Formatted: Right

percent confidence in seeing one or more positive tests during the year for testing composites from either 60 or 30 samples weekly. At higher rates of contamination, more positives would be detected.

There can be significant benefits to a facility testing finished products over time for process control. First, if a lot of product tests positive for a hazard, that lot of product can be disposed of such that the consumer is not exposed to the hazard (i.e., the product can be destroyed, reprocessed, or diverted to another use, as appropriate). If the testing involves enumeration of an indicator organism, it may even be possible to detect a trend toward loss of control before exceeding the criterion that separates acceptable from unacceptable. The process can be adjusted before there is a need to dispose of product. Second, the detection of loss of control, or potential loss of control, e.g., an unusual number of positives in a given period of time, allows a facility to evaluate and modify its processes, procedures, and food safety plan as appropriate to prevent loss of control in the future. In fact, the nature of the trends can provide information useful in determining the root cause of the problem (Ref. 222). A third benefit to ongoing verification testing is the accumulation of data that can help bracket any problem that occurs. For products in which there are large production runs without intervening sanitation cycles, this may provide data that can be used in conjunction with other information to limit the scope of a recall. A fourth benefit may be in detection of a problem associated with an ingredient supplier that results in changes to a supplier's processes, procedures, or food safety plan. For example, a positive in finished product due to routine verification testing was responsible for determining that hydrolyzed vegetable protein was contaminated with Salmonella spp., resulting in over 177 products being recalled (Ref. 24) and a recognition of the need for enhanced preventive controls for the production of this ingredient (Ref. 23). Industry commonly

Formatted: Right

uses finished product testing to verify preventive controls used by the facility and by the facility's suppliers. Additionally, it is common for customers to require suppliers to conduct testing of products and ingredients being provided.

G. Metrics for Microbiological Risk Management

Recently there has been much attention paid to microbiological risk management metrics for verifying that food safety systems achieve a specified level of public health control, e.g., the Appropriate Level of Protection (ALOP), for microbial hazards. Microbiological risk management metrics are fully discussed in Annex II of the Codex "Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)" (Ref. 245). These metrics include traditional metrics such as microbiological criteria, process criteria, and product criteria and emerging metrics such as food safety objectives (FSO), performance objectives and performance criteria. Of particular relevance are performance objectives and performance criteria. A performance objective is the maximum frequency and/or concentration of a microbiological hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable (Ref. 119). A performance criterion is the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective or an FSO (Ref. 119). FDA established a performance criterion (or performance standard) when we required that processors of juice products apply a control measure that will consistently produce, at a minimum, a 5-log reduction for the most resistant microorganism of public health significance (§ 120.24). Section 104 of FSMA (Performance Standards) requires the Secretary to determine the most significant foodborne contaminants and issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or

Formatted: Right

regulations for products or product classes. The proposed rule that is the subject of this document would not establish criteria or metrics for verifying that preventive controls in food safety plans achieve a specified level of public health control in this proposed rule. However, FDA will give consideration to appropriate microbiological risk management metrics in the future.

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

A food can become contaminated through the use of contaminated raw materials or ingredients. In the past several years, thousands of food products have been recalled as a result of contamination of raw materials or ingredients with pathogens such as Salmonella spp. and E. coli O157:H7. The ingredients included peanut-derived ingredients (Ref. 19) (Ref. 20), pistachio-derived ingredients (Ref. 152), instant nonfat dried milk, whey protein, fruit stabilizers (Ref. 21) Ref. 22) (Ref. 155) and hydrolyzed vegetable protein (Ref. 153).

The incident involving Salmonella spp. in hydrolyzed vegetable protein illustrates the impact one supplier can have on the food industry (Ref. 60). A receiving facility (manufacturer) detected Salmonella spp. in verification testing of finished product. In determining the source of the contamination, the manufacturer detected Salmonella spp. in samples of a hydrolyzed vegetable protein ingredient and reported the finding through FDA's RFR. After FDA determined that the ingredient was a reportable food, FDA requested that the supplier notify the immediate subsequent recipients of the reported hydrolyzed vegetable protein ingredient. Over one thousand reportable food reports were submitted to FDA from numerous companies concerning the potentially contaminated hydrolyzed vegetable protein or products made with the hydrolyzed vegetable protein. The hydrolyzed vegetable protein recall involved at least eleven different commodity categories and 177 products, showing the magnitude of this contamination event originating from one supplier (Ref. 60).

Formatted: Right

FDA recently reviewed CGMP-related food recall information from 2008-2009 to assess potential root causes for the contamination events. We determined that 36.9 percent of the 960 Class I and Class II recalls were directly linked to lack of supplier controls (Ref. 59). The recent large recalls of foods containing contaminated or potentially contaminated ingredients have focused attention on supplier approval and verification programs intended to help a manufacturer/processor prevent the introduction of a contaminated raw material or other ingredient into another product (Ref. 20) (Ref. 24) (Ref. 22). The application of preventive approaches by the entire supply chain (including ingredient vendors, brokers and other suppliers and, ultimately, the manufacturer of a food product) is recognized as essential to effective food safety management (Ref. 246).

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

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have

Formatted: Right

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 provides initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

Supplier approval and verification is widely accepted in the domestic and international food safety community. The NACMCF HACCP guidelines describe Supplier Control as one of the common prerequisite programs for the safe production of food products and recommend that each facility should ensure that its suppliers have in place effective GMP and food safety programs (Ref. 34). The American Spice Trade Association advocates that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. 247). 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. 246). 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

Formatted: Right

and/ or processing (Ref. 44). 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. 44).

Supplier verification activities include auditing a supplier to ensure the supplier is complying with applicable food safety requirements, such as CGMP requirements of current 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. 248). Other supplier verification activities include conducting testing or requiring supplier COAs, review of food safety plans and records, or combinations of activities such as audits and periodic testing.

An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requiring, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements (Ref. 248). There are many established third-party certification programs designed for various reasons that are currently being used by industry. Many third party audit schemes used to assess the industry's food safety management systems incorporate requirements for manufacturers and processors to establish supplier approval programs.

The GFSI was established in 2000 to drive continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide. Their objectives include reducing risk by delivering equivalence and convergence between

Formatted: Right

effective food safety management systems and managing cost in the global food system by eliminating redundancy and improving operational efficiency (Ref. 249). GFSI has developed a guidance document as a tool that fulfils the GFSI objectives of determining equivalency between food safety management systems (Ref. 249). The document is not a food safety standard, but rather specifies a process by which food safety schemes may gain recognition, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation) in relation to food safety (Ref. 249). This benchmark document has provisions relevant to supplier approval and verification programs. For example, it specifies that a food safety standard must require that the organization control purchasing processes to ensure that all externally sourced materials and services that have an effect on food safety conform to requirements. It also specifies that a food safety standard must require that the organization establish, implement, and maintain procedures for the evaluation, approval and continued monitoring of suppliers that have an effect on food safety. Thus, all current GFSI-recognized schemes require supplier controls to ensure that the raw materials and ingredients that have an impact on food safety conform to specified requirements. The GFSI guidance document also requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization's facility (Ref. 249).

Because GFSI is a document that outlines elements of a food safety management system for benchmarking a variety of standards, it does not have details about how facilities should comply with the elements. This type of information is found in the food safety schemes that are the basis for certification programs. For example, the Safe Quality Food (SQF) 2000 Code, a

Formatted: Right

HACCP-based supplier assurance code for the food industry, specifies that raw materials and services that impact on finished product safety be supplied by an Approved Supplier. SQF 2000 specifies that the responsibility and methods for selecting, evaluating, approving and monitoring an Approved Supplier be documented and implemented, and that a register of Approved Suppliers and records of inspections and audits of Approved Suppliers be maintained. SQF 2000 requires that the Approved Supplier Program contain, among other items, agreed specifications; methods for granting Approved Supplier status; methods and frequency of monitoring Approved Suppliers; and details of certificates of analysis if required.

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

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

III. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Formatted: Right

1. National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines," Journal of Food Protection, 61:1246-1259, 1998.

2. Codex Alimentarius Commission, "Principles for the Establishment and Application of Microbiological Criteria for Foods, CAC/GL 21 - 1997," 1997.

3. International Commission on Microbiological Specifications for Foods, "Microbiological Hazards and Their Control," In: Microorganisms in Foods 7. Microbiological Testing in Food Safety Management, edited by R. B. Tompkin, L. Gram, T. A. Roberts, R. L. Buchanan, M. van Schothorst, S. Dahms, and M. B. Cole, New York, Chapter 1, pp. 1-21, Kluwer Academic / Plenum Publishers, 2002.

4. International Commission on Microbiological Specifications for Foods, "Selection and Use of Acceptance Criteria," In: Microorganisms in Foods 7. Microbiological Testing in Food Safety Management, edited by R. B. Tompkin, L. Gram, T. A. Roberts, R. L. Buchanan, M. van Schothorst, S. Dahms, and M. B. Cole, New York, Chapter 4, pp. 79-97, Kluwer Academic / Plenum Publishers, 2002.

5. FDA, "Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-Derived Product as an Ingredient," 2009.

6. FDA, "Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Pistachio-Derived Product as an Ingredient," 2011.

7. CDC, "General Information. Escherichia coli (E. coli)," (http://www.cdc.gov/ecoli/general/index.html), July 17, 2012. Accessed and printed on July 27, 2012.

Formatted: Right

8. Scott, V. N., C. Yuhuan, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. Smoot, S. Hood, J. Shebuski, and J. Banks, "Control of Salmonella in Low-Moisture Foods I: Minimizing Entry of Salmonella into a Processing Facility," Food Protection Trends, 29:342-353, 2009.

9. Chen, Y., V. N. Scott, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. Smoot, S. Hood, J. Shebuski, and J. Banks, "Control of Salmonella in Low-Moisture Foods II: Hygiene Practices to Minimize Salmonella Contamination and Growth," Food Protection Trends, 29:435-445, 2009.

10. California Department of Public Health, "Union International Food Company Recall Widened Again," (http://www.cdph.ca.gov/Pages/NR2009-23.aspx), April 4, 2009. Accessed and printed on September 6, 2011.

11. Gabis, D. A., R. S. Flowers, D. Evanson, and R. E. Faust, "A Survey of 18 Dry Product Processing Plant Environments for Salmonella, Listeria and Yersinia," Journal of Food Protection, 52:122-124, 1989.

12. Vij, V., E. Ailes, C. Wolyniak, F. J. Angulo, and K. C. Klontz, "Recalls of Spices Due to Bacterial Contamination Monitored by the U.S. Food and Drug Administration: The Predominance of Salmonellae," Journal of Food Protection, 69:233-237, 2006.

13. FDA, "FDA Foods Program, The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration. First Annual Report: September 8, 2009 - September 7, 2010," (http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM240647.pdf), January, 2011. Accessed and printed on August 29, 2011.

Formatted: Right

14. FDA and USDA, "Listeria monocytogenes Risk Assessment: VII. Interpretation and Conclusions," (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm185289.htm), September, 2003. Accessed and printed on October 17, 2011.

15. Food and Agriculture Organization and World Health Organization, "Risk Assessment of Listeria monocytogenes in Ready-to-Eat Foods, Technical Report," 2004.

16. International Commission on Microbiological Specifications for Foods, "Sampling to Assess Control of the Environment," In: Microorganisms in Foods 7. Microbiological Testing in Food Safety Management, edited by R. B. Tompkin, L. Gram, T. A. Roberts, R. L. Buchanan, M. van Schothorst, S. Dahms, and M. B. Cole, New York, Chapter 11, pp. 199-224, Kluwer Academic / Plenum Publishers, 2002.

17. Tompkin, R. B., V. N. Scott, D. T. Bernard, W. H. Sveum, and K. Sullivan Gombas, "Guidelines to Prevent Post-Processing Contamination from Listeria monocytogenes," Dairy, Food and Environmental Sanitation, 19:551-562, 1999.

18. Tompkin, R. B., "Control of Listeria monocytogenes in the Food-Processing Environment," Journal of Food Protection, 65:709-725, 2002.

19. Carpentier, B. and O. Cerf, "Review: Persistence of Listeria monocytogenes in Food Industry Equipment and Premises," International Journal of Food Microbiology, 145:1-8, 2011.

20. Breuer, T., "CDC Investigations: The May 1998 Outbreak of Salmonella Agona Linked to Cereal," Cereal Foods World, 44:185-186, 1999.

21. CDC, "EPI-AID 98-60 Trip-Report: Multistate Outbreak of Salmonella Agona Infection Linked to Consumption of Oat Cereal, April-June 1997," 1999.

Formatted: Right

22. CDC, "Foodborne Outbreak Online Database (FOOD). Search Results Highlighted for 1998 Salmonella Agona Outbreak in Dry Cereal," 2011. Accessed and printed on October 21, 2011.

23. CDC, "Investigation of Outbreak of Infections Caused by Salmonella Agona," (http://www.cdc.gov/salmonella/agona/), May 13, 2008. Accessed and printed on September 9, 2011.

24. CDC, "Foodborne Outbreak Online Database (FOOD). Search Results Highlighted for 2006-2007 Salmonella Tennessee Outbreak in Peanut Butter.," 2011. Accessed and printed on October 18, 2011.

25. CDC, "Multistate Outbreak of Salmonella Serotype Tennessee Infections Associated with Peanut Butter - United States, 2006-2007," MMWR, 56:521-524, 2007.

26. FDA, "Peanut Products Recall," (http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Peanut/default.htm), June 18, 2009. Accessed and printed on September 9, 2011.

27. FDA, "Hydrolyzed Vegetable Protein Product Recalls," (http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/default.htm), December 21, 2011. Accessed and printed on July 27, 2012.

28. CDC, "Multistate Outbreak of Salmonella Infections Associated with Peanut Butter and Peanut Butter-Containing Products - United States, 2008-2009," MMWR, 58:85-90, 2009.

29. Cavallaro, E., K. Date, C. Medus, S. Meyer, B. Miller, C. Kim, S. Nowicki, S. Cosgrove, D. Sweat, P. Quyen, J. Flint, E. R. Daly, J. Adams, E. Hyytia-Trees, P. Gerner-Smidt, R. M. Hoekstra, C. Schwensohn, A. Langer, S. V. Sodha, M. C. Rogers, F. J. Angulo, R. V.

Formatted: Right

Tauxe, I. T. Williams, and C. Barton Behravesh, "Salmonella Typhimurium Infections Associated with Peanut Products," New England Journal of Medicine, 365:601-610, 2011.

30. FDA, "Amended Form 483 (Inspectional Observations) for Peanut Corporation of America, Blakely, GA, 02/05/2009," (http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM109834.pdf), February 5, 2009. Accessed and printed on October 19, 2011.

31. FDA, "Form 483 (Inspectional Observations) for Peanut Corporation of America, Plainview, TX, 02/26/2009," (http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM114852.pdf), February 26, 2009. Accessed and printed on October 17, 2011.

32. CDC, "Foodborne Outbreak Online Database (FOOD). Search Results Highlighted for 2008 Salmonella Typhimurium Outbreak in Peanut Butter and Peanut Paste," 2011. Accessed and printed on November 23, 2011.

33. FDA, "Company Recalls Various Products Due to Potential Salmonella Contamination. FDA, USDA, CDC Investigating; No Link to Human Illnesses at This Time," (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm169471.htm), June 28, 2009. Accessed and printed on September 9, 2011.

34. FDA, "FDA Form 483 (Inspectional Observations) for Plainview Milk Products Cooperative," (http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM173030.pdf), July 15, 2009. Accessed and printed on September 9, 2011.

Formatted: Right

35. FDA, "Peanut Butter and Other Peanut Containing Products Recall List," (http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm), October 28, 2009. Accessed and printed on September 9, 2011.

36. Jackson, K. A., M. Biggerstaff, M. Tobin-D'Angelo, D. Sweat, R. Klos, J. Nosari, O. Garrison, E. Boothe, L. Saathoff-Huber, L. Hainstock, and R. P. Fagan, "Multistate Outbreak of Listeria monocytogenes Associated with Mexican-Style Cheese Made from Pasteurized Milk Among Pregnant, Hispanic Women," Journal of Food Protection, 74:949-953, 2011.

37. Texas Department of State Health Services, "DSHS Orders Sangar Produce to Close, Recall Products," (http://www.dshs.state.tx.us/news/releases/20101020.shtm), October 20, 2010. Accessed and printed on September 9, 2011.

38. FDA, "FDA Form 483 (Inspectional Observations) for Sangar Fresh Cut Produce Co., LLC," (http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM232412.pdf), October 26, 2010. Accessed and printed on September 9, 2011.

39. FDA, "FDA Lab Results Positive for Listeria at SanGar Fresh Produce," (http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/ucm232237.htm), November 3, 2010. Accessed and printed on September 9, 2011.

40. FDA, "Information on the Recalled Jensen Farms Whole Cantaloupes," (http://www.fda.gov/Food/FoodSafety/CORENetwork/ucm272372.htm), January 9, 2012. Accessed and printed on July 19, 2012.

Formatted: Right

41. CDC, "Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado," (http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/), December 8, 2011. Accessed and printed on July 27, 2012.

42. FDA and USDA, "Listeria monocytogenes Risk Assessment: II. Hazard Identification," (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183981.htm), September, 2003. Accessed and printed on October 20, 2011.

43. Lyytikäinen, O., T. Autio, R. Maijala, P. Ruutu, T. Honkanen-Buzalski, M. Miettinen, M. Hatakka, J. Mikkola, V. J. Anttila, T. Johansson, L. Rantala, T. Aalto, H. Korkeala, and A. Siitonen, "An Outbreak of Listeria monocytogenes Serotype 3a Infections from Butter in Finland," Journal of Infectious Diseases, 181:1838-1841, 2000.

44. Fretz, R., J. Pichler, U. Sagel, P. Much, W. Ruppitsch, A. T. Pietzka, A. Stoeger, S. Huhulescu, S. Heuberger, G. Appl, D. Werber, K. Stark, R. Prager, A. Flieger, R. Karpiskova, G. Pfaff, and F. Allerberger, "Update: Multinational Listeriosis Outbreak Due to "Quargel", a Sour Milk Curd Cheese, Caused by Two Different L. Monocytogenes Serotype 1/2a Strains, 2009-2010," Eurosurveillance, 15:2, 2010.

45. FDA, "River Ranch Recalls Products Because of Possible Health Risk," (http://www.fda.gov/Safety/Recalls/ucm275854.htm), October 13, 2011. Accessed and printed on October 26, 2011.

46. FDA, "Taylor Farms Retail Inc. Initiates a Precautionary Recall Because of Possible Health Risk," (http://www.fda.gov/Safety/Recalls/ucm276459.htm), October 19, 2011. Accessed and printed on October 20, 2011.

Formatted: Right

47. FDA, "Del Bueno Recalls Queso Fresco Casero Cheese Because of Possible Health Risk," (http://www.fda.gov/Safety/Recalls/ucm272268.htm), September 16, 2010. Accessed and printed on October 26, 2011.

48. FDA, "Fine Mexican Food Products, Inc. Recalls 2.2 lb. Frozen Avocado Pulp & 3 lb. IQF Avocado Halves from Peru Because of Possible Health Risk," (http://www.fda.gov/Safety/Recalls/ucm271686.htm), September 13, 2011. Accessed and printed on November 23, 2011.

49. Cox, L. J., T. Kleiss, J. L. Cordier, C. Cordellana, P. Konkel, C. Pedrazzini, R. Beumer, and A. Siebenga, "Listeria spp. in Food Processing, Non-Food and Domestic Environments," Food Microbiology, 6:49-61, 1989.

50. Nelson, J. H., "Where Are Listeria Likely to be Found in Dairy Plants?" Dairy, Food and Environmental Sanitation, 10:344-345, 1990.

51. Pritchard, T. J., K. J. Flanders, and C. W. Donnelly, "Comparison of the Incidence of Listeria on Equipment Versus Environmental Sites Within Dairy Processing Plants," International Journal of Food Microbiology, 26:375-384, 1995.

52. Miettinen, M. K., K. J. Bjorkroth, and H. J. Korkeala, "Characterization of Listeria monocytogenes from an Ice Cream Plant by Serotyping and Pulsed-Field Gel Electrophoresis," International Journal of Food Microbiology, 46:187-192, 1999.

53. Pourshaban, M., M. Gianfranceschi, A. Gattuso, F. Menconi, and P. Aureli, "Identification of Listeria monocytogenes Contamination Sources in Two Fresh Sauce Production Plants by Pulsed-Field Gel Electrophoresis," Food Microbiology, 17:393-400, 2000.

54. Blatter, S., N. Giezendanner, R. Stephan, and C. Zweifel, "Phenotypic and Molecular Typing of Listeria monocytogenes Isolated from the Processing Environment and Products of a Sandwich-Producing Plant," Food Control, 21:1519-1523, 2010.

55. Pappelbaum, K., K. Grif, I. Heller, R. Wuerzner, I. Hein, L. Ellerbroek, and M. Wagner, "Monitoring Hygiene On- and At-Line Is Critical for Controlling Listeria monocytogenes During Produce Processing," Journal of Food Protection, 71:735-741, 2008.

56. Aguado, V., A. I. Vitas, and I. Garcia-Jalon, "Characterization of Listeria monocytogenes and Listeria innocua from a Vegetable Processing Plant by RAPD and REA," International Journal of Food Microbiology, 90:341-347, 2004.

57. Codex Alimentarius Commission, "Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods, CAC/GL 61 - 2007," 2007.

58. Scott, V. N., M. Wiedmann, D. Hicks, R. Collette, M. L. Jahncke, and K. Gall, "Guidelines for Listeria Testing of Environmental, Raw Product and Finished Product Samples in Smoked Seafood Processing Facilities," Food Protection Trends, 25:23-34, 2005.

59. Chen, Y., V. N. Scott, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. Smoot, S. Hood, J. Shebuski, and J. Banks, "Control of Salmonella in Low-Moisture Foods III: Process Validation and Environmental Monitoring," Food Protection Trends, 29:493-508, 2009.

60. Jarl, D. L. and E. A. Arnold, "Influence of Drying Plant Environment on Salmonellae Contamination of Dry Milk Products," Journal of Food Protection, 45:16, 1982.

61. Buchanan, R. L., "Acquisition of Microbiological Data to Enhance Food Safety," Journal of Food Protection, 63:832-838, 2000.

Formatted: Right

Formatted: Right

62. National Advisory Committee on Microbiological Criteria for Foods, "Response to the Questions Posed by FSIS Regarding Performance Standards with Particular Reference to Ground Beef Products," (http://www.fsis.usda.gov/OPHS/NACMCF/2002/rep_stand2.pdf), October 8, 2002. Accessed and printed on September 12, 2011.

63. Evancho, G. M., W. H. Sveum, L. J. Moberg, and J. F. Frank, "Microbiological Monitoring of the Food Processing Environment," In: Compendium of Methods for the Microbiological Examination of Foods, edited by F. P. Downes and K. Ito, 4th edition, Washington, D.C., Chapter 3, pp. 25-35, American Public Health Association, 2001.

64. FSIS, "FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products," 2012.

65. Kraft Foods, "Re: Docket No. 2007D-0494; Draft Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods; Availability," 2008.

66. Kraft Foods, "Appendix, Comments on the FDA Guidance for Industry, Control of Listeria monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods," 2008.

67. Grocery Manufacturers Association, "Re: Docket No. 2007-D-0494: Draft Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods; Availability," 2008.

68. Alliance for Listeriosis Prevention, "Re: Docket No. 2007-D-0494: Draft Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods; Availability," 2008.

69. CGMP Coalition, "Re: Docket No. 2004N-0230; Food, Current Good Manufacturing Practice Regulations," 2006.

70. European Food Safety Authority, "Scientific Opinion of BIOHAZ Panel on the Request from the Commission for Review of the Opinion on Microbiological Risks in Infant Formulae and Follow-on Formulae with Regard to Enterobacteriaceae As Indicators," The EFSA Journal, 444:1-14, 2007.

71. International Commission on Microbiological Specifications for Foods, "Drying Foods for Infants and Young Children," In: Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance, edited by K. M. J. Swanson, R. L. Buchanan, M. B. Cole, J.-L. Cordier, R. S. Flowers, L. G. M. Gorris, M. H. Taniwaki, and R. B. Tompkin, New York, Chapter 25, pp. 339-348, Springer, 2011.

72. International Commission on Microbiological Specifications for Foods, "Cereal and Cereal Products," In: Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance, edited by K. M. J. Swanson, R. L. Buchanan, M. B. Cole, J.-L. Cordier, R. S. Flowers, L. G. M. Gorris, M. H. Taniwaki, and R. B. Tompkin, New York, Chapter 15, pp. 218-219, Springer, 2011.

73. International Commission on Microbiological Specifications for Foods, "Spice, Dry Soups and Asian Flavorings," In: Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance, edited by K. M. J. Swanson, R. L. Buchanan, M. B. Cole, J.-L. Cordier, R. S. Flowers, L. G. M. Gorris, M. H. Taniwaki, and R. B. Tompkin, New York, Chapter 14, pp. 199, Springer, 2011.

74. International Commission on Microbiological Specifications for Foods, "Cereal and Cereal Products," In: Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance, edited by K. M. J. Swanson, R. L. Buchanan, M. B. Cole, J.-L. Cordier,

Formatted: Right

Formatted: Right

R. S. Flowers, L. G. M. Gorris, M. H. Taniwaki, and R. B. Tompkin, New York, Chapter 15, pp. 216, Springer, 2011.

75. International Commission on Microbiological Specifications for Foods, "Nuts, Oilseeds, Dried Legumes and Coffee," In: Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance, edited by K. M. J. Swanson, R. L. Buchanan, M. B. Cole, J.-L. Cordier, R. S. Flowers, L. G. M. Gorris, M. H. Taniwaki, and R. B. Tompkin, New York, Chapter 16, pp. 230, Springer, 2011.

76. International Commission on Microbiological Specifications for Foods, "Cocoa, Chocolate and Confectionery," In: Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance, edited by K. M. J. Swanson, R. L. Buchanan, M. B. Cole, J.-L. Cordier, R. S. Flowers, L. G. M. Gorris, M. H. Taniwaki, and R. B. Tompkin, New York, Chapter 17, pp. 241-246, Springer, 2011.

77. International Commission on Microbiological Specifications for Foods, "Milk and Dairy Products," In: Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance, edited by K. M. J. Swanson, R. L. Buchanan, M. B. Cole, J.-L. Cordier, R. S. Flowers, L. G. M. Gorris, M. H. Taniwaki, and R. B. Tompkin, New York, Chapter 23, pp. 315, Springer, 2011.

78. Proudy, I., D. Bougle, R. Leclercq, and M. Vergnaud, "Tracing of Enterobacter sakazakii Isolates in Infant Milk Formula Processing by BOX-PCR Genotyping," Journal of Applied Microbiology, 105:550-558, 2008.

79. Mullane, N. R., P. Whyte, P. G. Wall, T. Quinn, and S. Fanning, "Application of Pulsed-Field Gel Electrophoresis to Characterise and Trace the Prevalence of Enterobacter

sakazakii in an Infant Formula Processing Facility," International Journal of Food Microbiology, 116:73-81, 2007.

80. International Commission on Microbiological Specifications for Foods, "Establishment of Microbiologial Criteria for Lot Acceptance," In: Microorganisms in Foods 7. Microbiological Testing in Food Safety Management, edited by R. B. Tompkin, L. Gram, T. A. Roberts, R. L. Buchanan, M. van Schothorst, S. Dahms, and M. B. Cole, New York, Chapter 5, pp. 99-112, Kluwer Academic / Plenum Publishers, 2002.

81. FDA, "Investigations Operations Manual (IOM)," 2011.

82. FDA, "Bacteriological Analytical Manual, 8th Edition, Revision A, 1998," 1998.

83. FDA, "Bacteriological Analytical Manual (BAM), Chapter 1. Food Sampling and Preparation of Sample Homogenate," 2003.

84. FDA, "Recall: Products Containing Hydrolyzed Vegetable Protein," (http://www.accessdata.fda.gov/scripts/HVPCP/), April 1, 2010. Accessed and printed on September 9, 2011.

85. Codex Alimentarius Commission, "Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM), CAC/GL 63-2007," 2007.

86. Codex Alimentarius Commission, "Codex Alimentarius Commission Procedural Manual, Twentieth Edition," 2011.

87. FDA, "Pistachios and Other Pistachio Containing Products Recall List," (http://www.accessdata.fda.gov/scripts/pistachiorecall/index.cfm), June 23, 2009. Accessed and printed on September 9, 2011.

Formatted: Right

88. FDA, "Plainview Milk Cooperative Ingredient Recall," (http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Milk/default.htm), July 23, 2009. Accessed and printed on September 9, 2011.

89. FDA, "Plainview Milk Cooperative Ingredient Recall Product List," (http://www.accessdata.fda.gov/scripts/Milk/), July 28, 2009. Accessed and printed on September 9, 2011.

90. FDA, "For Consumers: The HVP Recall (Updated)," (http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm202989.htm), March 24, 2010. Accessed and printed on October 14, 2011.

91. FDA Memorandum, "Analysis of Food Recalls Initiated in 2008-2009 by an FDA CGMP Working Group," 2012.

92. Grocery Manufacturers Association, "Food Supply Chain Handbook," 2008.

93. American Spice Trade Association, "Clean, Safe Spices," 2011.

94. Codex Alimentarius Commission, "General Principles of Food Hygiene, CAC/RCP 1-1969 (Rev. 4-2003)," 2003.

95. FDA, "Guidance for Industry - Voluntary Third-Party Certification Programs for Foods and Feeds," 2009.

96. Global Food Safety Initiative, "GFSI Guidance Document, Version 6.1," (http://www.mygfsi.com/gfsifiles/Guidance_Document_Sixth_Edition_Version_6.1.pdf), August, 2011. Accessed and printed on October 17, 2011.

Formatted: Right

Formatted: FR Preamble Para Indent First Line 0.5 inch