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

A. Proposed § 117.126--Requirement for a Food Safety Plan

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

Section 418(h) of the FD&C Act requires that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act to address those hazards. Section 418(h) of the FD&C Act also requires that such written plan, together with the documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 117.126(a)--Requirement for a Food Safety Plan

Proposed § 117.126(a) would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, and implement a written food safety plan. We use the term "written food safety plan" in proposed § 117.126(a) to mean the "written plan" referred to in section 418(h) of the FD&C Act. To make clear that the written plan is related to food safety rather than to other plans a facility may have (such as quality control plans or food defense plans), we have designated the "written plan" to be a "food safety plan."

Proposed § 117.126(a) would require that the plan be written as is expressly required by section 418(h). A written food safety plan is essential for the facility to implement the plan consistently, train its employees, and periodically reanalyze and update the plan. It is also essential to a facility's food safety team, to auditors, and to inspectors. Proposed § 117.126(a)

Style Definition: FR Preamble Bullets 1st Level: Indent: Left: 0", Tab stops: 1", Left + Not at 0.54"

Style Definition: FR Preamble Bullets 2nd Level: Indent: Left: 0", Tab stops: 1", Left + Not at 0.54"

Style Definition: FR Preamble Bullets 3rd Level: Indent: Left: 1.25", No bullets or numbering, Tab stops: 1", Left + Not at 1.55"

Deleted: Subpart C--

Deleted: ¶ A.

Deleted: § 110

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: :¶ "The

Deleted: [

Deleted:],

Deleted: [

Deleted:]

Deleted: [

Deleted:]

Deleted: " and ¶ "Such

Deleted: [

Deleted:],

Deleted: ."

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

would implement section 418(h) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The recordkeeping provisions of the NACMCF HACCP guidelines recommend that the HACCP plan include a list of the HACCP team and assigned responsibilities; a description of the food, its distribution, intended use, and consumer; a verified flow diagram; a HACCP Plan Summary Table that includes information for steps in the process that are CCPs, the hazard(s) of concern, critical limits, monitoring, corrective actions, verification procedures and schedule, and record-keeping procedures (Ref. 34). The Codex HACCP Annex recommends that HACCP procedures be documented, including the hazard analysis, and determinations of CCPs and critical limits (Ref. 35). Federal HACCP regulations for seafood, juice, and meat and poultry require a written plan (§§ 123.6(b)) and 120.8(a) and 9 CFR 417.2(b), respectively).

Proposed § 117.126(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf. This flexibility is consistent with the NACMCF HACCP guidelines (Ref. 34), which advise that a HACCP team may need assistance from outside experts who are knowledgeable in the hazards associated with the product and the process. This flexibility also is consistent with the Codex HACCP Annex, which acknowledges that small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan and recommends that expert advice be obtained when necessary from other sources, such as trade and industry associations, independent experts and regulatory authorities. In addition, proposed § 117.126 would provide flexibility for facilities in the development of their food safety plans by allowing

Deleted: NACMCF, 1998

Deleted: Codex 2003

Deleted: 110

Deleted: NACMCF, 1998

Deleted: 110

facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical.

Proposed § 117.126(a) would require that the owner, operator, or agent in charge of a facility implement the written food safety plan. Although section 418(h) of the FD&C Act is silent with respect to implementation of the required written plan, other provisions of section 418 address implementation. For example, section 418(c) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility both establish and implement preventive controls (emphasis added). In addition, other provisions of section 418 (e.g., section 418(d) regarding monitoring, section 418(e) regarding corrective actions, and section 418(f) regarding verification) all establish requirements related to the preventive controls required under section 418(c). As discussed immediately below, the written food safety plan would include the hazard analysis required under section 418(b) of the FD&C Act, the preventive controls required under section 418(c) of the FD&C Act, the monitoring procedures required under section 418(d) of the FD&C Act, the corrective action procedures required under section 418(e) of the FD&C Act, the verification procedures required under section 418(f) of the FD&C Act, and the recall plan as authorized by section 418(o)(3)(E) of the FD&C Act. Specific provisions for implementing these sections of the statute would be established throughout proposed subpart C.

3. Proposed § 117.126(b)--Contents of a Food Safety Plan

Proposed § 117.126(b)(1) through (6) would require that the contents of a food safety plan include:

- The written hazard analysis as required by proposed § 117.130(a)(2);
- The written preventive controls as required by proposed § 117.135(b);

Deleted: 110

Deleted: , and the procedures for supplier approval and verification as authorized by section 418(o)(3)(G).

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 7

Deleted: 110

Deleted: 110

- The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by proposed § 117.140(a);
- The written corrective action procedures as required by proposed § 117.145(a)(1);
- The written verification procedures as required by proposed § 117.150(e); and
- The written recall plan as required by § 117.137(a).

Section 418(h) requires that the written plan document and describe the procedures used by the facility to comply with the requirements of section 418, "including analyzing the hazards under [section 418(b) of the FD&C Act] and identifying the preventive controls adopted under [section 418(c) of the FD&C Act] to address those hazards" (emphasis added). Although section 418(h) of the FD&C Act explicitly references sections 418(b) and (c), the term "including," indicates that the contents of a food safety plan need not be limited to the provisions of sections 418(b) and (c) of the FD&C Act.

FDA interprets the requirement in section 418(h) of the FD&C Act that the written plan document and describe the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act to mean that the written food safety plan would include all procedures required under section 418 of the FD&C Act. As discussed in sections XII.E.6.a, XII.F.2, XII.G.6, and XII.D.2 of this document, the proposed rule would require written procedures for monitoring the implementation of the preventive controls (proposed § 117.140(a)); written corrective action procedures (proposed § 117.145(a)(1)); written procedures for some verification activities (proposed § 117.150(e)); and a written recall plan (proposed § 117.137(a)).

Deleted: 110

Deleted: 110

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

Deleted: 110

Deleted: a);

Deleted: 110

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

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: XII.D.2,

Deleted: H

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

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

FDA interprets the requirement in section 418(h) that the written plan describe the procedures used by the facility to comply with the requirements of section 418, including analyzing the hazards and identifying the preventive controls adopted to address those hazards, to mean that the contents of the food safety plan must include the hazard analysis conducted by the facility and the preventive controls that a facility must establish for hazards that its hazard analysis identifies as reasonably likely to occur, rather than procedures for analyzing the hazards and procedures for identifying the preventive controls. The general requirement in section 418(a) of the act is directed, in relevant part, to evaluating the hazards that could affect food manufactured, processed, packed, or held by a facility, and identifying and implementing preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Review of the evaluation of hazards in the hazard analysis is sufficient to determine the adequacy of the hazard analysis. Written procedures for conducting the hazard analysis are not necessary. Similarly, the preventive controls identified by the facility can be reviewed fully for adequacy without having a separate procedures document.

Under our interpretation of section 418(h) of the FD&C Act, proposed § 117.126(b)(1) and (2) are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that a HACCP plan include the hazards of concern (which are the end product of the hazard analysis), the CCPs (which are the steps at which control can be applied and which are essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level), and critical limits (which are the maximum or minimum values established at a CCP to

Deleted: 110

control a hazard) (Ref. 34). The Codex HACCP Annex (Ref. 35) recommends that the HACCP plan include documentation of the hazard analysis and determinations of CCPs and critical limits. Federal HACCP regulations for seafood, juice, and meat and poultry all require that the HACCP plan list the food [safety] hazards that are reasonably likely to occur (§§ 123.6(c)(1) and 120.8(b)(1) and 9 CFR 417.2(c)(1), respectively), the CCPs (§§ 123.6(c)(2) and 120.8(b)(2) and 9 CFR 417.2(c)(2), respectively), and critical limits (§§ 123.6(c)(3) and 120.8(b)(3) and 9 CFR 417.2(c)(3), respectively). The FSIS HACCP regulation for meat and poultry further requires that the written hazard analysis be maintained as part of the documentation for the establishment's HACCP plan (9 CFR 417.5(a)(1)). None of these documents recommends or requires that the HACCP plan include the procedures for analyzing the hazards or procedures for identifying the CCPs and critical limits. Rather, these documents are clear that it is the outcomes rather than the procedures for conducting the hazard analysis and identifying the preventive controls that are part of the plan.

4. Proposed § 117.126(c)--Preparation of the Food Safety Plan by a Qualified Individual

Proposed § 117.126(c) would require that the food safety plan be prepared by (or its preparation overseen by) a qualified individual. (See the discussion in section XII.H of this document regarding the qualifications of a qualified individual as would be established in proposed § 117.155(b)). Section 418 of the FD&C Act requires that firms identify and implement preventive controls and that facilities monitor and verify the effectiveness of the preventive controls. A qualified individual must develop the food safety plan in order to ensure the preventive controls are effective. The plan must be designed to identify and to significantly minimize or prevent hazards in order to prevent illness or injury. Designing a plan requires an individual who is knowledgeable in the concepts of preventive controls, the hazards associated

Deleted: NACMCF, 1998

Deleted: Codex 2003

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: I

Deleted: 110

with a product and process, the appropriate preventive controls, with associated monitoring and corrective actions for those hazards, and appropriate verification activities for the applicable preventive controls. Such knowledge requires scientific and technical expertise developed through training, experience, or both.

Section 418 of the FD&C Act does not address the qualifications of the individual who would prepare the food safety plan. However, proposed § 117.126(c) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that, because of the technical nature required for the hazard analysis, experts who are knowledgeable in the food process either participate in or verify the hazard analysis and the HACCP plan (Ref. 34). Our HACCP regulations for seafood and juice require that the individual developing the HACCP plan complete training in the application of HACCP principles to juice or seafood processing under a standardized curriculum or be qualified through job experience that provides knowledge at least equivalent to that provided through the standardized curriculum (§§ 123.10 and 120.13, respectively). The FSIS HACCP regulation for meat and poultry requires that the individual developing the HACCP plan complete training in the application of HACCP principles to meat or poultry product processing (9 CFR 417.7).

One way to comply with proposed § 117.126(c) could be for a team of individuals (for example, a "HACCP team" or a "food safety team") to develop the food safety plan under the oversight of a qualified individual. Each member of a HACCP or food safety team generally brings specific expertise important in developing the plan. For example, a microbiologist could provide knowledge of microbial hazards, an engineer could establish the critical parameters for delivery of heat treatments, and a maintenance supervisor could identify sources of metal

Deleted: 110

Deleted: NACMCF, 1998

Deleted: 110

contamination. Proposed § 117.126 would not require that all such members of a food safety team satisfy the requirements in proposed § 117.126(c) for a qualified individual. However, under proposed § 117.126(c), a qualified individual must be responsible for ensuring that all components the food safety plan have been developed, including reviewing all information contained in the food safety plan, thereby verifying the hazard analysis and food safety plan developed by the food safety team.

5. Facility-Based Nature of the Written Food Safety Plan

The overall framework of section 418 of the FD&C Act is directed to a facility rather than, for example, a corporate entity that may have multiple facilities. For example, under section 418(b) of the FD&C Act the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility (emphasis added). Thus, proposed § 117.126 establishes a requirement for every facility to have its own written food safety plan. The facility-based nature of the written food safety plan that would be required by proposed § 117.126 is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines emphasize that it is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan (Ref. 34). The Codex HACCP Annex states that HACCP should be applied to each specific operation separately (Ref. 35). Federal HACCP regulations for seafood, juice, and meat and poultry require that HACCP plans be specific to each location where the product is processed (§§ 123.6(b)(1) and 120.8(a)(1) for seafood and juice, respectively) or to "every official establishment" (9 CFR 417.2(a)) for meat and poultry).

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: NACMCF, 1998

Deleted: Codex 2003

Federal HACCP regulations for seafood, juice, and meat and poultry allow the HACCP plan to group food types or production method types if the hazards, critical control points, critical limits and required procedures such as monitoring are essentially identical, provided that any required features of the plan that are unique to a specific product or production method are clearly delineated in the plan and are observed in practice (§§ 123.6(b)(2) and 120.8(a)(2) and 9 CFR 417.2(b)(2) for seafood, juice, and meat and poultry, respectively). This type of grouping would be allowed under proposed § 117.126 and, thus, would provide flexibility for facilities in the development of their HACCP plans.

B. Proposed § 117.130--Hazard Analysis

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

Section 418(b)(1) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including (A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and (B) hazards that occur naturally, or may be unintentionally introduced. Section 418(b)(3) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall develop a written analysis of the hazards.

As discussed in section II.B.2.f of this document, this rulemaking is not intended to address "hazards that may be intentionally introduced, including by acts of terrorism." Therefore, we are not implementing section 418(b)(2) of the FD&C Act in this proposed rule.

Section 418(c)(1) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points,

Deleted: 110

Deleted: 110

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: :¶
"(1)

Deleted: "¶
"(

Deleted: "

Deleted: <#>"(B) hazards that occur naturally, or may be unintentionally introduced" ¶
<#>"(3) develop a written analysis of the hazards."¶

Deleted: "[t]he

if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(3) of the FD&C Act specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Sections 418(c)(1) and (c)(3) of the FD&C Act, which we will address more fully in section XII.C.1 of this document, are relevant to our discussion of proposed § 117.130(a) regarding the purpose of the hazard analysis required by section 418(b) of the FD&C Act.

2. Proposed § 117.130(a) –Hazard Analysis

a. Proposed § 117.130(a)(1)--Requirement to identify and evaluate hazards. Proposed § 117.130(a)(1) would require that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards, for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. As discussed more fully in the remainder of this section, proposed § 117.130(a)(1) would implement section 418(b)(1) of the FD&C Act.

Proposed § 117.130(a)(1) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines describe a two-stage process for conducting a hazard analysis (Ref. 34), i.e., hazard identification and hazard evaluation. Hazard identification has been described as a brainstorming session designed to facilitate the development of a list of potential hazards, including those known to be associated with a type of food or process and those known to have occurred in a particular facility, for consideration during the hazard evaluation step (Ref. 143). Hazard evaluation is conducted after development of the list of

Deleted: ” that:

Deleted: <#>“(1) hazards identified in the hazard analysis conducted under [section 418(b)(1) of the FD&C Act] will be significantly minimized or prevented;” and ¶
<#>“(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under [section 402 of the FD&C Act] or misbranded under [section 403(w) of the FD&C Act].” ¶

Deleted: 6

Deleted: 110

Formatted: Level 1

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: NACMCF, 1998

Deleted: Bernard et al, GMA HACCP Ch 8).

potential hazards associated with each step in the product's process. The Codex HACCP Annex recommends that the HACCP team list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption and then conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food (Ref. 35). Our HACCP regulation for juice requires that a hazard analysis both identify hazards and evaluate whether they are reasonably likely to occur (§§ 120.7(a)(1) and (2)). Federal HACCP regulations for seafood and meat and poultry require that a processor or establishment conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur (§ 123.6(a) and 9 CFR 417.2(a)).

Deleted: .

Deleted:

In considering the proposed requirement for a hazard analysis, we considered the language of section 418(b)(1) of the FD&C Act describing the hazards that a facility would identify and evaluate – i.e., "known or reasonably foreseeable hazards that may be associated with the facility." We consider that the "known or reasonably foreseeable hazards" in section 418(b) of the FD&C Act are analogous to the "potential hazards" discussed in the NACMCF HACCP guidelines, and the hazards that are required to be identified to determine if they are "hazards that may be reasonably expected to occur at each step" in the Codex HACCP Annex, or "reasonably likely to occur" in Federal HACCP regulations for seafood, juice, and meat and poultry.

Proposed § 117.130(a)(1) would establish the requirement to identify and evaluate hazards by conducting a hazard analysis; we propose specific requirements for the hazard identification in proposed § 117.130(b) (see section XII.B.3 of this document) and specific

Deleted: 110

Deleted: 110

requirements for the hazard evaluation in proposed § 117.130(c) (see section XII.B.4 of this document).

Proposed § 117.130(a)(1) would require that the identification and evaluation of hazards be done "for each type of food manufactured, processed, packed, or held at the facility." In considering the proposed requirement for a hazard analysis, we considered the language of section 418(b)(1) of the FD&C Act. The purpose of sections 418(b)(1) appears clear – i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards that may be associated with the food produced by the facility. The known or reasonably foreseeable hazards associated with the facility's food may differ based on the type of food and, thus, the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry all apply a hazard analysis to each type of food manufactured, processed, packed, or held at the facility. Proposed § 117.130(a) would do likewise.

The NACMCF HACCP guidelines (Ref. 34) and Codex HACCP Annex (Ref. 35) describe several preliminary tasks that need to be accomplished before application of the HACCP principles to a specific product and process, including describing the food and its distribution, describing the intended use and consumers of the food, and developing a flow diagram for the process. Our HACCP regulations for seafood and juice require that the hazard analysis be conducted for each kind of fish or fishery product (or for each type of juice product) processed by the processor (§§ 123.6(a) and 120.7(a)) but do not mandate any particular process for the hazard analysis. The FSIS HACCP regulation for meat and poultry requires that a flow chart be prepared describing the steps for each process and product flow in the establishment (9 CFR § 417.2(a)(2)) and also requires a HACCP plan for each product produced by the

Deleted: 110

Deleted: 110

Deleted: approach

Deleted: for

Deleted: 110

Deleted: NACMCF, 1998

Deleted: Codex 2003

establishment whenever the hazard analysis reveals one or more hazards that are reasonably likely to occur (9 CFR § 417.2(b)(1)).

The process of identifying and evaluating the hazards that may occur for specific types of food handled in a facility provides an efficient means for keeping track of multiple hazards that may occur in a facility that handles several types of foods. Such a process also provides an efficient means for ensuring that preventive controls are applied to specific foods when required. Thus, a facility may need to conduct multiple hazard analyses. For example, a facility that produces tea-based beverages may package its products in both glass and plastic bottles at the same facility. Although these two products might contain similar ingredients, we would consider them to be different types of food under proposed § 117.130(a)(1) because the two types of packaging entail significant differences in the handling of these products during processing. The hazard of glass particles resulting from glass container breakage during plant operations is a known hazard associated with glass-packaged products and, thus, should be identified and evaluated for the product packaged in glass but not for the product packaged in plastic.

Deleted: 110

Proposed § 117.130(a)(1) would identify the purpose of the hazard analysis - i.e., to determine whether there are hazards that are reasonably likely to occur. Although section 418(b)(1) of the FD&C Act does not explicitly identify the purpose of the hazard analysis, we interpret the combined requirements of sections 418(b), (c)(1) and (c)(3) of the FD&C Act to reflect a purpose, i.e., to enable the facility to identify and, where necessary, implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that the food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. If, for example, the facility concludes during the hazard

Deleted: 110

analysis that one or more (or even all) known or reasonably foreseeable hazards are not reasonably likely to occur in the facility for a certain type of food, the facility could conclude that there is no need to identify and implement preventive controls for those hazards. The purpose of the hazard analysis identified in proposed § 117.130(a)(1) is consistent with the purpose identified in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines identify the purpose of the hazard analysis as the development of a list of hazards that are of such significance that they are reasonably likely to cause illness or injury if not effectively controlled (Ref. 34). The Codex HACCP Annex recommends that the HACCP team identify for the HACCP plan hazards that are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food (Ref. 35). The stated purpose of the hazard analysis in Federal HACCP regulations for seafood, juice and meat and poultry is, in relevant part, to determine whether there are food safety hazards that are reasonably likely to occur for each kind of product (§§ 123.6(a) and 120.7(a), respectively, for seafood and juice) or in the production process for meat and poultry (9 CFR § 417.2(a)).

Deleted: 110

Deleted: NACMCF 1998

Deleted: Codex 2003

b. Proposed § 117.130(a)(2)--Requirement for the hazard analysis to be written.

Deleted: 110

Proposed § 117.130(a)(2) would require that the hazard analysis be written, as required by section 418(b)(3) of the FD&C Act. A written hazard analysis can help the facility organize the scientific basis for the hazard analysis and would be essential to the facility's food safety team, to auditors, and to inspectors. The facility's food safety team needs to fully understand the nature of the hazards in order to produce a safe food. For example, although the facility's food safety plan would include corrective action procedures that address problems that can be anticipated, the food safety team will need to make decisions as to appropriate corrective actions

Deleted: 110

when there is an unanticipated problem (see, e.g., the discussion of a proposed requirement (proposed § 117.145(b)) for corrective actions when there is an unanticipated problem in section XII.F.3 of this document). The written hazard analysis would be useful at these times. Having a written hazard analysis available for auditors and for inspectors is essential for them to assess the adequacy of the hazard analysis. A written hazard analysis also would be essential during reanalysis and updates of the hazard analysis, as would be required by proposed § 117.150(f) so that the person doing the reanalysis or update has a baseline from which to start. A written hazard analysis also would be useful for training purposes as a tool to make employees aware of food safety hazards that are reasonably likely to occur.

The written hazard analysis includes the justification for whatever conclusion the owner, operator, or agent in charge of a facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, proposed § 117.130(a)(2) would not limit the requirement for a written hazard analysis to those circumstances where the owner, operator, or agent in charge of a facility identifies one or more hazards that are reasonably likely to occur. Under proposed § 117.130(a)(2), a written hazard analysis would be required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur.

Proposed § 117.130(a)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry. The NACMCF HACCP guidelines and the Codex HACCP Annex each specify that the hazard analysis be documented in the HACCP plan (Ref. 34) (Ref. 35). Our HACCP regulation for juice requires a written hazard analysis (§ 120.7(a)). Our HACCP regulation for seafood requires that the list of food safety hazards that are reasonably likely to occur, identified in the hazard analysis, be included in the written HACCP plan (§ 123.6(c)). The FSIS HACCP

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted:

Deleted: Refs. NACMCF and Codex

regulation for meat and poultry requires a written hazard analysis, including all supporting documentation (9 CFR § 417.5(a)(1)).

3. Proposed § 117.130(b)--Hazard Identification

Proposed § 117.130(b) would require that the hazard analysis consider hazards that may occur naturally or may be unintentionally introduced, including:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance (proposed § 117.130(b)(1));
- Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens (proposed § 117.130(b)(2));
- Physical hazards (proposed § 117.130(b)(3)); and
- Radiological hazards (proposed § 117.130(b)(4)).

Proposed § 117.130(b) would implement section 418(b)(1) of the FD&C Act and would establish four groups of hazards (i.e., biological, chemical, physical, and radiological). Three of the proposed groups of hazards (i.e., biological, chemical, and physical) are the same as the groups of hazards in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry; the proposed group "radiological hazards" would be in addition to the groups of hazards in those HACCP systems. The additional group of "radiological hazards" is required by section 418(b)(1)(A) of the FD&C Act. The NACMCF HACCP guidelines and Codex HACCP Annex identify biological, chemical, and physical hazards as types of hazards in the definition of hazard (Ref. 34) (Ref. 35). Federal HACCP regulations for seafood, juice and meat and poultry identify biological, chemical, and

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted:)); and
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: Refs. NACMCF and Codex).

physical hazards as types of hazards in the definition of "food safety hazard" (§ 123.3(f) and 9 CFR § 417.1 for seafood and meat and poultry, respectively) or food hazard (§ 120.3(g) for juice). Federal HACCP regulations for seafood, juice, and meat and poultry identify as hazards microbiological contamination, parasites, chemical contamination, unlawful pesticide residues, decomposition, natural toxins, unapproved use of food or color additives and physical hazards (§§123.6(c)(1), 120.7(c), and 9 CFR 417.2(a)(3), respectively). Federal HACCP regulations for seafood and meat and poultry also identify as hazards drug residues (§ 123.6(c)(1)(v) and 9 CFR 417.2(a)(3)(v) for seafood and meat and poultry, respectively) and undeclared ingredients that may be allergens (§ 120.7(c)(8) for juice). The FSIS HACCP regulation for meat and poultry also identifies zoonotic diseases as a hazard (9 CFR 417.2(a)(3)).

Microbiological hazards.

Formatted: No underline

Proposed § 117.130(b)(1) would include microbiological hazards within the category of biological hazards. Examples of microbiological hazards include:

Deleted: 110

- Parasites (which are required to be considered by section 418(b)(1)(A) of the FD&C Act). A parasite is an organism that lives on or in an organism of another species (often called the host organism) and feeds off that other species. Cryptosporidium spp., Giardia intestinalis, and Toxoplasma gondii are examples of parasites.
- Environmental pathogens (e.g., Listeria monocytogenes and Salmonella spp.); and
- Other microorganisms of public health significance, including bacteria (e.g., Campylobacter spp., Clostridium perfringens, Shiga toxin-producing Escherichia coli (STEC) O157, STEC non-O157, Shigella spp., Staphylococcus aureus, Vibrio spp., and Yersinia enterocolitica) and viruses (e.g., hepatitis A virus and norovirus).

As discussed in section II.D.1 of this document, CDC has estimated that the total burden of foodborne illness is 48 million cases, 128,000 hospitalizations, and 3,000 deaths due to illnesses from both major pathogens and from unspecified agents (Ref. 45) (Ref. 46). Focusing only on the foodborne illnesses attributable to particular pathogens, a recent report estimated that 31 major pathogens (for which data for preparing national estimates are available, including those listed above) cause 9.4 million episodes of foodborne illness, 55,961 hospitalizations and 1351 deaths in the United States each year (Ref. 45). In addition to contaminating raw materials, some of these pathogens (e.g., Listeria monocytogenes and Salmonella spp.) are common pathogens of concern with respect to contamination from the processing environment for specific types of facilities (Ref. 144) (Ref. 145). (See sections J.D and J.E of the Appendix to this document for a discussion of testing programs for environmental pathogens). Contamination of food with some pathogens (e.g., Staphylococcus aureus and norovius) is often due to poor employee hygiene or practices.

Chemical hazards.

Proposed § 117.130(b)(2) would include substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens (all of which are required to be considered by section 418(b)(1)(A) of the FD&C Act) within the category of chemical hazards. As discussed in section II.D.2.b of this document, pesticide residues may be present in food in the absence of or in excess of a tolerance established by EPA. Residues of drugs (e.g., antibiotics administered to dairy cows) may be present in food derived from the animal (such as milk) in the absence of or in excess of a tolerance or safe levels established and enforced by FDA (Ref. 146). Natural toxins such as aflatoxin and patulin are well recognized as hazards in foods such as peanuts and apple juice products, respectively (Ref.

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: Refs. Scallan major pathogens; Scallan unspecified agents).

Deleted: Scallan major pathogens).

Deleted: Refs. Tompkin et al., 1999; Scott et al., 2009 FPT1).

Deleted: II.E.4

Deleted: II

Deleted: .5

Deleted:

Formatted: No underline

Deleted: 110

Deleted: the

Deleted: M-I-05-5

Deleted: Refs. CPG 570.375 and 510.150).

82) (Ref. 85). Decomposition products such as histamine, produced from the amino acid histidine when certain bacteria grow, can pose a risk to health. An undeclared food allergen (such as a peanut) can cause a life-threatening reaction (such as anaphylactic shock) in susceptible individuals (Ref. 147). Heavy metals (such as lead) can lead to impaired cognitive development in children (Ref. 88).

Physical hazards

Proposed § 117.130(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. Physical hazards may be associated with raw materials, especially RACs. The facility and equipment can also be a source of physical hazards, e.g., container glass and metal fragments such as nuts and bolts.

Radiological hazards

Proposed § 117.130(b)(4) would require that the hazard analysis consider radiological hazards. As discussed in section II.D.2.e of this document, examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium-235, uranium-238, strontium-90, iodine-131, and cesium-137. The NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry do not identify radiological hazards as a type of hazard to be considered in the hazard analysis. However, section 418(b)(1)(A) of the FD&C Act requires that radiological hazards be considered, and food may be subject to contamination with radiological hazards – e.g., if water used to manufacture a food contains a radionuclide. For additional information on how radiological hazards may

Deleted: Thresholds Food Allergens and for Gluten).

Deleted: supporting document lead in candy

Formatted: No underline

Formatted: FR Preamble Para Indent Line 1 36 point, Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Formatted: No underline

Formatted: FR Preamble Para Indent Line 1 36 point, Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: and

Deleted: For example, radiological hazards may result from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. In addition, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium have been detected in private wells (Refs. USGS

contaminate food, see section III.D.2.e of this document and references discussed therein (Ref. 107) (Ref. 108) (Ref. 109).

4. Proposed § 117.130(c)--Hazard Evaluation

a. Proposed § 117.130(c)(1)--Evaluation of whether a hazard is reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

Proposed § 117.130(c)(1) would require that the hazard analysis include an evaluation of the hazards identified in § 117.130(b) to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur. As discussed in more detail later in this section, proposed § 117.130(c)(1) would implement sections 418(b)(1) and (c)(3) of the FD&C Act. Proposed § 117.130(c)(1) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines define severity as the seriousness of the effects of a hazard. The severity of the illness or injury includes the magnitude and duration of the illness and impact of any sequelae (chronic conditions resulting from an illness, such as reactive arthritis following a Salmonella infection). The NACMCF HACCP guidelines also recommend considering the likelihood of an illness or injury (usually based upon a combination of experience, epidemiological data, and information in the technical literature) and the potential effects associated with both short-term and long-term exposure (Ref. 34). Likewise, the Codex HACCP Annex recommends that the hazard analysis consider the severity of the adverse health effects associated with the hazards (Ref. 35). Our juice HACCP regulation requires that the hazard evaluation include an assessment of the severity of the illness or injury if the hazard occurs (§ 120.7(a)(2)). The requirement for a hazard analysis in our seafood HACCP regulation does not specifically require an assessment of severity but addresses

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Formatted: No underline
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: Underline
Deleted: NACMCF
Deleted: Codex

the potential for illness or injury in its definition of a food safety hazard, which refers to biological, chemical or physical properties that may cause a food to be unsafe for human consumption (§ 123.3(f)) and in the description of a food safety hazard that is reasonably likely to occur, which includes illness data as a basis for establishing controls (§ 123.6(a)). Similarly, the FSIS HACCP regulation for meat and poultry does not specifically require an assessment of severity in the hazard analysis (9 CFR § 417.2(a)), but its definition of a food safety hazard refers to biological, chemical or physical properties that may cause a food to be unsafe for human consumption (9 CFR 417.1(c)). In the final rule to establish our juice HACCP regulation, we agreed with the NACMCF approach to conducting the hazard analysis - i.e., that the process of evaluating food hazards to determine which potential hazards need to be addressed in the HACCP plan (i.e., those that are reasonably likely to occur) takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact of the potential hazards in question (66 FR 6138 at 6155).

As discussed in section II.D.2.a of this document, contamination of food with biological hazards often leads to immediate or near-term onset of illness or injury (e.g., gastrointestinal illness). Exposure to some biological hazards may have long-term consequences as well (e.g., infections with Salmonella spp. may result in reactive arthritis). The effects of exposure to some biological hazards are severe (e.g., Hemolytic Uremic Syndrome (HUS) in individuals exposed to E. coli O157:H7 (63 FR 20450 at 20450) or invasive listeriosis in susceptible individuals exposed to L. monocytogenes in ready-to-eat foods (Ref. 55). Proposed § 117.130(c)(1) would require that such biological hazards be considered to determine whether they are reasonably likely to occur even if the biological hazard occurs infrequently.

Deleted: FDA/FSIS 2003. Executive Summary, LmRA).

Deleted: 110

As discussed in sections II.D.2.b and II.D.2.c of this document, contamination of food with chemical hazards may lead to immediate or near-term onset of illness – e.g., an allergic reaction to an undeclared peanut or to a residue in a milk product of penicillin used to treat the cow. In other instances the focus of the evaluation for chemical hazards is directed to their long term effects, such as impaired cognitive development in children exposed to lead in contaminated candy (Ref. 88) and liver cancer as the result of chronic exposure to the mycotoxin aflatoxin (Ref. 89) (Ref. 90). Proposed § 117.130(c)(1) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

We discuss the regulatory framework under the FD&C Act (including premarket approval or registration by FDA or EPA) of food additives, color additives, new animal drugs, and pesticides in section II.D.2.b of this document. An additive, drug, or pesticide that has been approved for use in some foods, but not other foods, is deemed by the FD&C Act to be unsafe for use with those other foods. Proposed § 117.130(c)(1) would require that chemical hazards such as unapproved food additives, unapproved color additives, new animal drugs, and pesticides be considered to determine whether they are reasonably likely to occur.

We provide information about natural toxins (such as aflatoxin and patulin), decomposition products (such as histamine and other biogenic amines), and heavy metals (such as lead) in section II.D.2.b of this document and references contained therein (Ref. 82) (Ref. 83) (Ref. 84) (Ref. 85) (Ref. 86) (Ref. 87) (Ref. 88) (Ref. 90). Proposed § 117.130(c)(1) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

Deleted: Supporting document lead in candy

Deleted: in persons exposed

Deleted: Gordon S. Shephard, 2008).

Deleted: 110

Deleted: Under

Deleted: , certain products, such as

Deleted: require premarket approval before they may be legally used. (In the case of pesticides, EPA "registers" (i.e., approves) the use

Deleted: pesticides and establishes tolerances (the maximum amounts of residues that are permitted in or on a food) if the use of a particular pesticide may result in residues in or on food. FDA enforces those tolerances, except for meat, poultry, and certain egg products, which are the responsibility of FSIS (Ref. FDA 2008 Pesticide Monitoring Report). Moreover,

Deleted: approval can be limited so that the product may only be used legally on or with specific foods, or for specific purposes, for which approval has been obtained. This limitation reflects a longstanding understanding that the safety of these types of products is variable and must be established on a use-by-use basis. Whether an additive, drug, or pesticide is safe for a particular use, in a particular food, at a particular level, depends on factors such as the amount of the food that is consumed and, if the additive, drug, or pesticide is ingested in a living animal before capture, how the product is metabolized in that animal. Therefore, an

Deleted: Natural toxins including aflatoxin in foods such as peanuts and tree nuts and patulin in apple juice products are well recognized as hazards (Refs. CPGs 570.375, 570.200, 570.500, and 510.150 for patulin in apple juice). In addition, decomposition products such as histamine, produced from the amino acid histidine when certain bacteria grow, can pose a risk to health. Further, biogenic amines other than histamine have been associated with illnesses, and these may also be formed when bacteria grow in some foods. Although certain fish species are the most common source of illness from histamine and other biogenic amines, illness from histamine has been reported from consumption of other foods, in particular cheese (Ref. Taylor, S. 1985). Heavy metals (such as lead) can lead to impaired cognitive development in children (Ref. supporting document lead in candy). Proposed § 110

Physical hazards such as hard and sharp foreign objects that may be present in food can pose a health risk (Ref. 148). Hard or sharp foreign objects in food may cause traumatic injury, including laceration and perforation of tissues of the mouth, tongue, throat, stomach and intestine as well as damage to the teeth and gums (Ref. 148) (Ref. 149). Thus, even if physical hazards occur infrequently, under proposed § 117.130(c)(1) the potential for severe consequences would require consideration of these physical hazards to determine whether they are reasonably likely to occur. Factors relevant to an evaluation of the severity of a physical hazard include the potential size of the object, the nature of the food (e.g., RTE or required to undergo further processing), and whether intended consumers of the food include special risk groups (Ref. 148).

Contamination of food with radiological hazards generally is evaluated for long-term effects such as the potential for cancer (Ref. 150). A significant radiation dose could be received as a result of consumption of food contaminated as a result of an accident at a nuclear power plant or other types of accidents (Ref. 150; see also (63 FR 43402, August 13, 1998)). Foods may contain unsafe levels of radionuclides (Ref. 151). Thus, although radiological hazards occur infrequently, under proposed § 117.130(c)(1) the potential for severe consequences would require consideration of radiological hazards to determine whether they are reasonably likely to occur for a particular food or facility, especially when circumstances arise that could lead to contamination of food with radiological hazards.

The purpose of sections 418(b)(1) and 418(c)(3) of the FD&C Act seems clear – i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for the purpose of identifying and implementing preventive controls to provide assurances that identified hazards will be significantly minimized or prevented and that the food manufactured, processed, packed or held by the facility will not be adulterated under

Deleted: CPG 555.425

Deleted: CPG 555.425; Olsen, 1998).

Deleted: although

Deleted: may

Deleted: 110

Deleted: ready to eat

Deleted: CPG 555.425

Deleted: 1998 document issued to states and local agencies).

Deleted: the 1998 document to states

Deleted: CPG 560.750

Deleted: 110

section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. The process of evaluating food hazards to determine which potential hazards require preventive controls must take into account the consequences of exposure (i.e., severity) as well as the probability of occurrence (i.e., frequency) to provide assurances that the food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Proposed § 117.130(c)(1) would implement this statutory direction.

b. Proposed § 117.130(c)(2)--Requirement to evaluate environmental pathogens. Proposed § 117.130(c)(2) would require that the hazard analysis include an evaluation of whether environmental pathogens are reasonably likely to occur whenever an RTE food is exposed to the environment prior to packaging. As noted in section II.D.2.a of this document, environmental pathogens can be a source of contamination of food. Examples of environmental pathogens that have contaminated foods (and, in particular, RTE foods) include Salmonella spp. and L. monocytogenes. Proposed § 117.130(b)(1) would include environmental pathogens as one of the biological hazards that must be considered in identifying hazards for evaluation. Under proposed § 117.130(c)(2), a facility that produces an RTE food that is exposed to the environment would be required to identify environmental pathogens as a known or reasonably foreseeable hazard under proposed § 117.130(b) and evaluate whether contamination of RTE food with the environmental pathogen is reasonably likely to occur in the facility.

c. Proposed § 117.130(c)(3)--Consideration of specific factors relevant to the hazard evaluation. Proposed § 117.130(c)(3) would require that, in conducting the hazard evaluation, consideration be given to the effect of several specific factors on the safety of the finished food for the intended consumer. We tentatively conclude that these are factors that a prudent person

Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted:
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: No underline
Deleted: 110

who manufactures, processes, packs, or holds foods would consider when evaluating identified hazards to determine whether they are reasonably likely to occur. As we indicated in proposing our HACCP regulation for juice, a prudent processor should consider factors such as these in doing a hazard analysis (63 FR 20450 at 20468).

Proposed § 117.130(c)(3)(i) would require that the hazard evaluation consider the formulation of the food. The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, since they may inhibit growth of, or even kill, microorganisms of public health significance. This could impact the evaluation at steps during production and storage with respect to the hazard of "pathogen growth." A multi-component food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or a_w), but when put together there may be an interface where the pH and a_w changes (e.g., pies, layered breads). Under proposed § 117.130(c)(3)(i), the interaction of the individual ingredients must be evaluated as part of the formulation of the food. Proposed § 117.130(c)(3)(i) also would require that the hazard evaluation consider whether or not the formulation contains an ingredient (such as a flavoring, coloring, or incidental additive) that may contain an allergen.

Proposed § 117.130(c)(3)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment. The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling and conveying equipment) may be more difficult to clean (e.g., with close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments.

Deleted: 110

Deleted: of the hazard of pathogen growth

Deleted: .

Deleted:)

Deleted: 110

Deleted: 110

Deleted: 110

Proposed § 117.130(c)(3)(ii) would require that facilities with such equipment consider the impact of the equipment on the potential for pathogens to be a hazard that is reasonably likely to occur; if so, a preventive control such as enhanced sanitation controls may be appropriate, particularly if the equipment is used in production of RTE food. Equipment designed such that there is metal-to-metal contact may generate metal fragments. Proposed § 117.130(c)(3)(ii) would require that facilities with such equipment consider the impact of the equipment on the potential for generation of such metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate. A facility that manufactures, processes, or packs soft, fresh cheese (such as queso fresco, which is consumed without cooking to adequately reduce pathogens) may have cold, moist conditions that are conducive to the development of a niche where the pathogen L. monocytogenes can become established and contaminate food-contact surfaces and, eventually, foods. Proposed § 117.130(c)(3)(ii) would require that facilities with such conditions consider the impact of the conditions on the potential for whether development of a niche where the pathogen L. monocytogenes can become established is a hazard that is reasonably likely to occur; if so, enhanced sanitation controls may be appropriate. A facility design that has closely spaced equipment would provide more opportunities for cross-contact (such as from allergens in powdered milk or soy) from one line to another (e.g., through dust) than a facility that has more spacing between equipment. Proposed § 117.130(c)(3)(ii) would require that facilities with such closely spaced equipment consider the impact of the close spacing on the potential for cross-contact to be a hazard that is reasonably likely to occur; if so, targeted food allergen controls may be appropriate.

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: of

Deleted: (such as

Deleted: 110

Proposed § 117.130(c)(3)(iii) would require that the hazard evaluation consider raw materials and ingredients. Current § 110.3 defines "food" to mean food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients, and that definition would be retained (with no proposed revisions) in this proposed rule. As discussed in section IX.E of this document, there is an overlap between raw materials and ingredients; not all raw materials are ingredients. A food can become contaminated through the use of contaminated food ingredients. For example, in the past several years thousands of foods have been recalled as a result of contamination of food ingredients with pathogens such as Salmonella spp. and E. coli O157:H7. The ingredients included peanut-derived ingredients (Ref. 19) (Ref. 20), pistachio-derived ingredients (Ref. 152), hydrolyzed vegetable protein (Ref. 23) (Ref. 24) (Ref. 153)), instant nonfat dried milk, whey protein, and fruit stabilizers (Ref. 21) (Ref. 22), and bagged spinach (Ref. 154). In some cases, the contamination was discovered only after the ingredient was associated with an outbreak of foodborne illness (Ref. 19). In other cases, the contamination was discovered in a food and associated with a particular ingredient without any known incidence of foodborne illness (Ref. 152) (Ref. 155) (Ref. 22) (Ref. 154). Following some of these recalls, we issued guidance recommending that manufacturers of foods containing a particular type of ingredient either obtain the ingredients from suppliers with validated processes in place to adequately reduce the presence of the applicable pathogen, or ensure that their own manufacturing process would adequately reduce the presence of that pathogen (Ref. 6) (Ref. 156). Specific pathogens would be considered to be a hazard that is reasonably likely to occur for raw materials and ingredients that have been documented to be contaminated with such pathogens, as well as for ingredients with similar characteristics (because such contamination might be expected in ingredients that are produced in a similar manner).

Deleted: 110

Deleted: in this proposed rule. There is an overlap between raw materials and ingredients. Not all raw materials are ingredients. For example, under section 201(f) of the FD&C Act, a food additive is food and, thus, the manufacture of a food additive is subject to part 110. An example of a food additive is sucrose fatty acid esters. Under § 172.859, sucrose fatty acid esters are the mono-, di-, and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or hydrogenated edible tallow or edible vegetable oils. The only solvents which may be used in the preparation of sucrose fatty acid esters are those generally recognized as safe in food or regulated for such use by an appropriate section in this part. Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters. The regulation for sucrose fatty acid esters identifies a number of raw materials used in the production of sucrose fatty acid esters. Because the production process transforms those raw materials into the substance "sucrose fatty acid esters," those raw materials generally would not be viewed as "ingredients" of the final chemical product. Likewise, if a facility adds the food additive "sucrose fatty acid esters" to a food product, the facility would view that food additive as an ingredient of its food product, but would not view the chemicals used to produce sucrose fatty acid esters as ingredients of its food product.¶

Deleted: Peanut butter recall info

Deleted: Pistachio recall info

Deleted: "For Consumers; The HVP Recall"),

Deleted: 2 Plainview pieces on FDA web site

Deleted: Pacific Coast Fruit

Deleted: FDA MajorProductRecalls/Peanut).

Deleted: Refs. to pistachio recall; Plainview press announcement and accessdata.fda.gov/scripts/HVPCP/; spinach archive recalls).

Deleted: Refs. peanut guidance and pistachio guidance).

A food also may become contaminated through the use of contaminated raw materials that are not food ingredients. In the example of the manufacture of the food additive sucrose fatty acid esters (see discussion in section IX.E of this document), § 172.859 establishes specifications for sucrose fatty acid esters, such as specifications that arsenic is not more than 3 parts per million, total heavy metal content (as lead) is not more than 50 parts per million, and lead is not more than 10 parts per million (§ 172.859(b)(6), (7), and (8)). The use of raw materials that are contaminated with arsenic, lead, or other heavy metals that would not be removed as part of the manufacturing process for sucrose fatty acid esters could lead to sucrose fatty acid esters that are contaminated with arsenic, lead, or other heavy metals such that they do not satisfy the specifications of the regulation.

As noted for formulation in the discussion of proposed § 117.130(c)(3)(i), ingredients must be evaluated for "hidden" allergens such as may be present in flavorings, colorings, or incidental additives. Production and harvesting practices may impact whether raw materials and ingredients contain hazards. For example, machinery-harvested produce is more likely to be contaminated with physical hazards than hand-picked produce, because the machinery often picks up foreign material from the field.

Proposed § 117.130(c)(3)(iv) would require that the hazard evaluation consider transportation practices. A food may become unsafe as a result of poor transportation practices for incoming raw materials and ingredients or for outgoing finished product. For example, failure to adequately control temperature during transportation could make a food unsafe if the product requires time and temperature controls to ensure safety. Distributing a food in bulk without adequate protective packaging makes the product susceptible to contamination during transportation – e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or

Deleted: ,

Deleted:

Deleted: 110

Deleted: flavors

Deleted: 110

Deleted: of

from other inadequately protected foods that are being co-transported and are potential sources of contamination (Ref. 157). (For additional examples of food safety problems that could occur during transportation, see 75 FR 22713, April 30, 2010).

The Sanitary Food Transportation Act of 2005 (SFTA) gives FDA authority to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. In 2010, we published an Advance Notice of Proposed Rulemaking to request data and information on the food transportation industry and its practices and we expect to issue a separate proposed rule to implement the SFTA (75 FR 22713, April 30, 2010). We do not expect a future rulemaking implementing the SFTA to eliminate the need for the owner, operator, or agent in charge of a facility to consider transportation practices when determining whether a hazard is reasonably likely to occur.

Proposed § 117.130(c)(3)(v) would require that the hazard evaluation consider manufacturing/processing procedures. For example, hazards may arise from manufacturing/processing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic sporeforming bacteria such as Clostridium perfringens and Bacillus cereus (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing/processing processes such as acidification due to the potential for germination of spores of C. botulinum, with subsequent production of botulinum toxin, if the acidification is not done correctly. Toxins can be produced by the bacteria Staphylococcus aureus or Bacillus cereus in a product that has been heated and held at room temperature during

Deleted: Wojtala 2007

Deleted: 110

Deleted: spore forming

the manufacturing process if the product formulation supports growth and toxin formation by the bacteria and S. aureus or B. cereus is present in the ingredients of the product or is introduced by poor employee hygiene (e.g., S. aureus). Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades or knives) is used to cut products during manufacturing.

Deleted: .

Proposed § 117.130(c)(3)(vi) would require that the hazard evaluation consider packaging activities and labeling activities. For example, as discussed earlier in this section XII.4.c the hazards that are reasonably likely to occur would be different depending on whether a product is packaged in glass bottles or in plastic bottles. A label on a food may direct consumers to cook a product to a certain temperature; the likelihood of consumers following those cooking instructions may vary depending on the type of food. For example, it is well known that consumers will eat raw cookie dough, even though the cookie dough is clearly intended to be cooked, and an outbreak of foodborne illness has been associated with the consumption of uncooked cookie dough (Ref. 77) (Ref. 76) (Ref. 78). Thus, although label information is a factor to consider, a hazard may be reasonably likely to occur even with label information such as cooking instructions.

Deleted: 110

Deleted: there have been outbreaks

Deleted: to cookie dough outbreak/recall

Proposed § 117.130(c)(3)(vii) would require that the hazard evaluation consider storage and distribution. For example, biological hazards are more likely to be a hazard that is reasonably likely to occur during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods. Shelf-stable foods are designed such that biological hazards are controlled.

Deleted: 110

Proposed § 117.130(c)(3)(viii) would require that the hazard evaluation consider intended or reasonably foreseeable use. An example of intended or reasonably foreseeable use is whether

Deleted: 110

the food would be cooked by the consumer. In some cases, the intended use of a product may include uses where it would be cooked by the consumer, as well uses where it would not be cooked. For example, soup is generally cooked, but a dried soup mix is often used in RTE form as a component of a dip. For another example, see the discussion of consumption of raw cookie dough earlier in this section. When it is known or reasonably foreseeable that a food would be consumed in RTE form, hazards such as Salmonella spp., L. monocytogenes, and E. coli O157:H7 would need to be considered to determine if they are hazards reasonably likely to occur.

Proposed § 117.130(c)(3)(ix) would require that the hazard evaluation consider sanitation, including employee hygiene. Sanitation measures and practices can impact the likelihood of a hazard being introduced into a food. For example, the frequency with which a production line is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw produce that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as Salmonella spp., hepatitis A and norovirus.

Proposed § 117.130(c)(3)(x) would require that the hazard evaluation consider any other relevant factors that might potentially affect the safety of the finished food for the intended consumer. For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful microorganisms or chemical residues. Following a natural disaster, environmental contaminants that could be brought into the facility could be a hazard reasonably likely to occur. As another example, when local water authorities advise the public to boil tap water for drinking, a facility

Deleted: Cookie dough is a product that is intended to be baked by

Deleted: consumer, but it is well known that consumers eat raw cookie dough, and an outbreak

Deleted: foodborne illness caused by E. coli O157:H7 has been linked to

Deleted: (Ref. cookie dough recall notice).

Deleted: ,

Deleted: 110

Deleted: ,

Deleted: 110

should consider whether bacterial, viral or parasitic (e.g., Cryptosporidium and Giardia) contamination presents a hazard reasonably likely to occur as a result of the events that triggered the advisory (Ref. 158).

Proposed § 117.130(c)(3) is consistent with the NACMCF HACCP guidelines, the Hazards and Controls Guides we have issued regarding our HACCP regulations for juice and seafood, and the Hazards and Controls Guide FSIS has issued regarding the FSIS HACCP regulation for meat and poultry. The NACMCF HACCP guidelines note that hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product – e.g., due to differences in equipment and/or maintenance programs (Ref. 34). Appendix C of the NACMCF HACCP guidelines provides examples of questions to be considered when conducting a hazard analysis and identifies factors to consider such as ingredients, formulation, processing procedures, design of facility, design and use of equipment, packaging, sanitation, worker health and hygiene, storage, intended use, and intended consumer. Our Hazards and Controls Guide for juice provides recommendations related to factors such as shelf life of the product, location of the processing, and type of processing, e.g., thermal or non-thermal processing (Ref. 4). Our Hazards and Controls Guide for seafood provides recommendations related to factors such as storage conditions (time and temperature), the role of manufacturing conditions in minimizing the potential for formation of C. botulinum toxin, manufacturing procedures (cooking and pasteurization) to control pathogenic bacteria, manufacturing procedures (such as high hydrostatic pressure processing, individual quick freezing with extended frozen storage, mild heat processing, and irradiation) designed to retain raw product characteristics, and the introduction of pathogenic bacteria after pasteurization and specialized cooking processes. The FSIS Hazards and Controls Guide for meat and poultry

Deleted: FDA boil water advisory

Deleted: 110

Deleted: NACMCF

Deleted: juice guide

provides recommendations related to factors such as receiving, thawing, formulation, manufacturing procedures, packaging, storage and shipping (Ref. 159).

C. Proposed § 117.135--Preventive Controls for Hazards That Are Reasonably Likely to Occur

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

Section 418(c)(1) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(1)(3) of the FD&C Act), in relevant part, specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

As discussed in section X.B.4 of this document, section 418(o)(3) of the FD&C Act defines preventive controls and proposed § 117.3 would include the statutory definition in proposed part 117. Under section 418(o)(3), the procedures, practices, and processes described in the definition of preventive controls may include the following:

- Sanitation procedures for food-contact surfaces and utensils and food-contact surfaces of equipment (section 418(o)(3)(A) of the FD&C Act);
- Supervisor, manager, and employee hygiene training (section 418(o)(3)(B) of the FD&C Act);
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment (section 418(o)(3)(C) of the FD&C Act);
- A food allergen control program (section 418(o)(3)(D) of the FD&C Act);

Deleted: FSIS Meat and Poultry Hazards and Controls Guide
Deleted: 110
Moved (insertion) [1]
Deleted: 1. Requirements of Section 418 of the FD&C Act¶
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: “
Deleted: ”: ¶ “[H]azards
Deleted: [
Deleted:]
Deleted: ” (section
Deleted:); and¶ “[T]he
Deleted: [
Deleted:]
Deleted: [
Deleted:]” (section 418(c)(3) of the FD&C Act).
Deleted: C
Deleted: 110
Deleted: 110
Deleted: “
Deleted:
Deleted: ”
Deleted: “
Deleted: ”
Deleted: “
Deleted: ”
Deleted: “
Deleted: ”

- A recall plan (section 418(o)(3)(E) of the FD&C Act);
- CGMPs under part 110 or any successor regulations (section 418(o)(3)(F) of the FD&C Act); and
- Supplier verification activities that relate to the safety of food (section 418(o)(3)(G) of the FD&C Act).

2. Proposed § 117.135(a)--Requirement to Identify and Implement Preventive Controls for Hazards that are Reasonably Likely to Occur

Proposed § 117.135(a) would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at CCPs, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

As discussed in section XII.B.2.a of this document, proposed § 117.130(a) would require that the owner, operator, or agent in charge of a facility conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are "reasonably likely to occur." Under proposed § 117.135(a), a facility that determines through its hazard analysis that there are hazards that are reasonably likely to occur would then be required to identify and implement preventive controls for those hazards. Preventive controls would be required when applicable hazards are identified as reasonably likely to occur. As discussed in sections XII.B.2 through XII.C.10 of this document, the types of preventive controls implemented would depend on the facility and the food it produces. Most hazards would be

Deleted: "
Deleted: "
Deleted: "(
Deleted:)
Deleted: … (
Deleted:)"
Deleted: "
Deleted: "
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: Some

addressed through process controls, food allergen controls, and sanitation controls. For any type of preventive control, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes available to it that would provide the assurances that would be required by proposed § 117.135(a).

Proposed § 117.135(a) would implement section 418(c) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry, although there are some differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. The NACMCF HACCP guidelines (Ref. 34), the Codex HACCP Annex (Ref. 35), and Federal HACCP regulations for seafood, juice, and meat and poultry (§§ 123.6 and § 120.7 and 9 CFR § 417.2, respectively) direct a processor to address potential hazards that are reasonably likely to cause illness or injury in the absence of their control by determining CCPs and establishing critical limits for those CCPs. As discussed in section II.C.2 of this document, although this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls. Under proposed § 117.135(a), a processor could address hazards that are reasonably likely to occur through preventive controls that would be applied at CCPs, but doing so would not be the only option available to the facility in all circumstances. In some cases adequate assurances could be achieved via preventive controls implemented through other procedures and practices of a facility, such as its food allergen control program, which may not have specific CCPs. (For discussion of the food allergen control program that would be required by proposed § 117.135(d)(2), see section XII.C.6 of this document.)

Deleted: In some cases hazards may be addressed through other programs such as a supplier approval and verification program.

Deleted: 110

Deleted: 110

Deleted: NACMCF, 1998

Deleted: Codex HACCP 2003

Deleted:

Deleted: the approach in section 418 of the FD&C Act is broader than the approach in

Deleted: systems,

Deleted: section 418 of the FD&C Act clearly contemplates that CCPs are only one place to apply a

Deleted: ,

Deleted: that there may in fact

Deleted: any CCPs.

Deleted: 110

Deleted: supplier approval and verification program or

Deleted: supplier approval and verification program that would be required by proposed § 110.152, see section XII.H of this document. For discussion of the

Deleted: 110

Whatever types of preventive controls a facility chooses to apply in its operations, the requirement in proposed § 117.135(a) would be risk based. Establishing risk-based preventive controls involves consideration of the available scientific data and information related to food safety risks. Typically, the hazard evaluation will enable the facility to determine appropriate risk-based preventive controls for the hazard based on the severity of the hazard and the likelihood of its occurrence.

For example, as discussed in section J.D.6 of the Appendix to this document, L. monocytogenes is an environmental pathogen that can establish a harborage in the environment such as on a production line used in wet manufacturing. Once established, L. monocytogenes can intermittently contaminate products on the production line. When a hazard analysis identifies L. monocytogenes as a hazard that is reasonably likely to occur in a food, the facility would establish sanitation controls to prevent L. monocytogenes from establishing itself in a harborage site. In addition to such sanitation controls, a facility may consider applying a listericidal process step (i.e., a process control applied to adequately reduce levels of L. monocytogenes in RTE foods). As discussed in section II.D.2.a of this document, some RTE foods (like soft cheese) support the growth of L. monocytogenes, while others (like hard cheese) do not. The FAO/WHO Listeria risk assessment demonstrated that the risk of serious illness from consumption of RTE products contaminated with L. monocytogenes increases with the number of L. monocytogenes in an RTE food (Ref. 160). Thus, as a risk-based approach to the control of the biological hazard L. monocytogenes, the facility may elect to apply a listericidal process step to those RTE foods that support growth of L. monocytogenes in addition to its sanitation controls, but not apply such a process to those RTE foods that do not support growth of L. monocytogenes.

Deleted: For example, potential biological hazards in raw materials such as spices include microorganisms of public health significance. When a facility identifies microorganisms of public health significance as reasonably likely to occur (e.g., when it uses spices as an ingredient in dehydrated soup mixes), control of that biological hazard could be achieved by treating the spices to adequately reduce that biological hazard in the spices. Such treatment could be conducted either by the supplier, which may be a component of a supplier approval and verification program, or by the receiving facility at a CCP within the manufacturing process for its product. ¶

Deleted: 110

Deleted: II.E.4.f

Deleted:)

Deleted: .

Deleted:

Deleted: Chapter 5 of the FAO/WHO Listeria risk assessment).

3. Proposed § 117.135(b)--Requirement for Written Preventive Controls

Proposed § 117.135(b) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur be written. Proposed § 117.135(b) would implement section 418(h) of the FD&C Act which, as discussed in section XII.A.2 of this document, requires that the owner, operator, or agent in charge of a facility prepare a written food safety plan that, among other things, identifies the preventive controls within the plan. Written preventive controls are essential for the facility to implement the preventive controls consistently and essential for the facility's food safety team, auditors, and inspectors. Written preventive controls also would be essential for training purposes and during reanalysis and updates of the preventive controls. Proposed § 117.135(b) is consistent with our HACCP regulation for juice, which requires that the written hazard analysis identify control measures that the processor can apply to control the food hazards identified as reasonably likely to occur (§ 120.7(a)).

4. Proposed § 117.135(c)--Requirement for Parameters Associated with the Control of Hazards That Are Reasonably Likely to Occur

Proposed § 117.135(c)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the food, parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, dehydrating, and refrigerating foods. Proposed § 117.135(c)(1) would include examples of several measures identified in current § 110.80(b)(4) (Manufacturing Operations) (proposed § 117.80(c)(4)) that if used as a preventive control must be adequate when used to prevent adulteration, but would not establish an exhaustive list of such processes, just as current § 110.80(b)(4) (proposed § 117.80(c)(4)) does not establish an

Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: to
Deleted: 110
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110

exhaustive list of measures that must be adequate. Examples of other processes that would require the identification of parameters if used as a preventive control are brining, chilling, high pressure processing, treating with ultraviolet light, and washing with antimicrobial agents. The parameters are those factors that must be controlled to ensure the hazard will be significantly minimized or prevented. The specific parameters required, and how they would be controlled, would depend on the facility and the food. For example, for a heat process, parameters such as temperature and time must be controlled. Temperature may be controlled through controls on product temperature (as when treating a fluid product in a heat exchanger) or through controls on oven temperature (as when heating product in an oven). Foods such as beverages lend themselves to a heat exchanger; foods such as baked goods lend themselves to an oven. Heating time may be controlled automatically by a pump setting that controls flow of the fluid through the heat exchanger and hold tube or manually by an operator recording the time a product is put in the oven and the time it is removed. Heating time may also be controlled by the belt speed for the conveyor on a continuous oven. A facility would have flexibility to establish controls on heating time through these or other mechanisms.

Formatted: Not Highlight

Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal contamination. Sanitation procedures may include scrubbing certain pieces of equipment by hand; this may not require the identification of specific parameters. Similarly, label controls for food allergens do not involve identification of specific parameters.

Proposed § 117.135(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the food, the maximum or minimum value, or combination of values, to which any biological, chemical, radiological, or physical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. Some of the preventive controls a facility may implement may be based upon scientific studies or other information that demonstrate the effectiveness of the control measure at specific values of a physical, biological, radiological or chemical parameter, e.g., the application of heat to food at a specific time/temperature combination to adequately reduce pathogens. Proposed § 117.135(c)(2) would require that a facility that establishes such a preventive control specify values of the essential parameters to be applied in implementing the control. Specifying these values would enable the facility to implement them consistently, would facilitate validation of the preventive controls as would be required by proposed § 117.150(a), and would facilitate audits and inspection.

Deleted: 110

Deleted: 110

Deleted: 110

Proposed § 117.135(c)(1) and (2) would implement section 418(c) of the FD&C Act and are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry, although there are some differences related to the differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. The NACMCF HACCP guidelines and the Codex HACCP Annex (Ref. 34) (Ref. 35) each specify that the critical limits be documented in the HACCP plan. Federal HACCP regulations for seafood, juice, and meat and poultry each require that HACCP plan list the critical limits that must be met at each of the CCPs (§§ 123.6(c)(3) and 120.8(b)(3), and 9 CFR 417.2(c)(3), respectively). The NACMCF HACCP guidelines define "critical limit" to mean a maximum and/or minimum value to which a biological, chemical, or

Deleted: 110

Deleted: Refs. NACMCF and Codex

physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The definition of "critical limit" in Federal HACCP regulations for seafood, juice, and meat and poultry are, for practical purposes, identical to the definition in the NACMCF HACCP guidelines (§§ 123.3(c) and 120.3(e) and 9 CFR 417.1(b), respectively). The Codex HACCP Annex defines "critical limit" to mean a criterion which separates acceptability from unacceptability (Ref. 35).

FSMA does not use the term "critical limit." As discussed in section II.C.2 of this document, although this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls. Critical limits may not be appropriate for preventive controls that are not applied at CCPs. Thus, proposed § 117.135(c)(1) and (2) use a broader term – i.e., parameter – to encompass preventive controls that may or may not apply at CCPs. Consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry, proposed § 117.135(c)(2) would require the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. This is similar to requiring critical limits at CCPs but would apply to values set for parameters that apply to preventive controls, whether these apply at a CCP or not.

5. Proposed § 117.135(d)(1)--Process Controls

Proposed § 117.135(d)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include process controls that include those procedures, practices, and processes performed on a food during manufacturing/processing that

Deleted: Codex HACCP 2003

Deleted: the approach in section 418(c) of the FD&C Act is broader than the approach in

Deleted: systems,

Deleted: section 418(c) of the FD&C Act is less prescriptive than HACCP systems in terms of mechanisms to

Deleted: hazards. As also discussed in section XII.C.2 of this document, section 418 of the FD&C Act clearly contemplates that CCPs are only one place to apply a preventive control,

Deleted: that there may in fact

Deleted: any CCPs

Deleted: 110

Deleted: to

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Process controls do not include those procedures, practices, and processes that are not applied to the food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards that are reasonably likely to occur but are not applied to the food itself. Specifying that process controls are employed during manufacturing/processing to significantly minimize or prevent hazards that are reasonably likely to occur would distinguish those controls applied in manufacturing/processing that significantly minimize or prevent hazards (e.g., cooking, cooling, irradiating, refrigerating, and reducing water activity) from other types of controls that may be applied in manufacturing/processing to provide the desired product (e.g., controls for product size and shape). Many process controls, such as the application of heat to a food to adequately reduce pathogens, are applied in the same manner and for the same purpose as control measures established within HACCP plans and applied at CCPs as recommended by the NACMCF HACCP guidelines (Ref. 34) and the Codex HACCP Annex (Ref. 35) and as required by Federal regulations for seafood, juice, and meat and poultry (§§ 123.6(c)(3) and 120.8(b)(3)) and 9 CFR 417.2(c)(3), respectively).

As discussed in section XII.C.4 of this document, proposed § 117.135(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, when applicable, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled. For process controls in particular, the term "parameter" used in proposed § 117.135(c)(1), and the value associated with the parameter in proposed § 117.135(c)(2), are associated with the term "critical limit" used in HACCP systems. We described the use of the term "critical limit" in other contexts in the previous section of this document. Collectively, proposed §§ 117.135(b),

Deleted: NACMCF 1998

Deleted: Codex 2003

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

(c) and (d)(1) would require that a facility include in its written process controls information equivalent to that provided when listing critical limits that must be met at each of the CCPs, such as is required in our HACCP regulations for seafood and juice (§§ 123.6(c)(3) and 120.8((b)(3), respectively). However, the process controls may or may not apply at CCPs.

For example, a facility that holds in-shell pistachios in bulk storage units for an extended time period until they are shelled and packaged may identify the potential for growth of aflatoxin-producing molds on the nuts as a hazard reasonably likely to occur. As a process control to prevent such molds from growing on the nuts during storage, the facility may elect to dry (dehydrate) the nuts to a specific moisture content (e.g., no more than seven percent) prior to placing them in storage. The process control would be "drying" and the associated parameter would be moisture level, with its maximum value, or limit, being seven percent.

As another example, a facility that manufactures refrigerated deli salads may identify the potential for growth of L, monocytogenes in the salads as a hazard reasonably likely to occur. As a process control to prevent such growth, the facility may elect to add an acidifying agent during its process to ensure that the pH of the product does not exceed 4.4. The process control would be "acidifying" and the associated parameter would be pH, with its maximum value, or limit, being 4.4.

A facility that manufactures a deli salad product may establish refrigeration as a process control to prevent growth of pathogenic sporeformers such as B. cereus, if it determines this organism is a hazard reasonably likely to occur in the deli salads being produced. (A facility may conclude that refrigeration is not necessary to prevent the growth of pathogenic sporeformers if, for example, it controls this potential hazard through product formulation, such as pH.) The facility may also establish process controls addressing the amount of time that in-process

materials are held above 4 °C (40 °F) during manufacturing and addressing their temperatures during this time period. If so, the process control would be "manufacturing time" and the associated parameters would be time and temperature, with the maximum time that in-process materials are held above 4 °C (40 °F) being specified.

6. Proposed § 117.135(d)(2)--Food Allergen Controls

Proposed § 117.135(d)(2)(i) would require that food allergen controls include those procedures, processes, and practices employed for ensuring protection of food from cross-contact, including during storage and use. Examples of such controls include procedures for separating ingredients and finished products that contain allergens from those that do not contain allergens, and procedures for separating foods that contain different allergens. Such controls are essential to prevent the inadvertent incorporation of an allergen into a product for which it is not an ingredient. Examples of such procedures for controlling food allergens include procedures that:

- Provide physical barriers;
- Eliminate or minimize the formation of dust, aerosols, or splashes;
- Conduct manufacturing/processing of foods in different parts of a facility;
- Emphasize separation in time, such as by production sequencing or by cleaning equipment between production runs;
- Emphasize storage and handling appropriate to reduce the potential for cross-contact; and
- Control the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods that do not, or when the same production lines are used for foods that contain different allergens.

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: product

Proposed § 117.135(d)(2)(ii) would require that food allergen controls include those procedures, practices, and processes employed for labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the act. Such controls can prevent application of the wrong label to a food, use of the wrong packaging, and use of packaging with an incorrect allergen declaration. Examples of such procedures for controlling food allergens include procedures that:

- Ensure that the food label correctly declares all of the food allergens present (including those contained in flavorings, colorings, and incidental additives);
- Ensure that the correct food label is applied to a food;
- Ensure that the correct food is in the correct package (e.g., by checking that the correct packaging is used for each food); and
- Review formulations and compare them to the labels (especially when new batches of labels are received).

Proposed § 117.135(d)(2) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3) of the FD&C Act. Proposed § 117.135(d)(2) is consistent with our HACCP regulation for juice, which requires processors to consider whether the presence of undeclared ingredients that may be allergens is a hazard that is reasonably likely to occur (§ 120.7(c)(8)). Proposed § 117.135(d)(2) also is consistent with the recommendations in the CGMP Working Group Report (Ref. 1) that food processing establishments that produce foods containing a major food allergen be required to have a food allergen control plan that addresses segregation of food allergens during storage and handling, prevention of cross-contact during processing, product label review, and label usage and control.

Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: flavors);
Deleted:); and
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: CGMP workgroup report
Deleted: , and a supplier control program for ingredients and labels

7. Proposed § 117.135(d)(3)--Sanitation Controls

Proposed § 117.135(d)(3)(i)(A) and (B) would establish two requirements for sanitation controls where necessary to significantly minimize or prevent hazards that are reasonably likely to occur, (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard). Proposed § 117.135(d)(3)(i)(A) would require that sanitation controls include procedures for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. Such hazards would include any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging and any food allergen hazard. (We would generally not expect that microorganisms of public health significance contaminating an RTE food due to employee handling would be a hazard relevant to procedures for cleaning food-contact surfaces.) Examples of sanitation controls related to the cleanliness of food-contact surfaces include cleaning and sanitizing procedures (including appropriate frequencies for these procedures, concentrations of cleaning and sanitizing compounds, method of application, and contact time). Such controls can prevent contamination of food with microorganisms of public health significance, including environmental pathogens, that result from inadequate cleaning of food-contact surfaces. Such controls also can prevent cross-contact that results from inadequate cleaning of food-contact surfaces or surfaces that transfer material to food-contact surfaces.

Proposed § 117.135(d)(3)(i)(B) would require that sanitation controls include procedures for the prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted:

Deleted:

Deleted:

Deleted:

Deleted: 110

product to processed product. Such hazards would include any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to contaminate food if employees are handling RTE food, and any food allergen hazard. Examples of sanitation controls to prevent cross-contact include procedures for ensuring that production utensils and maintenance tools do not transfer an allergen from one product to another (e.g., by proper cleaning of utensils and maintenance tools between uses if it is not practical to dedicate utensils and tools to specific processing lines); procedures for ensuring that personnel practices do not result in transfer of allergens from one production line to another (e.g., by ensuring employees do not handle food containing an allergen and one that does not without washing hands and changing outer garments); and procedures for minimizing the transfer of dust containing allergens (e.g., by cleaning powder spills around dumping stations as they occur).

Examples of sanitation controls to prevent cross-contamination include procedures for ensuring that personnel do not touch insanitary objects (e.g., waste, trash cans, the floor, and rest room fixtures or surfaces) and then food, food-contact surfaces, or food packaging material without first washing and sanitizing their hands; procedures for protecting food packaging material from environmental contamination; procedures for protecting exposed food products from contamination from the environment; and procedures for controlling traffic (including traffic of people and traffic of equipment such as forklifts) between the raw and finished sides of the operation.

To make clear that sanitation controls are required when an environmental pathogen is a hazard that is reasonably likely to occur in an RTE food that is exposed to the environment prior to packaging, proposed § 117.135(d)(3)(i) includes this circumstance as an example where

Deleted:

Deleted: 110

sanitation controls would be required. Recent outbreaks of foodborne illness caused by environmental pathogens (e.g., Salmonella spp. and L. monocytogenes), as well as the scientific literature, emphasize the critical need for sanitation controls to minimize the potential for food, particularly RTE food, to become contaminated with environmental pathogens. (See sections J.D and J.E of the Appendix to this document for a discussion of the importance of controlling environmental pathogens.) Any time a food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated. Appropriate sanitation controls can minimize the presence and transfer of contaminants, including environmental pathogens, to food. The need for sanitation controls related to food workers has long been recognized; however, appreciation of the importance of sanitation controls in preventing contamination due to environmental pathogens is more recent. We request comment on whether proposed § 117.135(d)(3) should be more explicit about the two most common environmental pathogens (i.e., Salmonella spp. and L. monocytogenes) - e.g., by including these two environmental pathogens as examples.

To make clear that sanitation controls are required when a microorganism of public health significance is a hazard reasonably likely to occur in an RTE food due to employee handling, proposed § 117.135(d)(3)(i) includes this circumstance as an example where sanitation controls would be required. Sanitation controls have long been used to prevent cross-contamination with pathogens (such as Staphylococcus aureus or enteric pathogens such as Salmonella spp.) that may be introduced by workers. People are common carriers of S. aureus – at any time up to 50 percent of humans will be carriers of this organism (e.g., in the nose and on the skin) (Ref. 161). People are also a source of enteric pathogens, including both symptomatic and asymptomatic infected workers (Ref. 162). Workers can contaminate RTE foods during

Deleted: II.E.4
Deleted: II
Deleted: .5
Deleted:
Deleted: 110
Deleted:)
Deleted: %
Deleted: ICMSF 5, Chapter 17
Deleted: Grieg et al. 2007

handling, which can result in foodborne illness, in particular if the food is then held at temperatures that support growth and, in the case of S. aureus, production of enterotoxin (Ref. 161) (Ref. 163). Appropriate sanitation controls can minimize the transfer of microorganisms of public health significance from workers to food.

To make clear that sanitation controls are required when a food allergen hazard is reasonably likely to occur, proposed § 117.135(d)(3)(i) includes this circumstance as an example where sanitation controls would be required. As discussed in section IX.D of this document, cross-contact can occur in a facility that manufactures, processes, packs or holds a food that contains a major food allergen and other food that does not contain that allergen. Appropriate sanitation controls can minimize the transfer of food allergens that result in cross-contact.

Proposed § 117.135(d)(3)(i)(A) and (B) would implement section 418(c) of the FD&C Act. Proposed § 117.135(d)(3)(i)(A) also is consistent with the recommendation of the Food CGMP Working Group that food processors be required to develop and maintain, at a minimum, written sanitation procedures for all food-contact equipment and food-contact surfaces (Ref. 1). Under proposed § 117.135(b), the preventive controls for sanitation required by proposed § 117.135(d)(3)(i)(A) and (B) would have to be written.

HACCP plans, as described in the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP Annex (Ref. 35), and Federal HACCP regulations for seafood, juice, and meat and poultry (§ 123.6, § 120.7, and 9 CFR 417, respectively) require that control measures be established at CCPs to address hazards that are reasonably likely to occur. Because sanitation covers the entire processing environment, not just at CCPs, and is not limited to hazards reasonably likely to occur, sanitation controls have been difficult to fit into HACCP plans and are often addressed using prerequisite programs (e.g., SSOPs). The NACMCF HACCP

Deleted: Todd et al. 2007; ICMSF 5, Chapter 17).

Deleted: an

Deleted: 110

Deleted: and

Deleted: 110

Deleted: 110

Deleted:

Deleted:

Deleted: CGMP Working Group Report).

Deleted: 110

Deleted: 110

Deleted: NACMCF 1998

Deleted: CAC 2003

guidelines (Ref. 34) and the Codex HACCP Annex (Ref. 35) address sanitation measures as prerequisite programs and are silent on their inclusion in HACCP plans to address identified hazards. FSIS addresses sanitation controls for meat and poultry products in a separate sanitation regulation (9 CFR 416), which is similar to our CGMPs in current part 110 except that it includes SSOP requirements that, unlike our SSOPs, require written sanitation procedures.

In our HACCP regulations for seafood and juice, FDA provides processors with an option to include sanitation controls in their HACCP plans (§§ 123.6(f) and 120.8(c), respectively). Our HACCP regulations require monitoring for eight specified sanitary conditions and practices (referred to as SSOPs) regardless of whether these conditions and practices are related to hazards that are reasonably likely to occur (§ 123.11(b) and 120.6(a) and (b), respectively). The eight conditions and practices are:

- Safety of the water that comes into contact with food or food-contact surfaces or that is used in the manufacture of ice;
- Condition and cleanliness of food-contact surfaces, including utensils, gloves, and outer garments;
- Prevention of cross contamination from insanitary objects to food, food packaging material, and other food-contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;
- Maintenance of hand washing, hand sanitizing, and toilet facilities;
- Protection of food, food packaging material, and food-contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
- Proper labeling, storage, and use of toxic compounds;

Deleted: NACMCF 1998

Deleted: CAC HACCP Annex 2003

Deleted:

Deleted:

Deleted:

Deleted:

- Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food-contact surfaces; and
- Exclusion of pests from the food plant.

The PMO HACCP Appendix essentially includes the same requirements as described in the HACCP regulation for juice (part 120) with respect to the eight conditions and practices. However, in the PMO HACCP Appendix these conditions and practices are referred to as "required prerequisite programs (PPs)" rather than SSOPs.

The eight areas for which sanitation monitoring is required in our HACCP regulations for seafood and juice are those elements of sanitation in current part 110 that we identified as the most likely to have an impact on the safety of food. FDA's HACCP regulations impose mandatory monitoring, corrective action and recordkeeping for these activities to provide a framework to help ensure that the provisions of current part 110 that relate to the eight specific elements of sanitation are addressed in a systematic way, resulting in greater compliance with those provisions.

The HACCP regulation for seafood recommends but does not require that processors develop written SSOPs for the eight areas of sanitation (§ 123.11(a)). The HACCP regulation for juice requires that an SSOP be developed for these areas but does not require that it be written (§ 120.6(a)). In contrast, proposed § 117.135(d) would require written procedures for identified areas of sanitation and, in addition to monitoring and corrective actions as required in seafood and juice HACCP for the eight areas of sanitation, proposed § 117.135(d) would require monitoring procedures and verification activities.

In considering the application of preventive controls to the eight sanitation controls and practices, we considered the different framework for sanitation controls under this regulation

Deleted:

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: Part

Deleted: Part

Deleted: 110

Deleted: 110

(e.g., the additional requirements) as compared to the juice and seafood HACCP regulations, the traditional role of SSOPs as part of prerequisite programs, and the broad diversity of the food industry covered by this regulation. We tentatively conclude that it is necessary to require that the two areas included in proposed § 117.135(d)(3) be addressed as preventive controls under subpart C and therefore be subject to requirements such as mandatory written procedures. Further, we tentatively conclude that for each of the other six areas, the current CGMPs are sufficient to address any hazards and further requirements in subpart C are not necessary. For these six areas, the value of mandating written procedures and other additional requirements (e.g., written monitoring procedures and verification) would not be significant because the relevant CGMP provisions in essence serve as the written procedures to which the facility must adhere. Some facilities may find value in adding more detail to the material contained in subpart B, but FDA has tentatively concluded that that would not be necessary in order to ensure that the hazards that are reasonably likely to occur are significantly minimized or prevented.

Deleted: 110

For example, one of the six areas of sanitation is the safety of water used in food operations. In many facilities, the water is supplied by a municipal water authority that monitors the water and alerts its customers of any safety problems. Where facilities use well water, monitoring usually consists of an annual collection and analysis of the water for microbiological (and sometimes also chemical and radiological) safety. Another of the six areas contains provisions that ill workers must be excluded from operations where their presence could lead to contamination of food. A requirement in this regulation to develop written procedures for ensuring that this condition is met does not appear to be necessary, given the rather straightforward and universal nature of the controls (i.e., observe employees for signs of illness and redirect their activities accordingly). Similarly, procedures for ensuring the cleanliness of

Deleted:

Deleted:

rest rooms or checking for the presence of pests appear to be unnecessary, given the rather straightforward and universal nature of the controls.

On the other hand, equipment cleaning procedures, as would be required by proposed § 117.135(d)(3)(i)(A) are very specific to the construction of the equipment, the nature of the food, the physical characteristics of the water used, the concentration of cleaning and sanitizing chemicals, the method of application, and the cleaning and sanitizing interval, among other things. For this reason, the procedures must be clearly stated to ensure that they are consistently followed. Often these procedures are performed by contract staff, often during night shifts where management is less likely to be present. In these circumstances, explicit cleaning procedures are essential.

Deleted: 110

Procedures to prevent cross-contact and cross-contamination, as required by proposed § 117.135(d)(3)(i)(B) are similarly complex and very situational. Identifying product and traffic flow within the facility, employee hand washing and sanitizing, and employee garbing requirements is critical to ensure that employees are trained on the correct procedures to ensure product safety.

Deleted: 110

Deleted: are

Proposed § 117.135(d)(3)(ii) would require that the owner, operator, or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures that would be established in proposed § 117.135(d)(3)(i)(A) or (B). Proposed § 117.135(d)(3)(ii) is consistent with our HACCP regulations for seafood and juice, which each require that the processor correct, in a timely manner, those sanitation conditions and practices that are not met (§§ 123.11(b) and 120.6(b), respectively). Proposed § 117.135(d)(3)(ii) also is consistent with 9 CFR 416, which requires, in general, that each establishment take appropriate corrective action(s) when the establishment's SSOPs or the

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

implementation or maintenance of the SSOPs, may have failed to prevent direct contamination or adulteration of product(s); corrective actions must include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the SSOPs or appropriate improvements in the execution of the SSOPs (9 CFR 416.15).

Proposed § 117.135(d)(3)(iii) would provide that the owner, operator, or agent in charge of a facility is not required to follow the corrective actions that would be established in proposed § 117.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with proposed § 117.135(d)(3)(ii), to correct conditions and practices that are not consistent with the procedures in proposed § 117.135(d)(3)(i) (A) or (B). As discussed in sections XII.F.2 and XII.F.3 of this document, proposed § 117.145(a) would require that the owner, operator or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, and outlines specific components that must be included. Proposed § 117.145(b) would require specific actions in the event of an unanticipated problem when a preventive control is not properly implemented and a specific corrective action procedure has not been established or a preventive control is found to be ineffective. For sanitation controls, proposed § 117.135(d)(3)(ii) would require that the owner, operator or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the established sanitation control practices.

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: X.II

Deleted: X.II

Deleted: 110

Deleted: 110

Deleted: 110

There are many different ways in which conditions and practices for sanitation can deviate from the established procedures. In many instances the actions taken will be the same,

regardless of the deviation. The corrective actions will generally involve re-establishing sanitary conditions (e.g., re-cleaning a piece of equipment) and/or retraining personnel to carry out the procedures correctly. In many instances the procedural deviations are not reasonably likely to impact product (e.g., insanitary food-contact surfaces are usually detected by a pre-production inspection of the equipment by plant personnel; deviations in cleaning solution strength rarely result in the production of unsafe product if other cleaning and sanitizing procedures were properly carried out). Thus, there is rarely a need to evaluate the impact of the sanitation failure on food and to prevent food from entering commerce, as would be required by proposed § 117.145(a)(2)(ii) and (iii). Because the corrective actions that will need to be taken for most sanitation controls are so general, we see little benefit in requiring a facility to develop written corrective action procedures for the many sanitation deviations that could occur. We do expect the facility to take action to correct conditions and practices as appropriate to the situation as would be required by proposed § 117.135(d)(3)(ii). The requirement in proposed § 117.135(d)(3)(ii) to take action to correct, in a timely manner, sanitation conditions and practices that are not in accordance with procedures is consistent with proposed § 117.145(a)(2)(i), which would require that appropriate action be taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur.

Proposed § 117.135(d)(3)(iv) would require that all corrective actions taken in accordance with proposed § 117.135(d)(3)(ii) be documented in records that would be subject to verification in accordance with proposed § 117.150(c) and records review in accordance with proposed § 117.150(d)(2)(i). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

Deleted:

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: Importantly, we are only proposing to limit the applicability of proposed § 110.145(a) and (b) when the owner, operator, or agent in charge of a facility takes corrective action in accordance with proposed § 110.135(d)(3)(ii). As discussed in section XII.F.4 of this document, proposed § 110.145(c) would establish a requirement for corrective actions – including increased efforts directed at sanitation - when the environmental monitoring conducted as a verification of sanitation controls in accordance with proposed § 110.150(d)(4) demonstrates a failure in sanitation controls as evidenced by the presence of an environmental pathogen or appropriate indicator organism. ¶

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 5

8. Proposed § 117.135(d)(4)--Recall Plan

Proposed § 117.135(d)(4) would require that preventive controls include, as appropriate, a recall plan as would be required by proposed § 117.137. Proposed § 117.135(d)(4) would incorporate the statutory definition of "preventive controls" from section 418(o)(3)(E) of the FD&C Act, which establishes that preventive controls may include a recall plan. We include the details of the recall plan in proposed § 117.137 and discuss it in section XII.D of this document.

9. Proposed § 117.135(d)(5)--Other Controls

Proposed § 117.135(d)(5) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include any other controls necessary to satisfy the requirements of proposed § 117.135(a) – i.e., to significantly minimize or prevent hazards identified in the hazard analysis and to provide assurance that the food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. For example, if a facility produces a refrigerated product that could support the growth of pathogens if proper temperature is not maintained during transportation, the facility must consider the need to implement preventive controls to minimize or prevent the potential for pathogen growth due to failure to control the temperature of the product during transportation. Most instances of failing to control temperature result primarily in quality issues such as product degradation or shortened shelf life, rendering the product unpalatable and thus precluding consumption. However, it is not common that products reach high enough temperatures for sufficient time to become hazardous due to growth of pathogens that may be present. For products that present a risk that pathogens would grow and present a health hazard, preventive controls could include temperature monitoring during transportation or other procedures that would ensure that product was not exposed to

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: Supplier Approval and Verification Program

Deleted: Proposed § 110.135(d)(5) would require that preventive controls include, as appropriate, a supplier approval and verification program as would be required by proposed § 110.152. Proposed § 110.135(d)(5) would incorporate the statutory definition of "preventive controls" from section 418(o)(3)(G) of the FD&C Act, which establishes that preventive controls may include supplier verification activities that relate to the safety of food. We include the details of the supplier approval and verification program in proposed § 110.152 and discuss it in section XII.H of this document.¶
10. Proposed § 110.135(d)(6)--Other Controls¶
Proposed § 110.135(d)(6

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

temperature/time intervals during transportation that would result in increased product temperatures for sufficient time to result in a potential safety issue. Often such procedures involve the shipper ensuring that product temperature is controlled during loading of the transportation vehicle, use of temperature recording devices that record the temperature of the transportation compartment during transportation, and the receiver verifying the temperature of product during transit as displayed by the temperature device.

FDA notes that some of the controls listed in section 418(o) of the FD&C Act are not explicitly identified in proposed § 117.135. In section XII.J of this document, we request comment on an environmental monitoring program (which section 418(o)(3)(C) of the FD&C Act indicates is one of the procedures, practices, and processes that preventive controls may include, and which section 418(f)(4) of the FD&C Act identifies as a verification activity). In section XII.J of this document, we also request comment on a supplier approval and verification program as one of the procedures, practices, and processes that preventive controls may include (section 418(o)(3)(G)). In section XI.M, of this document, we request comment on supervisor, manager, and employee hygiene training. We discuss CGMPs in section XI of this document. Further, as discussed in section XII.C.7 of this document, training and CGMP controls are traditionally considered to be part of prerequisite programs, essential to effective preventive controls but often not part of them. FDA expects that compliance with those requirements in proposed part 117, subpart B will be sufficient. However, a facility may determine that in some circumstances it would be appropriate to include certain Current Good Manufacturing Practice provisions among their preventive controls (i.e., as "other controls" in proposed § 117.135(d)(6)).

Deleted: 110

Deleted: We are addressing the

Deleted: provision of

Deleted: by establishing requirements for environmental monitoring within the verification requirements in proposed § 110.150 as discussed in section XII.G.3 of this document. Preventive controls for

Deleted: and Current Good Manufacturing Practices could be required as "other controls" in proposed § 110.135(d)(4). However, such controls differ from other controls in section 418(o)(3) of the FD&C Act in the extent to which they are addressed by requirements in proposed subpart B.

Deleted: such

Deleted: 110 (proposed

Deleted:)

10. Proposed § 117.135(e)--Applicability of Monitoring, Corrective Actions, and Verification

Proposed § 117.135(e)(1)(i) through (iii) would specify that, except as provided by proposed § 117.135(e)(2), the preventive controls required under this section would be subject to monitoring as would be required by proposed § 117.140; corrective actions as would be required by proposed § 117.145; and verification as would be required by proposed § 117.150. Proposed § 117.135(e)(1)(i) through (iii) would restate the requirements of proposed §§ 117.140, 117.145, and 117.150 to clearly communicate the applicability of proposed §§ 117.140, 117.145, and 117.150 to the preventive controls that would be required under proposed § 117.135 and would establish no new requirements.

Proposed § 117.135(e)(2) would provide that the recall plan that would be established in proposed § 117.137 would not be subject to the requirements of proposed § 117.135(e)(1). A recall plan would address food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at food while it remains at the facility. Thus, as proposed, the requirements for monitoring, corrective actions, and verification have limited applicability to a recall plan. However, a "mock recall" (i.e., a simulated recall situation) is a verification activity that could identify problems with a recall plan, enable a facility to correct the problems, and provide reasonable assurance that the recall plan would be effective in removing products from commerce. FDA requests comments on whether to include a requirement for a mock recall as verification activity in the final rule.

Deleted: 11
Deleted: 110
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: , and the supplier approval and verification program that would be established in proposed § 110.152,
Deleted: 110
Deleted:

D. Proposed § 117.137--Recall Plan for Food With a Hazard That is Reasonably Likely to Occur

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

Section 418(c) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act] will be significantly minimized or prevented (section 418(c)(1) of the FD&C Act); and
- The food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (section 418(c)(3) of the FD&C Act).

Under section 418(o)(3)(D), the procedures, practices, and processes described in the definition of preventive controls may include, in relevant part, a recall plan.

2. Proposed § 117.137--Recall Plan for Food With a Hazard That is Reasonably Likely to Occur

Proposed § 117.137(a) would require that the owner, operator, or agent in charge of a facility establish a written recall plan for food in which there is a hazard that is reasonably likely to occur. Although a recall is different from other preventive controls in that it is carried out after a product is distributed, it shares the purpose of significantly minimizing or preventing hazards, which is accomplished by limiting consumption of the affected food. Time is critical during a recall. A written recall plan is essential to minimizing the time needed to accomplish a recall; additional time during which the food is on the market can result in additional consumer exposure. Following an existing plan that addresses all necessary elements of a recall helps

Deleted: Proposed § 110.135(e)(2) would provide that the supplier approval and verification program that would be established in proposed § 110.152 would not be subject to the requirements of proposed § 110.135(e)(1). As discussed in section XII.H of this document, proposed § 110.152 would be a tailored, self-contained program that addresses all applicable activities for a supplier approval and verification program. ¶
D. Proposed § 110.137--Recall Plan for Food in Which ¶
There is a Hazard that

Moved (insertion) [2]

Moved up [1]: 1. Requirements of Section 418 of the FD&C Act¶

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: “

Deleted: ”:

Deleted: “[H]azards

Deleted: [

Deleted: ”

Deleted: “[T]he

Deleted: [

Deleted:]

Deleted: [

Deleted:]”

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: in Which There is

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted:

minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked.

Proposed § 117.137(a) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3)(E) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex GPFH. The NACMCF HACCP guidelines recommend that a recall system be in place (Ref. 34). The GPFH recommends that managers ensure effective procedures are in place to enable the complete, rapid recall of any implicated lot of the finished food from the market (Ref. 44). Our HACCP regulations for seafood and juice do not include any requirements for a recall plan; recommendations for addressing a recall for food can be found in our general guidance on policy, procedures, and industry responsibilities regarding recalls in subpart C of part 7 (§§ 7.40 through 7.59). The guidance advises firms to prepare and maintain a current written contingency plan for use in initiating and effecting a recall (§ 7.59). Likewise, the FSIS HACCP regulation for meat and poultry does not require a recall plan; FSIS addresses recalls through guidance to industry.

Proposed § 117.137(b) would require that the recall plan include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

- Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected food (proposed § 117.137(b)(1));
- Notify the public about any hazard presented by the food when appropriate to protect public health (proposed § 117.137(b)(2));
- Conduct effectiveness checks to verify that the recall is carried out (proposed § 117.137(b)(3)); and

Deleted: 110

Deleted: general principles of food hygiene (

Deleted:).

Deleted: NACMCF 1998

Deleted: recommend

Deleted: Codex GPFH, 2003

Deleted:

Deleted: 110

Deleted: product

Deleted: 110

Deleted: 110

Deleted: 110

- 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 (proposed § 117.137(b)(4)).

Procedures that describe the steps to be taken would enable a facility to act promptly by following its plan when the facility determines that a recall is warranted rather than developing a plan of action after the need for a recall is identified. Procedures that assign responsibility for taking those steps would save the time needed to make such determinations during a recall and enable the owner, operator, or agent in charge of a facility to clearly communicate such responsibilities to applicable managers or staff so that such managers or staff can take action as soon as the decision to conduct a recall is made.

Directly notifying direct consignees about the recall (proposed § 117.137(b)(1)) is the most effective mechanism to ensure direct consignees know that the product is being recalled and is consistent with our general guidance on recall communications in § 7.49(a). Further, instructing direct consignees how to return or dispose of an affected product minimizes the chance the affected product will be disposed of improperly and allows direct consignees to act quickly. Further, it is consistent with our guidance on the content of recall communications in § 7.49(c)(4). We have provided guidance to industry on model recall letters (Ref. 164) (Ref. 165). This guidance may be useful in developing procedures for directly notifying direct consignees about the recall and on how to return or dispose of an affected product.

Notification procedures could identify a variety of communication means, including email, telephone, fax, text messaging, and urgent mail delivery. Notification procedures that would establish only a general notification to the public (e.g., through a press release or through information posted on a facility's Web site), without procedures for concurrent contact directly

Deleted: product

Deleted: product

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: Recall Guidance

with direct consignees about how to access the general notification, would not satisfy proposed § 117.137(b)(1); a general notification to the public would rely on the chance that the direct consignees would see the information and may not be effective.

Notifying the public about any hazard presented by the food when appropriate to protect public health is a common practice (e.g., see FDA's Web site that provides information gathered from press releases and other public notices about recalls of food (Ref. 166)). Notifying the public in such circumstances is consistent with our guidance on a recall strategy that the purpose of a public warning is to alert the public that a product being recalled presents a hazard to health (§ 7.42(b)). Notifying the public, in addition to direct consignees, may not be necessary to protect the public if, for example, the food being recalled was all distributed to food service operations (who were notified as a direct consignee) and not distributed for retail sale. Procedures in the recall plan for notifying the public could include model press releases and procedures for disseminating information to the public though press releases or other means, such as by information posted on the facility's Web site or provided to consumers using social media. We have provided guidance to industry with examples of model press releases for the presence in food of undeclared food allergens and several foodborne pathogens, including Salmonella spp. and L. monocytogenes (Ref. 164) (Ref. 165) (Ref. 167) (Ref. 168) (Ref. 169).

An effectiveness check is a procedure designed to verify that all notified consignees have received notification about the recall and have taken appropriate action; procedures to conduct effectiveness checks would be consistent with our guidance on a recall strategy in § 7.42(c)(3). Procedures to conduct an effectiveness check could expand on the procedures used to directly contact consignees about the recall –e.g., to include forms for consignees to provide information about the amount of recalled product on hand, to include information on follow up contacts via

Deleted: 110

Deleted: Recalls, Market Withdrawals, & Safety Alerts)).

Deleted: Recall Guidance

phone or email, or to include personal visits to consignees by sales representatives. We have provided guidance to industry on conducting effectiveness checks (Ref. 164); this guidance includes a model effectiveness check letter (Ref. 170), a model effectiveness check response form that could be sent to a consignee (Ref. 171), and a model questionnaire to be used during effectiveness checks conducted by telephone or by personal visit (Ref. 172).

Deleted: Recall Guidance

Deleted: ,

Deleted: ,

Deleted: .

A facility that receives recalled product from their customers must appropriately dispose of the product – e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the product. These types of disposition actions are similar to the disposition actions that a facility would consider as a corrective action as a result of a problem that is discovered before the product leaves the facility (see, e.g., the discussion of corrective actions in the final rule to establish our HACCP regulation for seafood; 60 FR 65096 at 65127). Procedures for disposition of a product can help the facility ensure that disposition of recalled product will be appropriate and will not present a risk to consumers. Implementation of such procedures is part of determining whether a recall can be considered terminated. Thus, having procedures in place can result in more efficient completion of a recall. Under § 7.55, appropriate disposition of recalled product is a consideration in determining whether a recall is terminated.

We request comment on whether the procedures to be included in the recall plan (i.e., to directly notify consignees, to notify the public, to conduct effectiveness checks and to appropriately dispose of recalled product) are appropriate for all types of facilities or if they should be modified for certain facilities.

We request comment on whether we should require a recall plan to include procedures and assignments of responsibility for notifying FDA of recalls subject to the plan. Notifying FDA could enhance the effectiveness of a recall by allowing FDA to take appropriate steps to

minimize the risk of illness or injury related to recalled products. As discussed in section II.A.6 of this document, notifying FDA of a reportable food is required by section 417 of the FD&C Act. Reportable food reports include information about whether a reportable food is being recalled. Thus, in some cases, reporting a recall to FDA could be accomplished by submitting a reportable food report required under section 417. In other cases, facilities could notify the local FDA district office of the recall.

E. Proposed § 117.140--Monitoring

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

Section 418(a) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the performance of the preventive controls. Section 418(d) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act to provide assurances that the outcomes described in section 418(c)] shall be achieved. The outcomes relevant to this proposal are those that provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that food manufactured, processed, packed or held by a facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Section 418(g) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act.

Deleted:

Deleted: 110

Moved (insertion) [3]

Moved up [2]: 1. Requirements of Section 418 of the FD&C Act¶

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: "[t]he

Deleted: . . .

Deleted: [

Deleted:]."

Deleted: "[t]he

Deleted: [

Deleted:]

Deleted: [

Deleted: ."

Section 418(h) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act.

2. Monitoring in HACCP Systems

Proposed § 117.3 would define "monitor" to mean "to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification." We discussed this definition, and how it is used in HACCP systems, including in guidelines developed by NACMCF and Codex, in section X.B.4 of this document. Examples of monitoring activities include: visual observation and measurement of temperature, time, pH, and moisture level (Ref. 34). The NACMCF HACCP guidelines identify three purposes of monitoring (Ref. 34). First, monitoring is essential to managing food safety because it facilitates tracking of the operation (i.e., the "process, point or procedure" that is being controlled). This provides ongoing information about whether the process, point or procedure is under control (i.e., operating according to plan), and can provide information about shifts away from control. If monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a deviation from a critical limit occurs. For example, if the temperature needed to ensure safety of roasted nuts is 290ºF, and the procedure for roasting the nuts in an oil roaster calls for an operating temperature of 350ºF, monitoring would detect that the temperature in the oil roaster was dropping and enable the facility to identify and fix the problem with temperature before the temperature drops to 290ºF. Second, monitoring is used to determine when a deviation occurs at a critical control point (i.e., exceeding or not meeting a critical limit), indicating there is loss of control. In the previous example, there would be loss of control if the temperature drops to

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: C

Deleted: NACMCF, 1998

Deleted: NACMCF, 1998

289ºF. When a deviation occurs, an appropriate corrective action must be taken – e.g., stop the roasting process until the temperature in the oil roaster can be maintained above 290ºF and reprocess nuts that were not roasted at the appropriate temperature. Third, monitoring provides written documentation for use in verification. For example, if the facility monitors the temperature of the oil roaster continuously, using a temperature recording device, the output of the temperature recording device is available during the verification activity of review of records. Under this approach, monitoring is directed to evaluating implementation of the preventive controls, and the written documentation of the monitoring is then used in verification.

3. Verification in HACCP Systems

Proposed § 117.3 would define "verification" to mean "those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan." We discussed this definition, and how it is used in HACCP systems, in section X.B.4 of this document. The NACMCF HACCP guidelines identify several aspects of verification (Ref. 34). One aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Another aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. Both of these aspects are directed at the effectiveness of a preventive control; they establish that the preventive control is scientifically valid for controlling the hazard and verify that the preventive control is accomplishing its intended purpose. The Codex HACCP Annex addresses verification as determining compliance with the HACCP plan and confirming that the HACCP system is working effectively (Ref. 35). Examples of verification activities include review of monitoring records and review of records

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: C

Deleted: NACMCF, 1998

Deleted: Codex 2003

for deviations and corrective actions. We discuss verification activities in more detail during our discussion of proposed § 117.150 (Verification) in section XII.G of this document.

Deleted: 110

4. Relationship Between Monitoring and Verification

Monitoring and verification are closely related; both address the performance of preventive controls, and verification relies in part on monitoring records to establish that preventive controls developed to significantly minimize or prevent hazards are being implemented according to plan. Three provisions of section 418(f) of the FD&C Act (Verification) are particularly relevant when considering the role of monitoring. First, section 418(f)(1) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the preventive controls implemented . . . are adequate to control the hazards identified. . . ." Second, section 418(f)(2) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the owner, operator, or agent is conducting monitoring. . . ." Third, section 418(f)(4) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the preventive controls implemented . . . are effectively and significantly minimizing or preventing the occurrence of identified hazards. . . ."

Formatted: FR Preamble Para Indent Line 1 36 point

5. Monitoring the Performance of Preventive Controls

Section 418(a) requires monitoring the "performance" of preventive controls whereas section 418(d) requires monitoring their "effectiveness." We tentatively conclude that the language of section 418 regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the performance of preventive controls. "Performance" means "the execution or accomplishment of an action, operation, or process undertaken or ordered" (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 2157) and is consistent with use of the term "monitoring" in traditional HACCP. Monitoring the performance of preventive controls would

Formatted: FR Preamble Para Indent Line 1 36 point

be undertaken to determine whether a facility is implementing its preventive controls and would generate records that would be used to verify implementation of the controls. For example, monitoring performance could include visual observations and measurements of temperature, time pH, and moisture level. In contrast, “effectiveness” refers to the quality of "having an effect or result" (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 794) and is not consistent with use of the term “monitoring” in traditional HACCP. The term “verification,” not “monitoring” is used to refer to effectiveness in traditional HACCP systems. Monitoring the effectiveness of preventive controls would evaluate whether the preventive controls were working.

Deleted:

Requiring monitoring of the effectiveness of the preventive controls would be redundant with required verification activities. Section 418(f) requires verification that the preventive controls “are effectively and significantly minimizing the occurrence of the identified hazards. . . .” The activities necessary for such verification are the same as would be required for monitoring the effectiveness of the preventive controls. For example, because effectiveness addresses whether the hazard is controlled, monitoring the effectiveness could include testing for the presence of the hazard, such as testing for the presence of staphylococcal enterotoxin that can occur during cheese making if the pH does not drop to a low enough level in a short enough time. Further, requiring monitoring of effectiveness rather than performance of the preventive controls would create a significant gap in the preventive controls system if the factors that are critical to control of the hazard, e.g., pH of the cheese curd and time, are not monitored to ensure the process is implemented correctly. In contrast, monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately (e.g., pH of the cheese curd drops below 5.6 within 8

hours) and thereby are effectively and significantly minimizing or preventing the hazards (e.g., staphylococcal enterotoxin).

As discussed more fully in the next section of this document, this interpretation also is grounded in our existing HACCP regulations and guidance. Section 418(n)(5) of the FD&C Act directs the Secretary, in promulgating these regulations, to review hazard analysis and preventive control programs in existence to ensure that this regulation is consistent to the extent practicable with applicable domestic and internationally-recognized standards in existence. Requiring monitoring of the performance of preventive controls is consistent with applicable domestic and internationally recognized standards.

Therefore, we tentatively conclude that this interpretation is reasonable, and we propose to adopt it in the proposed requirements implementing section 418(d) of the FD&C Act. We request comment on this interpretation.

6. Proposed § 117.140--Monitoring

a. Proposed § 117.140(a)--Requirement for written procedures for monitoring. Proposed § 117.140(a) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. Proposed § 117.140(a) would implement sections 418(d) and (h) of the FD&C Act.

Proposed § 117.140(a) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. We discuss the purposes that the NACMCF HACCP guidelines identify for monitoring under a HACCP system in section II.C.4.d of this document. Each of these purposes applies to preventive controls as well, and we tentatively conclude that these purposes would be achieved

Deleted:

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

by proposed § 117.140(a). Proposed § 117.140(a) would facilitate tracking the implementation of the preventive controls to provide assurance that they are consistently performed; if monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a preventive control is not properly implemented and potentially unsafe product is produced. Further, if monitoring is conducted with sufficient frequency to ensure preventive controls are consistently performed, it will detect if a preventive control is not properly implemented (e.g., if the temperature of an oven falls below the temperature needed to ensure safety), indicating loss of control and signaling the need for an appropriate corrective action. Finally, the proposed monitoring requirement would result in written documentation for use in verification.

The Codex HACCP Annex advises that monitoring procedures must be able to detect loss of control at the CCP and ideally should provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. The Codex HACCP Annex also recommends that, where possible, process adjustments be made when monitoring results indicate a trend towards loss of control at a CCP, before a deviation occurs (Ref. 35). Federal HACCP regulations for seafood, juice, and meat and poultry require in the written HACCP plan monitoring of control measures to determine whether physical, chemical, or biological parameters are being met (i.e., monitoring of critical control points to ensure compliance with the critical limits) (§ 123.6(b) and (c)(4)), § 120.8(a) and (b)(4), and 9 CFR 417.2(b)(1) and (c)(4), respectively). Like the Federal HACCP regulations for seafood, juice, and meat and poultry, the requirements for monitoring in proposed § 117.140(a) focus on evaluating performance of the preventive controls.

Deleted: 110

Deleted: 110

Deleted: Codex 2003

Deleted: 110

Proposed § 117.140(a) would require that the monitoring procedures be written. Under section 418(d) of the FD&C Act, the owner, operator, or agent in charge of a facility must monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act, and under section 418(h) of the FD&C Act the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act must be included in the written plan. The NACMCF HACCP guidelines note under record-keeping and documentation procedures that the procedures for monitoring should be provided (Ref. 34). The Codex HACCP Annex includes "monitoring procedures" in its example of a HACCP worksheet (Ref. 35). Federal HACCP regulations for seafood, juice and meat and poultry require that the HACCP plan be written (§§ 123.6(b), 120.8(a), and 9 CFR 417.2(b)(1), respectively) and that procedures for monitoring be included in the written HACCP plan (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively).

Proposed § 117.140(a) would require that the monitoring procedures include the frequency with which they are to be performed. We discuss the frequency of monitoring in the next section of this document. Briefly, the frequency of monitoring must be sufficient to ensure that the preventive control is consistently performed in order to help ensure that the preventive control is effective. The NACMCF HACCP guidelines note that the frequency of monitoring should be provided in the HACCP Plan Summary Table (Ref. 34). Federal HACCP regulations for seafood, juice and meat and poultry require that the written HACCP plan include the procedures, and frequency thereof, that will be used for monitoring (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively).

b. Proposed § 117.140(b)--Frequency of monitoring. Proposed § 117.140(b) would require that the owner, operator, or agent in charge of a facility monitor the preventive controls

Deleted: 110

Deleted: NACMCF 1998

Deleted: Monitoring

Deleted: Codex 2003

Deleted: 110

Deleted: NACMCF 1998).

Deleted:

Deleted: 110

Deleted: 110

with sufficient frequency to provide assurance that they are consistently performed. Proposed § 117.140(b) does not specify a single monitoring frequency applicable to all facilities and processes. Rather, it requires monitoring with "sufficient frequency" to assure that the preventive controls are consistently performed. Proposed § 117.140(b) would implement section 418(d) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex.

Deleted: 110

Deleted: 110

The NACMCF guidelines recommend continuous monitoring where possible (Ref. 34). Continuous monitoring is possible with many types of physical and chemical parameters. For example, the temperature and time for many thermal processes can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the affected product can be retained and evaluated to determine the appropriate disposition. Examples of other parameters that can be monitored continuously include pressure, flow rate and pH.

Deleted: NACMCF 1998

However, the NACMCF guidelines acknowledge that continuous monitoring may not be possible, or even necessary, in all cases. For example, it may not be practical to continuously monitor the size of particles in a food to ensure they do not exceed the maximum dimensions that are required to ensure a process such as cooking, cooling, or acidification can be properly implemented. NACMCF states that if monitoring is not continuous it may be difficult to ensure that the preventive controls are consistently implemented and a problem has not occurred. Thus, according to NACMCF, the frequency of non-continuous monitoring must be sufficient to ensure that a critical control point (or, in the case of this proposed rule, a preventive control) is under control (Ref. 34). The Codex HACCP Annex also notes that, if monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control

Deleted: NACMCF 1998

(Ref. 35). The frequency of non-continuous monitoring would depend on factors such as the proximity of operating conditions to the conditions needed to ensure safety and the variability of the process. For example, if the temperature needed to ensure safety of roasted nuts is 290ºF, non-continuous monitoring would need to be more frequent when an oil roaster for nuts is operated at 300ºF than when the oil roaster is operated at 350ºF. As another example, if temperatures vary by 10-15ºF during processing, monitoring would need to be more frequent than if the variation is only 1-2 degrees.

As discussed in the previous section of this document, Federal HACCP regulations for seafood, juice, and meat and poultry require that the written HACCP plan include the procedures, and frequency thereof, that will be used for monitoring (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively). Our Fish and Fishery Products Hazards and Controls Guidance discusses the frequency of monitoring and notes that the frequency of monitoring depends upon the circumstances, with continuous monitoring being desirable; in some cases, continuous monitoring may be necessary, while in other cases, it may not be necessary or practical (Ref. 173). Our Juice HACCP Hazards and Controls Guidance provides examples of "Summary HACCP Plans," which show how the frequency of monitoring would depend on the circumstances (Ref. 4).

c. Proposed § 117.140(c)--Requirement for records. Proposed § 117.140(c) would require that all monitoring of preventive controls in accordance with proposed § 117.140 be documented in records that are subject to verification in accordance with § 117.150(b) and records review in accordance with proposed § 117.150(d)(2)(i). Proposed § 117.140(c) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and

Deleted: Codex 2003

Deleted: Seafood HACCP edition 4).

Deleted: Juice HACCP guide

Deleted: 110

Formatted: No underline

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 5

Deleted: 110

meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan (Ref. 34). The Codex HACCP Annex gives records of CCP monitoring activities as an example of records (Ref. 35). Our HACCP regulations for seafood and juice require that the HACCP plan provide for a recordkeeping system that documents the monitoring of the critical control points (§§ 123.6(c)(7) and 120.8(b)(7), respectively). The FSIS HACCP regulation for meat and poultry requires records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values.

The monitoring records would be used to verify that the preventive controls are adequate, as would be required by proposed § 117.150(a), and to verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, as would be required by proposed § 117.150(d). This is further discussed in section XII.G.5.b of this document. Together, proposed §§ 117.140(a), (b), and (c) and 117.150(a), (b), and (d) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

F. Proposed § 117.145--Corrective Actions

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

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the

Deleted: NACMCF 1998

Deleted: Codex 2003

Deleted: .

Deleted: 110

Deleted: 110

Deleted: f

Deleted: 110

Deleted: 110

Deleted: 110

Moved (insertion) [4]

Moved up [3]: 1. Requirements of Section 418 of the FD&C Act¶

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: "[t]he

procedures used by the facility to comply with the requirements of section 418 of the FD&C Act. Section 418(e) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective:

- Appropriate action is taken to reduce the likelihood of recurrence of the implementation failure (section 418(e)(1) of the FD&C Act);
- All affected food is evaluated for safety (section 418(e)(2) of the FD&C Act); and
- All affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (section 418(e)(3) of the FD&C Act).

Section 418(f)(4) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility verify that the preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards.

2. Proposed § 117.145(a)--Corrective Action Procedures

Proposed § 117.145(a)(1) would require that the owner, operator, or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. Having written procedures in place would enable facilities to act quickly and appropriately when preventive controls are not properly implemented – e.g., when a parameter associated with heat processing exceeds a maximum value or falls below a minimum value. Proposed § 117.145(a)(1) would implement section 418(e) of

Deleted: [
Deleted:]…."
Deleted: "[t]he
Deleted: [
Deleted:]
Deleted: ":
Deleted: "[A]ppropriate
Deleted: "
Deleted: "[A]ll
Deleted: "
Deleted: "[A]ll
Deleted: [
Deleted:]
Deleted: [
Deleted:]"
Formatted: FR Preamble Para Indent Line 1 36 point, Indent: Left: 0"
Deleted: "
Deleted: [
Deleted:]
Deleted: …."
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110

the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

The NACMCF HACCP guidelines define a corrective action as procedures followed when a deviation occurs at a CCP and recommend that specific corrective actions be developed in advance for each CCP and included in the HACCP plan (Ref. 34). The Codex HACCP Annex advises that specific corrective actions be developed for each CCP in the HACCP system (Ref. 35). Our HACCP regulations for seafood and juice require that processers take corrective action whenever a deviation from a critical limit occurs, either by following specific corrective action procedures specified in the regulation, or by following procedures in written corrective action plans that the processor develops (§§ 123.7 and 120.10, respectively). If the processor of a seafood or juice product covered by the applicable HACCP regulation develops such plans, they must be included in the written HACCP plan (§§ 123.6(c)(5) and 123.7(b) and 120.8(b)(5), respectively). The FSIS HACCP regulation for meat and poultry requires that the written HACCP plan identify the corrective action to be followed in response to a deviation from a critical limit (9 CFR 417.3(a)).

As discussed in section XII.C.4 of this document, the proposed rule would establish requirements for preventive controls (which may be at critical control points), and proposed § 117.135(c)(2) would require that the preventive controls include, as appropriate to the facility and the food, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur (which reflects the NACMCF definition of a critical limit). As already noted earlier in this section, if a parameter associated with heat processing falls below a minimum value, corrective action would be triggered. Thus, the

Deleted: NACMCF,1998

Deleted: CAC, 2003

Deleted: 110

concept in the proposed rule of taking corrective action when a preventive control is not properly implemented is similar to the concept in HACCP systems of taking corrective action for a deviation from a critical limit at a critical control point.

The benefits from identifying corrective action procedures in advance of the need to actually take corrective action largely derive from having the procedures in written form. Written corrective action procedures would be essential to the facility's food safety team, to auditors, and to inspectors. The facility's food safety team will be responsible for ensuring that appropriate corrective actions are taken if preventive controls are not properly implemented. Having access to appropriate, written corrective action procedures determined in advance of the need for such action can ensure that correct and complete actions are taken in a timely fashion without the need for the team to meet and decide on the appropriate action. Having written corrective action procedures available for auditors and for inspectors is essential for them to assess the adequacy of the food safety plan; the procedures a facility will use to address implementation failures are essential to the production of safe food, and without them a complete assessment cannot be made. Written corrective action procedures also would be useful for training purposes, so that employees who would need to implement the corrective action procedures will be prepared for what they would need to do.

Proposed § 117.145(a)(2) would implement section 418(e) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must establish corrective action procedures) and section 418(h) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must prepare a written plan). Proposed § 117.145(a)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and with Federal HACCP regulations for seafood, and juice, and meat and poultry. The NACMCF HACCP guidelines recommend that

Deleted: 110

Deleted: 110

specific corrective actions be included in the HACCP plan (Ref. 34). In its discussion of corrective actions, the Codex HACCP Annex advises that deviation and product disposition procedures be documented in the HACCP record keeping (Ref. 35). Our HACCP regulations for seafood and juice both require that the written HACCP plan include any corrective action plans that have been developed by the processor (§§ 123.6(c)(5) and 123.7(b) and 120.8(b)(5)). The FSIS HACCP regulation for meat and poultry requires that the written HACCP plan identify the corrective action to be followed in response to a deviation from a critical limit (9 CFR 417.3(a)).

Proposed § 117.145(a)(2) would require that corrective action procedures describe the steps to be taken to ensure that:

- Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur (proposed § 117.145(a)(2)(i));
- All affected food is evaluated for safety (proposed § 117.145(a)(2)(ii)); and
- All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 117.145(a)(2)(iii)).

The hazard analysis and risk-based preventive controls in this proposed rule are designed to identify hazards that are reasonably likely to occur, and to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. However, a preventive controls system, similar to a HACCP system (Ref. 34), accounts for the possibility

Deleted: NACMCF, 1998

Deleted: Codex, 2003

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: NACMCF, 1998

of implementation and effectiveness problems and includes procedures for addressing those problems and any affected food.

Proposed § 117.145(a)(2) would implement sections 418(e)(1)-(3) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that corrective actions include elements to determine and correct the cause of non-compliance and to determine the disposition of non-compliant product (Ref. 34). The Codex HACCP Annex advises that the specific corrective actions must ensure that the CCP has been brought under control and that actions taken must also include proper disposition of the affected product (Ref. 35). Our HACCP regulations for seafood and juice establish that a corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation, and the cause of the deviation is corrected (§§ 123.7(b) and 120.10(a), respectively). The FSIS HACCP regulation for meat and poultry requires that the HACCP plan describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) the cause of the deviation is identified and eliminated; (2) the CCP will be under control after the corrective action is taken; (3) measures to prevent recurrence are established; and (4) no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce (9 CFR 417.3(a)).

Section 418(e)(1) of the FD&C Act and proposed § 117.145(a)(2)(i) explicitly require that action be taken to reduce the likelihood of recurrence of the implementation failure. Although not prescribed by proposed § 117.145(a)(2)(i), reducing the likelihood of recurrence of

Deleted: 110

Deleted: NACMCF, 1998

Deleted: CAC 2003

Deleted: 110

Deleted: 110

an implementation failure is best accomplished by identifying the root cause of failure and then taking action to address that root cause. If the root cause is not identified and corrected, it is more likely that the failure will recur. For example, if the temperature of a heat process cannot be maintained, a corrective action to raise the temperature using the controller may correct the problem short-term. However, if the root cause is a lack of boiler capacity to run multiple heating units at the same time, corrective action should address replacing the boiler to increase capacity. Similarly, if a facility cannot cool a food rapidly enough in a refrigerator to meet the cooling times and temperatures in its HACCP plan, the initial corrective action may be to move product into a freezer for cooling. If the root cause is determined to be that the product was filled too high in the cooling tray, the corrective action may be to include procedures to measure the depth of product in the tray. If the root cause is determined to be insufficient cooling capacity to remove heat from the amount of product being cooled, the corrective action may involve using a cooling unit with greater cooling capacity or changing the method of cooling, e.g., to a blast freezer.

Proposed § 117.145(a)(2)(ii) and (iii), would require that corrective action procedures include an evaluation of all food affected by a problem and procedures for ensuring that affected food is prevented from entering into commerce if the owner, operator or agent in charge of the facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Such an evaluation is implicit in our HACCP regulations for seafood and juice (§§ 123.7(b) and 120.10(a)) in that these sections do not explicitly require that food affected by the problem be evaluated, but do require that steps be taken to ensure that product that is injurious to health or otherwise adulterated does not enter commerce. Although our HACCP regulations for seafood and juice do not specify the steps that

Deleted: 110

must be described in a corrective action plan, the regulations require that specific steps be taken when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation (§§ 123.7(c) and 120.10(b), respectively). Under these regulations, required steps include segregating and holding effected product, performing or obtaining a review to determine the acceptability of the affected product for distribution and taking corrective action, when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. FDA notes that the corrective action procedures in the HACCP regulations do not reference misbranding under section 403(w) of the FD&C Act. Section 403(w) of the FD&C Act was added to the FD&C Act by the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II), which was enacted after issuance of both the seafood and juice HACCP regulations. However, our HACCP regulation for juice includes the presence of undeclared ingredients that may be allergens as a potential hazard that must be considered in the hazard analysis (§ 120.7(c)(8)), and our Fish and Fishery Products Hazards and Controls Guidance (Fourth Edition) (Ref. 173) and Juice HACCP Hazards and Controls Guidance (Ref. 4) both include recommendations directed to hazards from undeclared food allergens.

3. Proposed § 117.145(b)--Corrective Action in the Event of an Unanticipated Problem

Proposed § 117.145(b)(1) would require that if a preventive control is not properly implemented and a specific corrective action has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility take corrective action to identify and correct the problem, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under proposed § 117.145(a)(2)(i)-(iii). However, a facility might not anticipate all of

Deleted:

Deleted: seafood hazards/controls guide

Deleted: juice guide

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

the problems that may occur, and a facility may experience an implementation failure for which a corrective action procedure has not been established. Regardless of whether a problem was anticipated and a corrective action procedure was developed in advance, corrective actions to accomplish the steps that would have been included in a corrective action procedure are necessary. Likewise, a facility might determine (e.g., as a verification activity in accordance with proposed § 117.150(d), discussed in section XII.G.5 of this document), that a preventive control is ineffective. For example, detecting a pathogen in an RTE food may signal that preventive controls for that pathogen are ineffective. As in the case of an unanticipated implementation failure of a preventive control, corrective actions would be necessary if a preventive control is found to be ineffective.

Deleted: 110

Proposed § 117.145(b)(1) is consistent with Federal HACCP regulations for seafood, juice, and meat and poultry. Our HACCP regulations for seafood and juice require that, when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor segregate and hold the affected product; perform or obtain a review to determine the acceptability of the affected product for distribution; take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and take corrective action, when necessary, to correct the cause of the deviation (§§ 123.7(c)(1)-(4) and 120.10(b)(1)-(4), respectively). The FSIS HACCP regulation for meat and poultry (9 CFR 417.3(b)) requires, in relevant part, that if a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must: (1) segregate and hold the affected product, at least until the requirements of 9 CFR 417.3(b)(2) and (3) are met; (2) perform a review to determine the acceptability of the affected product for

Deleted: 110

distribution; and (3) take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce. The NACMCF HACCP guidelines and the Codex HACCP Annex are silent on the specific issue of taking corrective actions when a preventive control is not properly implemented and a specific corrective action has not been established or when a preventive control has been found to be ineffective. However, proposed § 117.145(b)(1) is consistent with HACCP principles, discussed earlier in this section, recommended in the NACMCF HACCP guidelines and Codex HACCP Annex regarding the importance of corrective actions whenever there is a deviation from a critical limit. In each of the situations described (following an established corrective action, taking corrective action in the absence of a plan, or taking corrective action when the preventive control is found to be ineffective) the intent of taking corrective action is to restore control and to ensure that hazardous foods do not reach the consumer.

Deleted: 110

Deleted:

Proposed § 117.145(b)(2) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 117.150(f) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented and a specific corrective action has not been established, or if a preventive control is found to be ineffective. (We use the term "reanalyze" when we refer to a reassessment of the validity of a preventive control or the food safety plan to control a hazard.) Under proposed § 117.150(a), the verification required by section 418(f) of the FD&C Act would include validation of the food safety plan, referring to whether it is effectively controlling the hazards or "working correctly." See section XII.G of this document for a discussion of proposed requirements for verification (including validation and reanalysis) under section 418(f) of the

Deleted: 110

Deleted: 110

Deleted: 110

FD&C Act. Proposed § 117.145(b)(2) would apply to unanticipated food safety problems, and the unanticipated nature of the problems is relevant to the reanalysis of the food safety plan. If the owner, operator, or agent in charge of a facility has assessed its procedures, practices, and processes and has not identified a specific failure as a foreseeable occurrence, the owner, operator, or agent in charge must assess whether the problem is simply an implementation failure that could be expected to occur in the normal course of manufacturing, processing, packing or holding the food, or the result of a system-wide problem that is not being properly addressed by the plan (e.g., ineffective preventive controls). If the problem is simply an implementation failure, and such a failure is now a foreseeable circumstance, reanalysis of the food safety plan would be necessary to determine whether a corrective action procedure should be established for that foreseeable failure. Likewise, if the problem is the result of a system-wide problem that is not being properly addressed by the plan (or is otherwise a result of ineffective preventive controls), reanalysis of the food safety plan would be necessary to identify effective preventive controls. Either way, reanalyzing the food safety plan and modifying it as necessary would be necessary to reduce the risk of recurrence of the problem.

Proposed § 117.145(b)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines, in relevant part, recommend that validations (i.e., an assessment of the validity of the HACCP plan) be conducted when there is an unexplained system failure (e.g., an implementation failure or ineffective preventive controls) (Ref. 34). The Codex HACCP Annex, in relevant part, advises that verification procedures be used to determine if the HACCP system is working correctly (Ref. 35); such verification procedures would also be used if an unexpected implementation failure of a preventive control suggests that the system is not

Deleted: 110

Deleted: processed

Deleted: 110

Deleted:

Deleted: NACMCF, 1998

Deleted: ;

working correctly. Our HACCP regulations for seafood and juice, in relevant part, require that, when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor must perform or obtain timely reassessment or verification by a trained individual to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation and to modify the HACCP plan as necessary (§§ 123.7(c)(5) and 120.10(b)(5), respectively). The FSIS regulation for meat and poultry requires, in relevant part, that if a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must perform or obtain reassessment to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan (9 CFR 417.3(b)(4)). (The FSIS HACCP regulation for meat and poultry uses the term "reassessment" much as this proposed rule would use the term "reanalysis.")

4. Proposed § 117.145(c)--Documentation.

Proposed § 117.145(c) would require that all corrective actions taken in accordance with this section be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(2)(i). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

G. Proposed § 117.150--Verification

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

Section 418(f) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that:

Moved down [5]: Environmental Monitoring

Deleted: 110

Deleted: Corrective Actions for

Deleted: As also discussed in section II.D.2.a of this document, the risk of serious illness or death from consumption of a food contaminated with L. monocytogenes increases with the number of L. monocytogenes in the food. L. monocytogenes can grow under refrigeration conditions and, thus, a small number of L. monocytogenes in a refrigerated food (such as soft cheese) that supports its growth could grow to a number sufficient to cause serious illness or death by the time the consumer eats the food. In contrast, a small number of L. monocytogenes in a refrigerated food (like hard cheese) that does not support its growth would remain a small number and would present a much lower risk of serious illness or death. Thus, where the intended use could involve extended storage under refrigeration, finished product testing is appropriate if Listeria spp. is detected on a food-contact surface, particularly if the food supports growth.¶
An example of a risk-based approach to finding Listeria spp. on a food-contact surface when the food will not be further processed to adequately reduce

Moved down [10]: L.

Deleted: Proposed § 110.150(d)(4) would establish a requirement for monitoring of environmental ...

Formatted: No underline

Deleted: monocytogenes is to implement "hold ...

Formatted ...

Moved down [6]: monocytogenes.

Moved down [7]: L.

Moved down [8]: L.

Formatted: No underline

Deleted: monocytogenes (Ref, FSIS Lm guidan ...

Deleted: monocytogenes is a hazard that must b ...

Moved down [9]: L.

Moved down [11]: L.

Formatted: No underline

Deleted: monocytogenes or Listeria spp. on foo ...

Formatted: No underline

Deleted: monocytogenes on a food-contact ...

Formatted: No underline

Deleted: 110

Deleted: 110

Deleted: 5

Deleted: 110

Moved up [4]: 1. Requirements of Section 418 ...

Moved (insertion) [12]

Formatted ...

- The preventive controls implemented under section 418(c) of the FD&C Act are adequate to control the hazards identified under [section 418(b) of the FD&C Act (section 418(f)(1) of the FD&C Act);
- The owner, operator, or agent is conducting monitoring in accordance with section 418(d) of the FD&C Act (section 418(f)(2) of the FD&C Act);
- The owner, operator, or agent is making appropriate decisions about corrective actions taken under section 418(e) of the FD&C Act (section 418(f)(3) of the FD&C Act);
- The preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means (section 418(f)(4) of the FD&C Act); and
- There is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f)(5) of the FD&C Act).

In addition, section 418(g) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Further, section 418(i) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall conduct a reanalysis under section 418(b) of the FD&C Act (the

Deleted: "[T]he
Deleted: [
Deleted:]
Deleted:]"
Deleted: "[T]he
Deleted: [
Deleted:]"
Deleted: "[T]he
Deleted: [
Deleted:]"
Deleted: "[T]he
Deleted: [
Deleted:]
Deleted: "
Deleted: "[T]here
Deleted: [
Deleted:]
Deleted: "
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: "[t]he
Deleted: [
Deleted:],
Deleted: [
Deleted:],
Deleted: ."
Deleted: "[t]he
Deleted: [

requirement to identify and evaluate known or reasonably foreseeable hazards) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is operative. The owner, operator, or agent shall revise the written plan required under section 418(h) of the FD&C Act if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under section 418(i) of the FD&C Act to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

2. Proposed Requirements for Validation

a. Proposed § 117.150(a)--Validation that preventive controls are adequate to control the hazard. Proposed § 117.150(a) (Validation) would require that, except as provided by paragraph (a)(3), the owner, operator, or agent in charge of a facility validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. Proposed § 117.150(a) would implement section 418(f)(1) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines describe verification as activities that, in relevant part, determine the validity of the HACCP plan (Ref. 34). The

Deleted:)]
Deleted: [
Deleted:]
Deleted: [
Deleted:]
Deleted: ."
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: NACMCF, 1998

NACMCF guidelines advise that an important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that, if the HACCP plan is properly implemented, these hazards will be effectively controlled (Ref. 34). The Codex HACCP guidelines recommend that, where possible, validation activities include actions to confirm the efficacy of all elements of the HACCP system (Ref. 35). Our HACCP regulation for seafood does not specifically use the term "validation," but it reflects the concept in requiring that every processor verify that the HACCP plan is adequate to control the hazards (§ 123.8(a)). Our HACCP regulation for juice addresses both validation of the HACCP plan (§ 120.11(b)) and the hazard analysis (§ 120.11(c)). The regulation requires each processor to validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur at least once within 12 months after implementation and at least annually thereafter. (This annual validation is the same as reanalysis proposed in § 117.150(f) and discussed in section XII.G.7 of this document. The requirement for validation of the hazard analysis in § 120.11(c) aligns more with a requirement for reanalysis and is discussed in section XII.G.2.a of this document). The FSIS HACCP regulation for meat and poultry (9 CFR 417.4(a)) requires that every establishment validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis. The regulations and guidelines described above reflect the widespread recognition of the importance of ensuring that preventive controls, if properly implemented, will adequately control the hazards.

Deleted: NACMCF, 1998

Deleted: CAC 2003

Deleted: 110

Deleted: e

Deleted: 6

b. Proposed § 117.150(a)(1)--Validation by a qualified individual prior to implementation and on reanalysis. Proposed § 117.150(a)(1) would require that the validation of the preventive controls be performed by (or overseen by) a qualified individual. The preventive controls must be adequate to control the hazards identified in the hazard analysis as reasonably likely to occur.

Deleted: 110

Deleted: 110

Determining whether specific preventive controls are adequate requires an individual who is knowledgeable in the hazards associated with a product and process and the appropriate preventive controls for those hazards. Such knowledge requires scientific and technical expertise developed through training, experience or both.

Proposed § 117.150(a)(1)(i) would require that validation occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production. The validation of preventive controls includes collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies), as discussed in the next section of this document. The collected data or information, or the studies, would establish a scientific and technical basis for the preventive controls used, in particular those that involve critical control points. This scientific and technical basis largely must be established prior to producing a product to ensure that the food produced using those preventive controls will be safe. However, as a practical matter, the scientific and technical basis for some aspects of a preventive control may require production conditions and, thus, would be established by the collection of data or information during, rather than before, producing a product. For example, ensuring that limits for control parameters can be met during production would be done under production conditions. FDA tentatively concludes that preventive controls that require the collection of data or information, or studies, during production conditions are part of validation, and, thus proposed § 117.150(a)(1)(i) would require that the validation of preventive controls be performed, when necessary, during the first six weeks of production. We selected six weeks as a time interval that would be adequate to allow facilities to methodically collect data and information during production, yet would be close to implementation of a preventive control.

Deleted: Under proposed § 110.150(a)(1), the validation could be performed or overseen by a qualified individual.

Deleted: 110

Deleted: 110

The NACMCF HACCP guidelines recommend that initial validation be conducted prior to and during initial implementation of the plan (Ref. 34). A Codex document entitled "Guidelines for the Validation of Food Safety Control Measures" (hereinafter the Codex validation guidelines) recommends that validation of control measures be performed, whenever possible, before their full implementation (Ref. 127). Codex also includes as a validation measure the collection of data, e.g., product and/or environmental sampling and testing, during operating conditions in the food operation for a specified period (e.g., 3-6 weeks) (Ref. 127). The HACCP regulation for juice requires that validation of HACCP plans be conducted once during the year after implementation and at least annually thereafter (§ 120.11(b)). The FSIS HACCP regulation for meat and poultry (9 CFR 417.4(a)) requires that initial validation be conducted upon completion of the hazard analysis and development of the HACCP plan to determine that the HACCP plan is functioning as intended (9 CFR 417.4(a)(1)). During the HACCP plan validation period, the meat or poultry establishment must repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan (9 CFR 417.4(a)(1)).

FDA requests comment on whether the proposed time frame for validation should be shorter or longer. Comments should provide the basis for an alternative time frame.

Proposed § 117.150(a)(1)(ii) would require that the validation of the preventive controls be performed whenever a reanalysis of the food safety plan reveals the need to do so. The circumstances under which a reanalysis would be required are addressed in proposed § 117.150(f). Proposed § 117.150(f)(1)(ii) would require that the owner, operator, or agent in charge of a facility complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is

Deleted: NACMCF 1998

Deleted: Codex Val 2008

Deleted: Codex Val. 2008

Deleted: 110

Deleted: 110

Deleted: 110

operative, or, when necessary, during the first six weeks of production. All preventive controls established to address a hazard identified as reasonably likely to occur must have a scientific and technical basis; establishing that scientific and technical basis is a validation activity regardless of whether the preventive control is established in the facility's initial food safety plan or as a result of reanalysis of the food safety plan.

c. Proposed § 117.150(a)(2)--Validation based on scientific and technical information. Proposed § 117.150(a)(2) would require that, except as provided by paragraph (a)(3) of this section, the validation of preventive controls include collecting and evaluating scientific and technical information or, when such information is not available or is insufficient, conducting studies to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur. The NACMCF HACCP guidelines note that information needed to validate the HACCP plan often includes (1) expert advice and scientific studies and (2) in-plant observations, measurements and evaluations (Ref. 34). The Codex validation guidelines address several approaches for validating control measures, including (1) reference to scientific or technical literature, previous validation studies or historical knowledge, (2) scientifically valid experimental data, (3) collection of data during operating conditions, (4) mathematical modeling, and (5) surveys, and note that these may be used individually or in combination (Ref. 127).

Deleted: 110

Deleted: 110

Deleted: NACMCF, 1998

Deleted: CAC Val 2008

The scientific and technical information that would be evaluated to determine whether preventive controls effectively control the hazards that are reasonably likely to occur may include scientific publications, government documents, predictive mathematical models and other risk-based models, and technical information from equipment manufacturers, trade associations, and other sources. If the qualified individual conducting the validation relies on

sources such as scientific publications, the qualified individual would need to ensure during validation that the conditions used by the facility are consistent with those described in the publication that is being used to support the adequacy of the preventive control measure to control the hazard. For example, if a study demonstrates adequate inactivation of Salmonella spp. in peanuts using a roasting process, conditions such as roaster temperature, heating time, bed depth and humidity that were critical to achieving inactivation in the study must be the same when the facility roasts peanuts (or any change in the critical parameters must be such that the same or greater lethality is achieved). Documents published by FDA, such as the Food Code (Ref. 174), the Pasteurized Milk Ordinance (Ref. 37), and the Fish and Fisheries Products Hazards and Controls Guidance (Ref. 173) may provide scientific and technical information useful in establishing the validity of a preventive control measure, such as times and temperatures for cooling foods in which bacterial pathogen growth may occur or minimum water activities, minimum pH values, and minimum and maximum temperatures for growth of a variety of pathogens.

Deleted: maintained

Deleted: FDA Food Code

Deleted: FDA's PMO

Deleted: FDA's 4th ed of the guidance

Predictive mathematical models that describe the growth, survival, or inactivation of microorganisms in foods may provide scientific and technical information useful in determining whether a process would be adequate to reduce microorganisms of public health concern (Ref. 34) (Ref. 127). Other risk-based models may examine the impact of a control measure on a hazard and may be useful if appropriately validated for a specific food. If the model is for a different food, it may still provide useful validation information that could be supplemented by additional data. For example, there are many mathematical models for thermal resistance of Salmonella spp. If a model for the thermal resistance of Salmonella spp. is developed for the same type of food as the food being produced, and the food being produced has the same critical

Deleted: CAC Val 2008; NACMCF, 2010).

Formatted: Underline

parameters such as pH and a_w that were used in developing the thermal resistance model, then heat processes based on the model would generally be considered validated. For example, if a model for the thermal resistance of Salmonella spp. is developed in tomatoes with a pH of 4.3, the model would be considered valid for tomatoes with a pH of 4.3 or below, but not for tomatoes with a higher pH. If, however, the model is for thermal resistance of Salmonella spp. in a type of food that is only similar to the food being produced, or has different critical parameters than were used in developing the thermal resistance model, it would be necessary to conduct additional thermal resistance studies in the food being produced to provide the data needed to show that a heat process adequately reduces Salmonella spp. in that food and to establish the critical parameters for the process. For example, a model for thermal resistance of Salmonella spp. on almonds may not apply to hazelnuts, even though the foods are similar in that both are tree nuts. The extent of such studies would, however, be less than the extent of such studies if there were no data on the heat resistance of Salmonella spp. in a similar food. For example, if the thermal resistance of Salmonella spp. in initial studies with hazelnuts is similar to that for almonds, then a thermal resistance study used to develop data for hazelnuts could investigate fewer times and temperatures, or use fewer replicates, than would be the case in the absence of the information about the thermal resistance of Salmonella spp. in almonds.

Formatted: Underline

Formatted: Underline

A process validation study would establish the relationship between parameters such as process times and temperatures and other factors and the rate at which pathogens are reduced, and a prevalence study would determine the levels at which pathogens may occur in the raw material, ingredient, or food product to establish the cumulative amount of pathogen reduction that would be required to adequately reduce the risk of illness from that pathogen. Such studies are typically published or otherwise broadly disseminated within the scientific community and,

when properly designed and carried out, are generally regarded by experts as scientifically definitive with respect to the matters addressed by the study. However, if scientific and technical information is not available or is insufficient to support the adequacy of a preventive control measure to control the hazard, the owner, operator or agent in charge of a facility would need to conduct controlled scientific studies to establish that a preventive control measure is adequate to control the hazard. As an example, a facility that wants to use propylene oxide (PPO) to inactivate enteric pathogens such as E. coli O157:H7 on shelled hazelnuts would need to conduct studies to establish that PPO could significantly minimize the hazard because no such studies currently exist in the public domain. Such studies would also establish the critical parameters and limits (e.g., critical limits at a CCP) that the facility would need to use to effectively control the hazard. For the hazelnut example, the critical factors might include amount of PPO, temperature of the nuts to be treated, treatment time, chamber temperature, PPO vaporizer temperature, chamber vacuum, and post-treatment hold time and temperature. Studies on inactivation of Salmonella spp. on almonds could provide information about appropriate parameters to investigate for the inactivation of E. coli O157:H7 on shelled hazelnuts, but additional studies would be needed to establish the specific values for those parameters in the inactivation of E. coli O157:H7 on shelled hazelnuts.

Information is available in the literature that can assist in the design of studies to support the adequacy of preventive control measures. For example, NACMCF has published information on "Parameters for Determining Inoculated Pack/Challenge Study Protocols" (Ref. 175) and "Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization" (Ref. 176). Studies to validate preventive control measures must be conducted by persons with experience and expertise relevant to the product, process and hazard

Deleted: NACMCF 2010

Deleted: NACMCF 2006

to be controlled. Under proposed § 117.150(a)(1)), any studies needed to provide the scientific and technical information to establish the validity of the plan would either be conducted by a qualified individual (as would be defined in proposed § 117.3) or would be overseen by a qualified individual. In other words, the qualified individual need not have the experience and expertise to conduct validation studies, but must have sufficient expertise in risk-based preventive controls to understand the studies and how they support the validity of the preventive controls with respect to the hazard of concern.

d. Proposed § 117.150(a)(3)--Preventive controls for which validation is not required

Proposed § 117.150(a)(3)(i) through (iii) would provide that validation need not address:

- The food allergen controls that would be established in proposed § 117.135(d)(2);
- The sanitation controls that would be established in proposed § 117.135(d)(3); and
- The recall plan that would be established in proposed § 117.137.

According to NACMCF, verification involves activities to determine the validity of the HACCP plan and that the system is operating according to the plan (Ref. 34). Thus, validation is a verification activity. The purpose of validation is to provide the scientific and technical basis for ensuring that the preventive controls implemented are adequate to control the hazards identified as reasonably likely to occur. FDA tentatively concludes that validation, i.e., the evaluation of scientific and technical information, is either not an essential activity, is not practical or is not relevant, for the controls identified in proposed § 117.150(a)(3).

Food allergen controls.

As discussed in section XII.C.6 of this document, proposed § 117.135(d)(2)(i) would require that food allergen controls include those procedures, practices, and processes employed

Deleted: 110.152

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: iv

Deleted: 110

Deleted: 3

Deleted: 110

Deleted: 110

Deleted: ; and ¶
The supplier approval and verification program that would be established in proposed § 110.152

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: NACMCF, 1998

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point, Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

for ensuring protection of food from cross-contact, including during storage and use. Examples of such procedures, practices, and processes include providing physical barriers between sections of a facility, conducting manufacturing/processing of foods in different parts of a facility, and controlling the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods those that do not, or when the same production lines are used for foods that contain different allergens. These types of controls generally are not evaluated through scientific studies or by the collection of technical information as would be required under proposed § 117.150(a)(2). Instead, monitoring (e.g., by visual observation) that these activities do not result in cross-contact provides sufficient assurance that the controls are functioning as intended to prevent the hazard of undeclared allergens in the food due to cross-contact. Examples of such visual observations include observations that bags of allergenic foods (such as soy flour) are stored in sealed containers, that spills of allergen powders are promptly cleaned, and that equipment is cleaned between manufacturing/processing of different foods. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the food allergen cross-contact controls that would be established in proposed § 117.135(d)(2)(i). We request comment on this approach.

Deleted: 110

Deleted: 110

As discussed in section XII.C.6 of this document, proposed § 117.135(d)(2)(ii) would require that food allergen controls include those procedures, practices, and processes employed for labeling the finished food, including, including ensuring that foods are not misbranded under section 403(w) of the FD&C Act. Examples of such procedures, processes, and practices include ensuring that the food label correctly declares all of the food allergens present (including those contained in flavorings, colorings, and incidental additives), ensuring that the correct food label

Deleted: 110

Deleted: flavors

is applied to a food, and ensuring that the correct food is in the correct package (e.g., by checking that the correct packaging is used for each food). These types of controls generally are not evaluated through scientific studies or by the collection of technical information as would be required under proposed § 117.150(a)(2). Instead, verifying that labels contain appropriate information and monitoring that the correct label is being applied to the product provide sufficient assurance that the controls are functioning as intended to prevent the hazard of undeclared allergens in the food due to incorrect labels. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the food allergen labeling controls that would be required by proposed § 117.135(d)(2)(ii). We request comment on this approach.

Sanitation controls.

As discussed in section XII.C.7 of this document, proposed § 117.135(d)(3)(i)(A) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. Traditionally, sanitarians employed by the facility or experts employed by companies that supply cleaning and sanitizing compounds will establish critical parameters and associated limits for cleaning and sanitation, including the choice and strength of the cleaning and sanitizing chemicals, contact time, and temperature requirements, based on studies conducted by the manufacturers of the products. Antimicrobial solutions applied to food processing equipment and utensils to sanitize such objects after they have been washed are included in the definition of "pesticide chemical" and therefore, are subject to regulation by EPA under section 408 of the FD&C Act (Ref. 118). Chapter 4 (Additional Considerations for Antimicrobial Products) of EPA's "Pesticide Registration Manual" (Ref. 177) outlines EPA's

Deleted: 110

Deleted:

Deleted: 110

Formatted: Level 1

Formatted: No underline

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted:

Deleted:

Deleted: FDA guidance for industry on antimicrobial food additives).

Deleted: http://www.epa.gov/pesticides/bluebook/chapter4.html

requirements and recommendations for registration of antimicrobial substances, including testing against a validated protocol to be granted EPA-registered claims for pathogen reduction. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the sanitation controls that would be required by proposed § 117.135(d)(3)(i)(A). Monitoring activities to ensure the procedures are followed will provide assurance that the controls are functioning as intended to prevent hazards from insanitary food-contact surfaces. We request comment on this approach.

As discussed in section XII.C.7 of this document, proposed § 117.135(d)(3)(i)(B) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the prevention of cross-contact and cross-contamination from insanitary objects and from employees to food, food packaging material, and other food-contact surfaces and from raw product to processed product. As already discussed with respect to proposed § 117.135(d)(3)(i)(A), sanitation controls to prevent cross-contamination can be established by sanitarians or by companies that supply cleaning and sanitizing compounds without the need for validation by the facility. Cleaning procedures established by sanitation experts should also be adequate to remove allergens from equipment and the environment in facilities where raw materials or ingredients containing allergens are used. Although it is prudent to validate the efficacy of cleaning with respect to allergens, appropriate allergen test methods may not be available at present for this purpose in all situations (Ref. 124). For example, when the same equipment is used to make milk-based and soy-based beverages, the availability of analytical methods that can detect milk protein and soy protein may make it practical to clean the equipment and then test a water rinse of the system to determine whether milk or soy proteins can be detected in the rinse water. However, this may not be the case when equipment used to

Deleted: ..

Deleted: 110

Deleted:

Deleted: 110

Deleted: 110

Deleted: .

Deleted: Jackson et al. 2008. JFP).

make breaded shrimp is subsequently used to make breaded fish. We tentatively conclude that validation by the facility to demonstrate that sanitation controls adequately protect against cross-contact is not feasible for all situations at this time.

Regardless of whether this proposed rule would require the specific verification activity of validation to demonstrate that sanitation controls adequately protect against cross-contact, proposed § 117.135(d)(3)(i)(A) would require that the owner, operator, or agent in charge of a facility establish appropriate allergen sanitation procedures to ensure that products do not contain undeclared allergens from other products. Cleaning procedures established to remove food residues and verification that food residues have been removed (e.g., by visual inspection) should significantly minimize or prevent the presence of undeclared food allergens. When appropriate tests are available, we recommend that facilities use testing as well as visual inspection to verify that procedures have been done adequately. We request comment on this approach. We also request comment on whether we should require validation of sanitation controls to protect against cross-contact in those situations where appropriate analytical methods for use in validation studies are currently available, even if such methods are not available for all major food allergens.

Deleted: 110

Recall plan.

As discussed in section XII.C.8 of this document, a recall plan can significantly minimize or prevent hazards by limiting consumption of affected food during a recall. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked. The proposed requirement to validate a preventive control by collecting and evaluating scientific and technical information or by conducting studies simply does not apply to

Formatted: FR Preamble Para Indent Line 1 36 point, Level 1

Formatted: No underline

Formatted: FR Preamble Para Indent Line 1 36 point

such a plan. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the recall plan that would be required by proposed § 117.137.

3. Proposed § 117.150(b)--Verification of Monitoring

Proposed § 117.150(b) would require that the owner, operator, or agent in charge of a facility verify that monitoring is being conducted, as would be required by proposed § 117.140. One example of verification that monitoring is being conducted is a periodic observation of the monitoring activity, e.g., by a supervisor. Another example of such a verification activity is an independent test made by a person other than the person doing the monitoring. For example, if the line operator is verifying the operation of a metal detector by running test pieces through the metal detector every two hours to verify it rejects them, a quality assurance technician could periodically run a similar test - e.g., once per shift. Proposed § 117.150(b) does not address the review of monitoring records, which would be required under proposed § 117.150(d)(2)(i) (see the discussion in section XII.G.5.b of this document).

Proposed § 117.150(b) would implement section 418(f)(2) of the FD&C Act and is consistent with the FSIS HACCP regulation for meat and poultry, which requires direct observations of monitoring activities as an ongoing verification activity (9 CFR 417.4(a)(2)(ii)). Proposed § 117.150(b) would differ from the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP guidelines (Ref. 35), and FDA's HACCP regulations for seafood and juice (§§ 123.8(a)(3)(i) and 120.11(a)(1)(iv)(A), respectively), which address verification of monitoring through the review of records (which would be required by proposed § 117.150(d)(2)(i)) but do not otherwise address verification activities for monitoring.

Deleted: 110

Deleted: Supplier approval and verification program.¶
As discussed in section XII.C.9 of this document, proposed § 110.152 would establish a requirement for a supplier approval and verification program that would be self-contained in that it would include targeted verification activities applicable to suppliers. The proposed requirement to validate a preventive control by collecting and evaluating scientific and technical information or by conducting studies does not apply to evaluation of suppliers. ¶

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 5

Deleted: f

Deleted: 110

Deleted: 110

Deleted: NACMCF 1998

Deleted: Codex 2003

Deleted: 110

Deleted: 5

Proposed § 117.150(b) would not specify the verification activities that must be conducted for monitoring. We request comment on whether proposed § 117.150(b) should do so, and if so, what verification activities should be required.

4. Proposed § 117.150(c)--Verification of Corrective Actions

Proposed § 117.150(c) would require that the owner, operator, or agent in charge of a facility verify that appropriate decisions about corrective actions are being made, as would be required by proposed § 117.145 and by proposed § 117.135(d)(3)(ii). An example of verification that appropriate decisions about corrective actions are being made is observation of the corrective actions being taken, e.g., by a supervisor. Proposed § 117.150(c) would implement section 418(f)(3) of the FD&C Act and is consistent with the FSIS HACCP regulation for meat and poultry, which includes direct observations of corrective actions as an ongoing verification activity (9 CFR 417.4(2)(ii)). Proposed § 117.150(c) would differ from the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP guidelines (Ref. 35), and FDA's HACCP regulations for seafood and juice (§§ 123.8(a)(3)(ii) and 120.11(a)(1)(iv)(B), respectively), which address verification of corrective actions through the review of records (which would be required by proposed § 117.150(d)(2)(i)) but do not otherwise address verification activities for corrective actions.

Proposed § 117.150(c) would not specify the verification activities that must be conducted for corrective actions. We request comment on whether proposed § 117.150(c) should do so, and if so, what verification activities should be required.

5. Proposed § 117.150(d)--Implementation and Effectiveness

Proposed § 117.150(d) would require that the owner, operator, or agent in charge of a facility verify the preventive controls are consistently implemented and are effectively and

Deleted: 110
Deleted: 110
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110.145.
Deleted: 110
Deleted: 110
Deleted: NACMCF, 1998
Deleted: Codex 2003
Deleted: 110
Deleted: 5
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110

significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the requirements in proposed § 117.150(d)(1) and (2), as appropriate to the facility and the food. Proposed § 117.150(d) would implement section 418(f)(4) of the FD&C Act, which requires in relevant part verification by "appropriate means" that the preventive controls "are effectively and significantly minimizing or preventing the occurrence of identified hazards."

a. Proposed § 117.150(d)(1)--Calibration. Proposed § 117.150(d)(1) would require calibration of process monitoring instruments and verification instruments. As discussed in section II.D.3 of this document, the combination of monitoring (proposed § 117.140(a)), recordkeeping (proposed § 117.175), and verification (proposed § 117.150(a) and (d)) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act would be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility would not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. In many instances, monitoring and verification activities rely on instruments (such as a pH meter or a thermometer) that must be calibrated. Calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance that hazards will be significantly minimized or prevented. If an instrument is calibrated against a known reference, the reference standard may also need periodic calibration (e.g., the standard reference thermometer used to calibrate a thermometer used in processing equipment will itself also need to be calibrated periodically).

Instrument calibration is performed on a regular or periodic basis based upon the type of instrument being used and its sensitivity to factors such as the operating environment and the

Deleted: , including

Deleted: 110

Deleted:)-(5

Deleted: 110

Deleted: a. Proposed § 110.150(d)(1)--Review of complaints. Proposed § 110.150(d)(1) would require a review of any consumer, customer, or other complaints to determine whether a complaint relates to the effectiveness of the food safety plan.

Moved down [13]: The role of consumer complaints in evaluating the effectiveness of a food safety plan is reflected in our HACCP regulations for seafood and juice. Our HACCP regulation for seafood (§ 123.8(a)(2)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points. Our HACCP regulation for juice (§ 120.11(a)(1)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether the complaints relate to the performance of the HACCP plan or reveal the existence of unidentified critical control points. FDA notes that the role of consumer complaints is not discussed in the NACMCF guidelines or the Codex guidelines, and their review is not required by the FSIS HACCP regulation for meat and poultry. However, as we discussed in the seafood HACCP proposed rule (59 FR 4142 at 4157), no system is foolproof, and consumer complaints may be the first alert for a processor that deviations are occurring and are not being prevented or uncovered by the processor's HACCP controls.¶
Further, although most consumer complaints will be related to quality issues, recent experience has demonstrated the value that consumer and customer complaints can provide in bringing attention to possible problems within a facility's preventive controls activities. FDA has received a number of submissions to the Reportable Food Registry (Ref.

Moved down [14]: that have suggested that environmental pathogens or food allergen hazards were not adequately addressed in a supplier's food safety plan. Some of these were identified through customer verification testing and others through complaints from consumers to a facility. A facility may also receive alerts as a result of state surveillance and testing programs. (For a discussion of such programs, see section II.A.6.e of this document). Many recall notices identify the results of a state surveillance and testing program as the trigger for a recall (

Deleted: FDA 2011 RFR Annual Report.)

Deleted: Refs. River Ranch recalls bagged salads, 2011; Del Bueno Recalls Queso Fresco Casero Cheese, 2011; Taylor Farms recalls bagged salads, 2011). ¶

Deleted: 110

Deleted: 110

Deleted: 110

wear and tear of ongoing use. The type of instruments used in a particular facility and the manner of their use will largely determine the need for, and the frequency of, calibration, and the frequency of calibration is often prescribed by the instrument manufacturer. Therefore, proposed § 117.150(d)(1) would not specify a frequency for calibration.

- b. Proposed § 117.150(d)(2)--Records review. Proposed § 117.150(d)(2) would require a review of specific records related to monitoring, corrective actions and certain

verification activities within specified time frames, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. Proposed § 117.150(d)(2)(i) would require review of the monitoring and corrective action records within a week after the records are made. Proposed § 117.150(d)(2)(ii) would require review of the records related to calibration within a reasonable time after the records are made. (As discussed in section XII.J.2 of this document, proposed § 117.175 would list the records that facilities must establish and maintain, including records that document the monitoring of preventive controls as required by § 117.140(c), corrective actions as required by § 117.140(d), and verification activities as required by § 117.150(g)).

Proposed § 117.150(d)(2) would implement section 418(f) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines provide examples of verification activities, including review of the HACCP plan for

Deleted: 110…17.150(d)(2

Deleted: c…. Proposed § 110…17.150(d)(3)--

Moved down [15]: are applied after a heat treatment and food (such as ice cream) to which nuts or other ingredients are added to an ice cream mix that has been pasteurized. ¶

Moved down [17]: The data from recalls and the RFR support a conclusion that Salmonella spp. is a hazard in low-moisture RTE food products (such as spices and seasonings, nuts and nut products, and seed products).

Deleted: <#>The outcome of the hazard analysis conducted under proposed § 110.130 is that a biological hazard is reasonably likely occur as a result of handling of a product or exposure of a product to the environment after a process control that significantly minimizes a hazard such that a hazard could be introduced or re-introduced into the product. Examples include the manufacture of nut butters from roasted nuts (where contamination with Salmonella from the environment is a concern); the mixing of dried, treated spices and herbs (where contamination with Salmonella

Deleted: <#>is a concern). ¶

Deleted: When RTE foods such as these are exposed to the environment, FDA expects that mo

Formatted: FR Preamble Para Indent Line 1 36 point

Moved down [16]: <#>from the environment is a concern); the addition of herbs or vegetables to

Moved down [18]: A robust environmental monitoring program for Salmonella spp. can verif

Deleted: Chen et al. FPT3 2009). Therefore, when Salmonella spp. from the environment is a hazard

Moved down [19]: ¶

Formatted: Default Paragraph Font

Deleted: When RTE foods such as these are exposed to the environment, FDA expects that mo

Moved down [20]: A robust environmental monitoring program for L. monocytogenes can

Deleted: CAC 2007 Lm control; Tompkin, et al., 1999; Tompkin, 2002; Scott et al., 2005). Therefo

Moved down [21]: this document, FDA's current thinking is that Listeria spp. may be an

Formatted: Underline

Deleted: Because there is no indicator organism for Salmonella, environmental monitoring progra

Moved down [22]: comment on whether there are appropriate indicator organisms for any

Deleted: Collection of Samples¶

Moved down [23]: <#> greater for an environmental pathogen that is frequently introdu

Deleted: <#>Tompkin et al. 1999) than for an environmental pathogen that is less frequently

Deleted: 110…17.150(d)(5

completeness, review of monitoring records, and review of records for deviations and corrective actions (Ref. 34). The examples of verification activities in the Codex HACCP Annex include a review of the HACCP plan and its records (Ref. 35). Our HACCP regulations for seafood (§ 123.8(a)(3)(i) through (iii)) and juice (§ 120.11(a)(1)(iv)(A) through (C)) require a review of the records that document the monitoring of critical control points, the taking of corrective actions, the calibrating of any process control instruments used at critical control points, and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The FSIS HACCP regulation for meat and poultry requires a review of all required records (9 CFR 417(a)(2)(iii)).

Proposed § 117.150(d)(2) would establish that the purpose of the review of records would be to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decision were made about corrective actions. We tentatively conclude that review of the records required by proposed § 117.150(d)(2)(i) and (ii) would accomplish these purposes. Reviewing monitoring records can reveal whether they contain information on all the parameters that were to be monitored to determine whether a process is delivered in accordance with the food safety plan. For example, if both the size of food particles to be acidified and the pH of the food after acidification are critical to the safety of the food, review of the monitoring records would demonstrate whether both particle size and pH were monitored and whether the values were within specified parameter values. Reviewing monitoring records can reveal whether a process followed the procedures specified in the facility's food safety plan (e.g., if the monitoring records show the pH of every other batch of an acidified food when the plan specified the measurement of every batch). Review of monitoring records also can reveal whether any

Deleted: NACMCF, 1998

Deleted: CAC, 2003

Deleted:

Deleted: 110

Deleted: 5

Deleted: 110

Deleted: 5

information is missing – e.g., a designated lot number – so that the missing information can be quickly identified and added to the record if necessary. We seek comment on this proposal.

If the review of the records reveals that the records do not contain all information specified by the food safety plan, or that the procedure in the food safety plan was not followed, the facility will not be able to conclude that its preventive controls were implemented in accordance with its food safety plan for those activities. Because the food safety plan establishes the procedures needed to ensure preventive controls are effective, if the records review indicates that the plan is not being followed, e.g., the records are missing critical information or the activities were not performed as specified in the plan, the facility will not be able to conclude its preventive controls were effective. For example, if the records show that food particle size is not being determined or that the particles are too large, acidification of all parts of the particle may not occur rapidly enough to ensure control of pathogens such as C. botulinum. If the plan requires determination of the pH of each batch of product but the records do not show that the pH was measured on all batches, the facility cannot be sure that the pH of those batches is correct, again posing a potential risk from C. botulinum. As a result, the facility would not be able to verify that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

Review of records can also reveal whether appropriate decisions were made about corrective actions. The review should determine whether all the corrective action procedures required by proposed § 117.145(a)(3) have been followed, e.g., that actions are taken to prevent recurrence of the problem, that affected food has been evaluated for safety, and that affected food is prevented from entering commerce unless it can be determined that the food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the

Deleted: 110

FD&C Act. For example, a food safety plan may require that each package of product pass through a properly functioning metal detector and that the operator determine every two hours whether metal test pieces of a specified type and size are rejected when passed through the metal detector. If one of the test pieces was not rejected but production continued until a supervisor doing a verification check noted the problem, then corrective actions should have been taken and a corrective action record produced. A review of the corrective action records should reveal that all packages of product that passed through the metal detector since the last test showing the metal detector was functioning appropriately were held and passed through a functioning metal detector before being released into commerce. The records should also show that the metal detector was adjusted to reject the metal test pieces before it was used again to check product during production.

Proposed § 117.150(d)(2) would require that the review of records be performed by (or under the oversight of) a qualified individual (see the discussion in section XII.H of this document regarding the activities that must be performed (or overseen) by a qualified individual as would be established in proposed § 117.155). The review of records is critical to assessing the facility's application of the preventive controls system and, thus, is fundamental to ensuring its successful operation. Our HACCP regulations for seafood (§ 123.8(a)(3)) and juice (§ 120.11(a)(1)(iv)) require that the review of records be conducted by an individual who has successfully completed training in the application of HACCP principles to the processing of the applicable food product at least equivalent to that received under standardized curriculum recognized as adequate by FDA, or who is otherwise qualified through job experience to perform this function. The FSIS HACCP regulation for meat and poultry requires that records be reviewed, "preferably" by an individual trained by successfully completing a course of

Deleted: 110

Deleted: 5

Deleted: I

Deleted: 110

instruction in the application of the HACCP principles to meat or poultry product processing (9 CFR 417.5(c) and 417.7(b)). The NACMCF HACCP guidelines stress the role of qualified experts in the development and evaluation of a HACCP plan, and recommend periodic comprehensive verification of the HACCP system by an unbiased, independent authority, internal or external to the food operation, including review of appropriate records from operation of the plan (Ref. 34). The Codex HACCP Annex does not specifically address the need for a qualified individual to review the records other than to recommend that where certain verification activities cannot be performed in-house, verification be performed on behalf of the business by external experts or qualified third parties (Ref. 35).

Proposed § 117.150(d)(2)(i) would require review of the monitoring and corrective action records within a week after the records are made. Although proposed § 117.150(d)(2)(i) would establish a more frequent review of these records than recommended in the NACMCF guidelines (which recommend monthly verification of monitoring records and corrective action records), it is consistent with our HACCP regulations for seafood (§ 123.8(a)(3)(i) and (ii)) and juice (§ 120.11(a)(1)(iv)(A) and (B)), which require that the review of monitoring records and corrective action records occur within one week of the day that the records are made. Even for shelf-stable foods (e.g., low-acid canned foods and acidified foods) our experience has demonstrated that review of these kinds of records is a critical verification tool (60 FR 65096 at 65133). We seek comment on the proposed one week timeline. The FSIS HACCP regulation for meat and poultry requires records to be reviewed prior to shipping product (9 CFR 417.5(c). As discussed in the seafood HACCP final rule (60 FR 65096 at 65132), review of records needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is

Deleted: NACMCF

Deleted: Codex). Under proposed § 110.150(d)(5), the review of records could be performed by or overseen by a qualified individual.

Deleted: 110

Deleted: 5

Deleted: 110

Deleted: 5

roughly that of a “feedback loop,” with information coming out of the record review process in such a timely manner that it can have impact on the production of subsequent lots of the product. If a problem with product is discovered during a review of records, all product since the last review could be affected. Although verification prior to shipment provides a valuable added assurance, FDA explained in the preamble to the seafood HACCP final rule (60 FR 65096 at 65132) that with highly perishable products this is not always possible and that a weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records.

Proposed § 117.150(d)(2)(ii) would require review of the records related to calibration within a reasonable time after the records are made. The review of calibration records will depend in part on the frequency with which calibrations occur, which will be established in the food safety plan. If calibrations occur daily, it would be reasonable to review these records weekly. Where several instruments are calibrated each month, a monthly review of all the calibrations would be reasonable. Consequently, FDA tentatively concludes that setting a specific frequency for review of these records is not warranted. Proposed § 117.150(d)(2)(ii) is, in relevant part, consistent with our HACCP regulations for seafood (§ 123.8(a)(3)(iii)) and juice (§ 120.11(a)(1)(iv)(C)), which require that the review of records of calibrating of any process control instruments used at critical control points occur within a reasonable time after the records are made.

As noted previously, proposed § 117.150(d)(2) would require a review of records in part to determine whether the preventive controls are effective. A review should determine whether monitoring and corrective actions have been done in accordance with the food safety plan and

Deleted: Proposed § 110.150(d)(5)(ii) would require review of the records related to consumer, customer, or other complaints, calibration, finished product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made. The frequency of these record reviews will be variable and will depend, in part, on the frequency with which those activities occur, which will be established in the food safety plan. For example, as discussed in section XII.G.5.d of this document environmental monitoring may be conducted monthly in some facilities and weekly in others. Because of the importance of environmental monitoring in identifying situations in which contamination of food from the environment may occur, it would be reasonable to review the results of the tests on the day that they are received. As discussed in section XII.G.5.c of this document, the frequency of finished product verification testing would depend on the food and the hazards reasonably likely to occur in the food. Similar to the results for environmental monitoring, it would be reasonable to review the results of the tests on the day that they are received.

Deleted: The review of consumer, customer or other complaints will depend on the frequency with which they are received.

Deleted: 110

Deleted: 5

Deleted: and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities

Deleted: 110

Deleted: 5

Deleted: , whether any complaints received indicate a food safety problem,

whether the instruments used in monitoring and verification were properly calibrated. If food safety activities appropriate to the facility have been conducted in accordance with the plan and this is reflected in the records, the facility thus verifies the preventive controls are effective, i.e., that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

6. Proposed § 117.150(e)--Written Procedures for Verification Activities

Proposed § 117.150(e) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments. We are proposing to require written procedures for the frequency of calibration because the frequency of calibration will vary depending on the instrument and the process or verification activity that it pertains to.

We are not proposing to require that written procedures be developed for all verification procedures. In some instances the records of verification activities provide the information needed to understand how the verification activity has been carried out and to assess whether the verification activity is adequately demonstrating that the preventive controls are effective in significantly minimizing or preventing the hazards reasonably likely to occur. For example, we are not proposing to require written procedures for validation, verification of monitoring and corrective actions, or calibration of process monitoring instruments and verification instruments (other than for the frequency of calibration). Validation involves a variety of procedures, including evaluation of scientific and technical information and conducting laboratory and in-plant studies that generally do not follow a standardized protocol or approach. Records of monitoring and corrective actions provide the information needed to understand how the verification activity was carried out. In many instances the calibration of process monitoring

Deleted: , whether finished product testing indicated a loss of process control, whether environmental monitoring results indicated that preventive controls minimized or prevented environmental pathogens from contaminating food, and whether supplier verification activities indicated that suppliers are minimizing hazards in raw materials and ingredients.

Deleted: all the above

Deleted: 110

Deleted: Proposed § 110.150(e)(1)(i) and (ii) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures to conduct finished product testing (proposed § 110.150(e)(1)(i)) and environmental monitoring (proposed § 110.150(e)(1)(ii)). We are proposing to require that written procedures be established and implemented for finished product testing and environmental monitoring because these procedures are essential to understanding whether the finished product testing and environmental monitoring are adequate to verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. Proposed § 110.150(e)(1)(iii

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: , review of consumer, customer or other complaints

Deleted: Likewise, conducting and documenting the review of consumer, customer or other complaints provides the needed verification information and having procedures for how the review is conducted provides no additional benefit.

instruments and verification instruments will be done by contract with other entities and the facility would not have access to the procedures used; having instruments calibrated and documenting the calibration provides the necessary assurance that such instruments will be accurate. However, the frequency of calibration must be specified to ensure that the instruments are calibrated on a schedule appropriate to the instrument and the process it controls.

Section 418(f) of the FD&C Act establishes certain requirements for verification, and section 418(h) of the FD&C Act requires that the procedures used by the facility to comply with the requirements of section 418 be included in the written plan. Our HACCP regulations for seafood and juice both require that the HACCP plan be written (§§ 123.6(b) and 120.8(a), respectively) and that procedures for verification be included in the written HACCP plan (§§ 123.6(c)(6) and 120.8(b)(6), respectively). The FSIS HACCP regulation for meat and poultry requires that the establishment maintain a record of the written HACCP plan, including, in relevant part, documents supporting the verification procedures selected and the frequency of those procedures (9 CFR 417.5(a)(2)). Thus, requiring verification procedures to be written implements the requirements in section 418 of the FD&C Act and is consistent with the requirements in HACCP regulations for seafood, juice, and meat/poultry.

7. Proposed § 117.150(f)--Reanalysis

a. Proposed § 117.150(f)(1)--Reanalysis on the initiative of the owner, operator, or agent in charge of a facility. Proposed § 117.150(f)(1)(i) would require that the owner, operator, or agent in charge of a facility conduct a reanalysis of the food safety plan:

- At least once every 3 years (proposed § 117.150(f)(1)(i)(A));
- Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential

Deleted: We request comment on whether we should require written procedures for verification activities other than for finished product testing, environmental monitoring, and the frequency of calibration.¶

Deleted: Proposed § 110.150(e)(1)(i) would require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency. We discussed the term "scientifically valid" with respect to testing in section II.E.2. Consistent with our previous discussion of the term "scientifically valid" in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements (68 FR 12157 at 12198; March 13, 2003), we use the term "scientifically valid" to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12157 at 12198). ¶
Proposed § 110.150(e)(1)(ii)(A) would require that procedures for environmental monitoring be scientifically valid. We discuss the meaning of "scientifically valid" immediately above. Proposed § 110.150(e)(1)(ii)(B) would require that procedures for environmental monitoring identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. Proposed § 110.150(e)(1)(ii)(B) would further require that the number and location of sampling sites be sufficient to determine whether preventive controls are effective and include appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces within the manufacturing, processing and packaging environment.¶
Under proposed § 110.150(d)(4), the purpose of environmental monitoring is to verify the implementation and effectiveness of preventive (i.e., sanitation) controls for environmental pathogens to assess whether the preventive controls significantly minimize or prevent the potential for environmental pathogens to contaminate food. The monitoring must be designed to find environmental pathogens that remain in the facility after routine cleaning and sanitizing procedures in order to prevent contamination of product that could lead to illness. To accomplish this purpose, there must be a scientific basis for the locations selected for sampling, the number of samples taken, the frequency of sampling, the sampling procedures used and the test methodology. The sampling must be biased – i.e., the locations to be tested must be those in which the environmental pathogens can enter the environment where the food is exposed and those areas where harborage of the pathogen is likely (Ref. ICMSF 7 Ch. 11; Jarl and Arnold, 1982). These r...

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: three

Deleted: 110

for a new hazard or a significant increase in a previously identified hazard (proposed § 117.150(f)(1)(i)(B));

- Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food (proposed § 117.150(f)(1)(i)(C));
- Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established (proposed § 117.150(f)(1)(i)(D)); and
- Whenever a preventive control is found to be ineffective (proposed § 117.150(f)(1)(i)(E)).

For example, if a facility that bottles beverages develops a food safety plan for its products packaged in plastic bottles and subsequently introduces a glass bottling line, the facility would be required to reanalyze its food safety plan because the glass bottling line creates a reasonable potential for a new hazard, i.e., glass particles. Similarly, if a facility that conducts dry roasting operations for nuts makes design changes to its roasters to increase product throughput, the facility would be required to reanalyze its food safety plan because a design change to equipment that is used to control a hazard that is reasonably likely to occur would be a significant change in the activities conducted at the facility.

The owner, operator or agent in charge of a facility may become aware of a problem due to the finding of a hazard in a food as the result of testing by a regulatory agency (Federal, State, tribal, or foreign government) that would require an analysis of the food safety plan to ensure the hazard is significantly minimized or prevented by appropriate preventive controls. In addition, new hazards can emerge – e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health agencies. For example, L. monocytogenes was not recognized as a food safety hazard until a series of outbreaks of foodborne illness associated with

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

the consumption of foods such as coleslaw and fresh soft cheese in the early 1980s (Ref. 178). As another example, in 2006-2007 there was an outbreak of salmonellosis due to contamination of peanut butter with Salmonella Tennessee (Ref. 63). This was the first outbreak of foodborne illness caused by peanut butter consumption in the U.S. and it demonstrated the need for manufacturers to address the hazard of Salmonella spp. in this product. Information about outbreaks and ensuing product recalls is widely disseminated, including on FDA's Web site, and modern communication tools make it possible for the owner, operator, or agent in charge of a facility to receive such information automatically. For additional discussion related to the proposed requirement that the owner, operator, or agent in charge of a facility conduct a reanalysis whenever such owner, operator or agent becomes aware of new information about potential hazards associated with the food, see the discussion in section XII.G.7 of this document of proposed § 117.150(f)(3), which would provide that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

As noted in section XII.F.3, proposed § 117.145(b)(2) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 117.150(f) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented or is found to be ineffective, and a specific corrective action has not been established. If the owner, operator, or agent in charge of a facility has not identified a specific failure as a foreseeable occurrence, the deviation may be the result of a system-wide problem that is not being properly addressed by the food safety plan (e.g., ineffective preventive controls). Thus, an unforeseen failure for which a corrective action was not identified may indicate an ineffective preventive control, and a reanalysis of the food safety plan is warranted. Similarly, when information arises indicating that the preventive control has

Deleted: Introduction of the FDA/FSIS Listeria risk assessment).

Deleted: CDC, 2007 MMWR 56:521-524).

Deleted: 6

Deleted: 110

Deleted: 110

Deleted: 110

not been effective in significantly minimizing or preventing a hazard from occurring, a reanalysis must be conducted to determine if the food safety plan should be modified to ensure that the preventive controls implemented are adequate to significantly minimize or prevent a hazard identified as reasonably likely to occur.

Proposed § 117.150(f)(1)(i) would implement sections 418(f)(5) and 418(i) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, the Codex validation guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. FDA notes that the terminology used in relation to the concept of "reanalysis" varies in the regulations and guidelines (e.g., "subsequent validation," "re-validation," "reassessment of the hazard analysis," and "validation" of the HACCP plan). The NACMCF HACCP guidelines include validation of a HACCP plan to ensure that the plan is scientifically and technically sound and that all hazards have been identified as an important verification activity, and advise a subsequent validation under circumstances such as an unexplained system failure; a significant product, process or packaging change; or the recognition of new hazards (Ref. 34). The NACMCF HACCP guidelines also discuss the need for a periodic comprehensive verification of the HACCP system, including a technical evaluation of the hazard analysis and each element of the HACCP plan, independent of other verification procedures to ensure that the HACCP plan is resulting in control of the hazards. If the results of the comprehensive verification identify deficiencies, the HACCP team modifies the HACCP plan as necessary (Ref. 34). Likewise, the Codex HACCP Annex recommends that the HACCP application be reviewed and necessary changes made when any modification is made in the product, process, or any step (Ref. 35). The Codex validation guidelines provide examples of situations that could lead to the need to re-

Deleted: 110

Deleted: NACMCF, 1998

Deleted: NACMCF 1998

Deleted: Codex HACCP, 2003

Deleted: on validation

validate a control measure or combination of control measures, e.g., system failure, process changes, and new scientific or regulatory information (Ref. 127).

Deleted: Codex Validation, 2008).

Our HACCP regulation for seafood requires a reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way, or at least annually (§ 123.8(a)(1)). Our HACCP regulation for juice requires an initial validation within 12 months after implementation and at least annually or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way (§ 120.11(b)). The FSIS HACCP regulation for meat and poultry requires that every establishment reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)).

In addition, Federal HACCP regulations for seafood, juice, and meat and poultry require a reassessment of the hazard analysis when a processor does not have a HACCP plan (because the hazard analysis revealed no hazards reasonably likely to occur) and there are changes that could affect whether a food safety hazard now exists (§§ 123.8(c) and 120.11(c), and 9 CFR 417.4(a)(4) for seafood, juice, and meat and poultry, respectively). Each of these HACCP regulations provides examples of changes that may be considered to reasonably affect whether a food safety hazard now exists and, thus, require reassessment of the adequacy of the hazard analysis (§§ 123.8(a)(1) and 120.11(b) and 9 CFR 417.4(a)(4)). Such changes include changes in raw materials or the source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; the intended use or consumers of the finished product; and slaughter or processing methods or systems for meat or poultry.

The requirement in proposed § 117.150(f)(1)(i)(A) that the periodic reanalysis of the food safety plan occur at least once every 3 years would be different from the current requirement in our HACCP regulations for seafood and juice and in the FSIS HACCP regulation for meat and poultry for reassessment (validation) of the adequacy of the HACCP plan to be done "at least annually" (§§ 123.8(a)(1) and 120.11(b) and 9 CFR 417.4(a)(3), respectively). The 3-year minimum frequency for the periodic reanalysis of the food safety plan is explicitly required by section 418(i) of the FD&C Act. We tentatively conclude that, as a practical matter, the proposed requirement for reanalysis whenever a significant change is made in the activities conducted at a facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard makes it likely that reanalysis would occur more frequently than every 3 years because such changes are likely to occur more frequently than every 3 years.

Proposed § 117.150(f)(1)(ii) would require that the owner, operator, or agent in charge of a facility complete the required reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production. The purpose of the reanalysis is to identify the need for, and implement, preventive controls in light of a reasonable potential for a new hazard, or a significant increase in a previously identified hazard, that is reasonably likely to occur. It follows that the preventive controls must be in place before making the change that creates the potential for a new hazard or a significant increase in a previously identified hazard. As with initial validation in proposed § 117.150(a)(1)(i), we are proposing to provide the first six weeks of production, when necessary, to implement any additional preventive controls to allow facilities to methodically collect data and information during

Deleted: 110

Deleted: three

Deleted: three

Deleted: three

Deleted: 110

Deleted: six

Deleted: 110

production to ensure the needed change can be implemented in the facility. We seek comment on this timeframe. Proposed § 117.150(f)(1)(ii) would implement section 418(i) of the FD&C Act. Although proposed § 117.150(f)(1)(ii) has no explicit counterpart in the NACMCF HACCP guidelines, the Codex HACCP guidelines, or Federal HACCP regulations for seafood, juice, and meat and poultry, it is consistent with the importance placed on reanalysis of the HACCP plans in those guidelines and regulations and with requirements to modify the HACCP plan immediately whenever validation reveals the need to do so, as discussed immediately below.

Deleted: 110

Deleted: 110

Proposed § 117.150(f)(1)(iii) would require that the owner, operator, or agent in charge of a facility revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. Proposed § 117.150(f)(1)(iii) would implement section 418(i) of the FD&C Act, which requires that the written plan be revised "if … a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed." As discussed in section XII.B.2.b of this document, the written hazard analysis is required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur. It is also important to document that a reanalysis has been conducted even if no change has been made, as required by section 418(i) of the FD&C Act. Such documentation demonstrates that a facility has considered all relevant information on the safety of the products being produced, including new information that has become available since the last analysis, and determined that current procedures for implementing preventive controls are adequate to significantly minimize or prevent hazards that are reasonably likely to occur. Our HACCP regulations for juice and seafood, and the FSIS regulation for meat and poultry, require that the HACCP plan be modified immediately whenever a validation/reassessment reveals that the plan is no longer adequate to fully meet the

Deleted: 110

Deleted: 110

requirements of the HACCP regulations (§§ 120.11(b) and 123.8(a)(1) and 9 CFR 417.4(a)(3) for juice, seafood, and meat/poultry, respectively), although they do not explicitly require documentation of the basis for the conclusion that no additional or revised preventive controls are needed. Although proposed § 117.150(f)(1)(iii) has no explicit counterpart in the NACMCF HACCP guidelines or the Codex HACCP guidelines, it is consistent with the importance placed on reanalysis of the HACCP plans in those guidelines and regulations, and with the written nature of the HACCP plan. The Codex validation guidelines indicate that if a system failure for which a process deviation cause cannot be identified occurs, re-validation may be needed (i.e., reanalysis is needed whenever a preventive control is found to be ineffective) (Ref. 127).

b. Proposed § 117.150(f)(2)--Requirement for a qualified individual. Proposed § 117.150(f)(2) would require that the reanalysis be performed or overseen by a qualified individual. Proposed § 117.150(f)(2) is consistent with proposed §§ 117.126(c) which would require that the food safety plan be developed or overseen by a qualified individual. We tentatively conclude that the same qualifications are needed whether initially conducting a hazard analysis and establishing a food safety plan, or reanalyzing a hazard analysis and plan.

c. Proposed § 117.150(f)(3)--Reanalysis on the initiative of FDA. Proposed § 117.150(f)(3) establishes that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding. This authority will be delegated to the Commissioner of Food and Drugs. Proposed § 117.150(f)(2) would implement section 418(i) of the FD&C Act, which provides in relevant part that "[t]he Secretary may require a reanalysis . . . to respond to new hazards and developments in scientific understanding …." As discussed in section XII.G.7.a of this document, new hazards can emerge – e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health

Deleted: 110

Deleted: Codex Validation 2008

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: Under proposed § 110.150(f)(2), the reanalysis could be performed by or overseen by a qualified individual.

Deleted: 110

Deleted: 110

Deleted: 110

agencies. In addition, new developments can occur in the scientific understanding of existing or potential hazards – e.g., if scientists and food safety regulatory agencies develop a better understanding of the causes of these events. For example, the outbreak from Salmonella Tennessee in peanut butter resulted in a greater understanding of the risks posed by environmental contamination and the importance of control of water in facilities producing low-moisture foods (Ref. 145) (Ref. 179). Information submitted to the RFR – which is a relatively recent addition to the regulatory framework for food safety – has the potential to identify new hazards or routes of contamination even before outbreaks occur. For example, the January 2011 RFR Annual Report (Ref. 60) identified a high number of primary reports involving Salmonella spp. in spices and seasonings, and we have requested comments and scientific data and information to assist us in our plans to conduct a risk profile for pathogens and filth in spices (75 FR 20615, April 20, 2010). The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and potential new interventions to reduce or prevent illnesses from contaminated spices.

8. Proposed § 117.150(g)--Requirement for Records for Verification

Proposed § 117.150(g) would require that all verification activities taken in accordance with this section be documented in records. Proposed § 117.150(g) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan and includes verification records as an example of HACCP records in an appendix (Ref. 34). The Codex HACCP Annex

Deleted: Scott et al. 2009 FPT1; Chen et al. 2009 FPT2).

Deleted: 2011 RFR Annual Report

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted:

Deleted: 110

Deleted: NACMCF 1998

gives records of verification procedures performed as an example of records (Ref. 35). Our HACCP regulations for seafood and juice require that recordkeeping include the calibration of process-monitoring instruments (§§123.8(d) and 120.11(a)(2), respectively). The FSIS HACCP regulation for meat and poultry requires records documenting the calibration of process-monitoring instruments, as well as verification procedures and results.

H. Proposed §

117.155--Requirements Applicable to a Qualified Individual

Proposed § 117.155(a) would require that one or more qualified individuals prepare the food safety plan (proposed § 117.126(c)), validate the preventive controls (proposed § 117.150(a)(1)), review records for implementation and effectiveness of preventive controls (proposed § 117.150(d)(2)), and perform reanalysis of the food safety plan (proposed § 117.150(f)(2)). We have discussed the basis for requiring that a trained individual perform or oversee these functions in our discussion of each applicable proposed provision. We are listing the functions that must be performed by a trained individual in § 117.155(a) for simplicity and are not imposing any additional requirement through this list. A single individual with appropriate qualifications could perform all of the listed functions, but there would be no requirement for the same individual to perform all the listed functions.

Proposed § 117.155(b) would establish the qualification requirements applicable to a qualified individual. 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 the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. Training or job

Deleted: Codex 2003

Deleted: , and the performing of any periodic end-product and in-process testing

Moved down [24]: Supplier Approval and Verification Program¶

Deleted: 110.152--

Deleted: 1.

Moved up [12]: Requirements of Section 418 of the FD&C Act¶

Moved down [25]: The NACMCF HACCP guidelines describe supplier controls as one of the common prerequisite programs for the safe production of food products and recommend that each facility assure that its suppliers have in place effective CGMP and food safety programs (Ref.

Deleted: NACMCF 1998). Likewise, Codex addresses the safety of ingredients in the General Principles of Food Hygiene and recommends that, where appropriate, specifications for raw materials be identified and applied and laboratory tests be conducted to establish fitness for use. Federal HACCP regulations for seafood, juice, and meat and poultry do not include explicit requirements for supplier controls.¶
Proposed § 110.152(a)(1) is consistent with recommendations from industry trade associations. For example, as discussed in section II.F of this document, the American Spice Trade Association recommends that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. ASTA Spice Guidance 2011). GMA recommends that all suppliers through the food chain consider approval programs for their own suppliers (Ref. GMA Supply Chain Handbook 2008). One of the requirements for GFSI recognition of food safety schemes relates to cont ...

Moved down [26]: 155.

Deleted: Section 418(c) of the FD&C Act specifies, in relevant part, that "[t]he owner, ...

Deleted: ¶ ...

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: a

Deleted: individual

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 5)),

Deleted: 110

Deleted:), and perform an onsite audit (§ 110.152(e)(1).

Deleted: 110

Deleted: 110

Deleted: require that

experience is essential to the effective development and implementation of a hazard analysis and risk-based preventive controls. Only a trained individual or individual qualified by job experience is capable of effectively executing certain activities, such as identifying hazards that are reasonably likely to occur; identifying preventive controls that will address those hazards; evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the hazards that are reasonably likely to occur; determining the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur; determining whether monitoring procedures and corrective action procedures are appropriate; and determining whether specific corrective actions have been appropriate and effective. In addition, the products produced by the food industry are diverse, and the hazards that are reasonably likely to occur in a particular facility depend on a range of factors that vary from one facility to the next. We seek comment on the scope of the qualifications identified.

Deleted: physical,

Deleted: , or chemical

Proposed § 117.155 is consistent with the NACMCF HACCP guidelines, our HACCP regulations for seafood and juice, and USDA's HACCP regulations for meat and poultry. The NACMCF HACCP guidelines recommend that experts who are knowledgeable in the food process either participate in or verify the completeness of the HACCP plan (Ref. 34). Our HACCP regulations for seafood and juice both require that only a trained individual be responsible for developing the hazard analysis (juice only), developing the HACCP plan, verifying and modifying the HACCP plan, and performing the record review (§§ 123.10(a)-(c) and 120.13(a)(1)-(4), respectively). These regulations also provide that job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent

Deleted: 110

Deleted: NACMCF, 1998

Deleted:

to that provided through the standardized curriculum. USDA's HACCP regulations for meat and poultry require that only an individual who has completed a training course can conduct certain activities, such as development and modification of the HACCP plan (9 CFR § 417.7).

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

Proposed § 117.155(b) also would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. Proposed § 117.155(b) is consistent with HACCP regulations for seafood and juice, which have virtually identical requirements (§§ 123.10 and 120.13(b), respectively). The option in proposed § 117.155(b) would provide flexibility to facilities subject to the rule. Such flexibility may be particularly important for those facilities that have limited technical expertise.

Proposed § 117.155(c) would require that all applicable training be documented in records, including the date of the training, the type of training, and the person(s) trained. Such records would be a simple mechanism to demonstrate that a person has successfully completed

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, as would be required under proposed § 117.155(b) should the qualified individual not be otherwise qualified through job experience to develop and apply a food safety system.

J. Proposed § 117.175--Records Required for Subpart C

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

Section 418(g) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act to address those hazards. Section 418(h) of the FD&C Act also specifies that the written plan, together with the documentation described in Section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 117.175--Records Required for Subpart C

Proposed § 117.175(a)(1) through (5) would require that the owner, operator, or agent in charge of a facility establish and maintain the following records:

Deleted: 110

Deleted: J.

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: "[t]he

Deleted: [

Deleted:],

Deleted: [

Deleted:],

Deleted: ."

Deleted: "[t]he

Deleted: [

Deleted:],

Deleted: [

Deleted:]

Deleted: [

Deleted:]

Deleted: ."

Deleted: "

Deleted: ."

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 6

- The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;
- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification, including, as applicable, those related to validation; monitoring; corrective actions; calibration of process monitoring and verification instruments; records review; and reanalysis; and
- Records that document applicable training for the qualified individual.

Proposed § 117.175(a) would not establish any new requirements but merely make it obvious at a glance what records are required under proposed part 117, subpart C.

Proposed § 117.175(b) would provide that the records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of part 117, subpart F. As discussed in section XV of this document, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by part 117, including provisions for retention of records and for making records available for official review.

J. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed

1. Overview

As discussed in section II.B.2 of this document, section 418(n) requires FDA to establish science-based minimum standards for, among other things, implementing preventive controls. In addition, section 418(f) requires certain verification of those preventive controls. In this section

Deleted: , and the supplier approval and verification procedures

Deleted: (including corrective actions for environmental monitoring); review of consumer, customer, or other complaints

Deleted: finished product testing; environmental monitoring;

Deleted: <#>Records that document the supplier approval and verification program; and¶

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: part 110, subpart C. This listing of records is consistent with our approach in part 110, subpart B (see discussion of proposed § 110.120 in section XI.K of this document).

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: K

of the preamble, we discuss several preventive controls (i.e., supplier controls) and verification measures (i.e., environmental and product testing programs) that FDA is not including as provisions in proposed part 117, subpart C.

As we have already discussed (see section XII.C.1 of this document), section 418(c) requires the owner, operator, or agent in charge of a facility to identify and implement preventive controls. Section 418(o)(3) defines "preventive controls" to mean "those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding…." Section 418(o)(3) indicates that those procedures, practices and processes may include environmental monitoring, supplier verification activities, certain sanitation controls, and allergen controls. In addition, environmental and product testing programs are set out in section 418(f)(4): section 418(f)(4) requires that the owner, operator, or agent in charge of a facility "verify that ... the preventive controls … are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means."

We believe that the preventive controls and verification measures discussed in this section are an important part of a modern food safety system. We believe that the preventive controls discussed in this section (i.e., a supplier approval and verification program), when implemented appropriately in particular facilities, are "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

[identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding ..." The verification procedures discussed in this section (i.e., environmental and product testing programs), when implemented appropriately in particular facilities, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. The use of and need for these preventive controls and verification measures, which are science-based, are widespread and commonly accepted in many sectors of the food industry. We request comment on these conclusions.

As discussed (see section I of this document), food safety is best assured if each facility understands the hazards that are reasonably likely to occur in its particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate those hazards. From a regulatory perspective, specifying the circumstances and manner in which these controls and practices are to be applied must take into account the wide array of factors, including the diversity among food products, the wide variety of manufacturing and processing methods used to produce the food, the variety of sources for raw materials and ingredients, variations in the nature and types of hazards associated with manufacturing, processing, packing and holding human food, and the possibility that different mitigation methods may achieve the same end. Further, regulatory requirements should make clear when one of these preventive controls or verification measures is necessary yet also be sufficiently flexible to account for a vast number of food and facility combinations and circumstances.

Although we are not including provisions for environmental and product testing programs or a supplier approval and verification program in this proposed rule, we recognize that these preventive controls and verification measures, when implemented appropriately in

particular facilities, can play important roles in effective food safety programs. The role and need for these measures varies depending on the type of products and activities of the facility. To facilitate comment and share our current thinking, we discuss the topics of environmental and product testing programs and a supplier approval and verification program immediately below. See the Appendix to this document for additional background information relevant to these topics.

2. Product Testing

As discussed in section XII.G.1 of this document, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that "the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means" The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to establish a product testing program.

Although finished product testing is rarely considered a preventive control, it plays a very important role as a verification measure in ensuring the safety of food, when implemented appropriately in particular facilities. Similarly, testing of raw materials or ingredients by a facility that is receiving the product often plays an important role in verification of hazard control that is performed by their supplier. Thus, an important purpose of testing is to verify that preventive controls, including those related to suppliers and those related to 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.

Finished product testing is more important and useful when there is a reasonable probability that exposure to an identified hazard will result in serious adverse health consequences or death to humans or animals. FDA believes that there are certain situations in which finished product testing is particularly useful as a verification measure, including the following circumstances:

- The outcome of the hazard analysis conducted under proposed § 117.130 is that a biological hazard is reasonably likely to occur in an ingredient and the preventive controls established and implemented under proposed § 117.135 do not include a process control that will significantly minimize the hazard. Examples include cut raw vegetables (such as celery, onions, leafy greens and tomatoes) that may contain Salmonella spp. or L. monocytogenes and that are intended to be used in RTE foods; nutrition bars in which dry ingredients (such as fruits, nuts, dried milk, soy proteins and chocolate) that may contain Salmonella spp. are formed into a bar without a lethal step; and mixtures of shelled nuts in which the nuts may be contaminated with Salmonella spp.

- The outcome of the hazard analysis conducted under proposed § 117.130 is that a biological hazard is reasonably likely to occur in an ingredient that is added during manufacturing after the stage that applies a process control to significantly minimize biological hazards. Examples include food (such as chips, nuts and cereals) in which untreated seasonings

that may contain Salmonella spp. are applied after a heat treatment and food (such as ice cream) to which nuts or other ingredients are added to an ice cream mix that has been pasteurized.

- The outcome of the hazard analysis conducted under proposed § 117.130 is that a biological hazard is reasonably likely to occur as a result of handling of a product or exposure of a product to the environment after a process control that significantly minimizes a hazard such that a hazard could be introduced or re-introduced into the product. Examples include the manufacture of nut butters from roasted nuts (where contamination with Salmonella spp. from the environment is a concern); the mixing of dried, treated spices and herbs (where contamination with Salmonella spp. from the environment is a concern); the addition of herbs or vegetables to products such as cream cheese or cottage cheese (where contamination with L. monocytogenes from the environment is a concern); and the manual assembly of sandwiches (where contamination with S. aureus, L. monocytogenes, and enteric pathogens such as Salmonella spp. is a concern).

In addition, the frequency of testing and the number of samples tested must be determined and needs to take into account a variety of hazard/commodity/facility considerations. FDA believes that factors to consider include whether ingredients that may contain a hazard have been tested, the extent of any environmental monitoring program, and whether other programs established by the facility provide added assurance that the potential for hazards has been minimized. The frequency of testing and the number of samples tested should have a scientific basis. Sampling plans and their performance have been described in the literature (Ref. 180) (Ref. 181) (Ref. 182) and are included in several Codex documents (Ref. 52) (Ref. 183). We discuss likely considerations that could impact finished product verification testing in more detail in section I.F of the Appendix to this document.

Moved (insertion) [15]

Moved (insertion) [16]

Formatted: Default Paragraph Font

Although we are not including a testing provision in this proposed rule, we estimate that a requirement for a finished product testing program, when implemented appropriately in particular facilities, could impose an incremental annual cost of $14,000 – $813,000 per facility based on size (number of employees) that adopts a testing and holding regime. This would result in an estimated aggregate cost of $23,500,000 for domestic facilities based on an average of a range of $12,000,000 - $35,000,000 (assuming between 25 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $25,600,000 for foreign facilities. (As described in the PRIA, foreign costs are estimated by multiplying the domestic per facility cost by the total number of foreign facilities. See section XIX of this document for a discussion of the PRIA.) These costs assume that facilities will take 5 finished product samples per product line on a monthly basis. The facilities that would adopt a testing and holding regime are facilities producing products for which finished product testing would be particularly useful as a verification measure, e.g., the production process does not have a step that will eliminate or reduce hazards to an acceptable level. This estimate excludes facilities that would be exempt under this proposed rule (using a definition of $250,000 for a very small business) and facilities that are already conducting finished product testing. Further details are provided in the "Consideration of Other Provisions" section of the PRIA.

FDA requests comment on when and how product testing programs are an appropriate means of implementing the statutory directives set out above. Although we have not included these provisions in the proposed rule, we request comment on their inclusion in a final rule. Should a product testing program be limited to finished product testing or include raw material testing? What is the appropriate level of specificity for a product testing program? For example, should we simply require that the owner, operator, or agent in charge conduct, as appropriate to

the facility and the food, 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? This would provide flexibility to account for the wide diversity of food and food manufacturing, processing, packing and holding systems subject to this rule and be consistent with the discussions within this proposed rule.

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

- Specifying particular hazards, situations or product types for which finished product testing would be required;
- Specifying the frequency of testing and, if so, whether this frequency should depend on the type of product;
- Identifying appropriate sampling plans for finished product testing;
- Requiring periodic testing for trend analysis and statistical process control; and
- Requiring written procedures for conducting finished product testing and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency.

FDA also requests comment on the impact of product testing requirements on small businesses and on whether any product testing verification requirements should differ based on the size of the operation.

3. Environmental Monitoring

Moved (insertion) [5]

As discussed in section XII.G.1 of this document, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that "the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly

minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means". In addition, section 418(o)(3) indicates that preventive controls may include environmental monitoring to verify the effectiveness of pathogen controls is an example of preventive controls. The statute does not indicate the specific circumstances where environmental testing would be required or the specific manner in which such testing should be performed. Nevertheless, FDA believes that this testing can form an important component of a modern food safety system. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, is particularly useful as a verification measure for preventive controls (i.e., sanitation controls) when contamination of food with an environmental pathogen is a hazard reasonably likely to occur.

As discussed in sections XII.B.3 and XII.B.4.b of this document, proposed § 117.130(b) would require a hazard identification that must consider hazards that may occur naturally or may be unintentionally introduced; proposed § 117.130(c)(2) would require that the hazard evaluation include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a RTE food is exposed to the environment prior to packaging. The data from recalls and the RFR support a conclusion that Salmonella spp. is a hazard in low-moisture RTE food products (such as spices and seasonings, nuts and nut products, and seed products). When RTE foods such as these are exposed to the environment, FDA believes that most facilities producing such foods would identify Salmonella spp. as a known or reasonably foreseeable hazard under proposed § 117.130(b) and evaluate whether Salmonella spp. contamination from the

Formatted: FR Preamble Para Indent Line 1 36 point

Moved (insertion) [17]

environment is reasonably likely to occur in the facility under proposed § 117.130(c)(2). A robust environmental monitoring program for Salmonella spp. can verify the effectiveness of sanitation controls designed to prevent Salmonella spp. from contaminating food-contact surfaces and food (Ref. 184).

Likewise, the data from recalls and the RFR support a conclusion that L. monocytogenes is a hazard in refrigerated or frozen RTE food products (such as dairy products, fresh-cut produce, prepared foods such as sandwiches, and frozen foods). When RTE foods such as these are exposed to the environment, FDA believes that most facilities producing such foods would identify L. monocytogenes as a potential hazard under proposed § 117.130(b) and evaluate whether L. monocytogenes is reasonably likely to occur in the facility under proposed § 117.130(c)(2). A robust environmental monitoring program for L. monocytogenes can verify the effectiveness of sanitation controls designed to prevent L. monocytogenes from contaminating food-contact surfaces and food (Ref. 52) (Ref. 144) (Ref. 185) (Ref. 186).

As discussed in section A.5.c of the Appendix to this document, FDA's current thinking is that Listeria spp. may be an appropriate indicator organism for L. monocytogenes, because tests for Listeria spp. will detect multiple species of Listeria, including L. monocytogenes. However, FDA's current thinking is that there are no currently available indicator organisms for Salmonella spp. We request comment on these findings and conclusions.

Although we are not including an environmental testing provision in this proposed rule, we estimate that an environmental monitoring program for Salmonella spp., when implemented appropriately in particular facilities, could impose an incremental annual cost of $3,000 – $6,000 per facility. These costs assume that facilities will take 5-15 environmental samples per month, based on facility size, and send the samples to an outside laboratory for testing. This would

Moved (insertion) [18]

Moved (insertion) [19]

Moved (insertion) [20]

Moved (insertion) [21]

Formatted: Underline

result in an estimated aggregate cost of $4,000,000 for domestic facilities based on an average of a range of $3,000,000 - $5,000,000 (assuming between 50 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $4,400,000 for foreign facilities.

Similarly, we estimate that a requirement for an environmental monitoring program for Listeria, when implemented appropriately in particular facilities, could impose an incremental annual cost of $3,000 – $6,000 per facility. These costs assume that facilities will take 5-15 environmental samples per month, based on facility size, and send the samples to an outside laboratory for testing. This would result in an estimated aggregate cost of $5,000,000 for domestic facilities based on an average of a range of $4,000,000 - $6,000,000 (assuming between 50 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $5,400,000 for foreign facilities. (As described in the PRIA, foreign costs are estimated by multiplying the domestic per facility cost by the total number of foreign facilities. See section XIX of this document for a discussion of the PRIA.)

The facilities that could adopt environmental monitoring programs are facilities producing ready-to-eat products exposed to the environment whereby they may become contaminated and for which such testing would be particularly useful as a verification measure for sanitation controls. These estimates exclude facilities that would be exempt under this proposed rule (using a definition of $250,000 for a very small business) and facilities that are already conducting finished product testing. Further details are provided in the "Consideration of Other Provisions" section of the PRIA.

FDA requests comment on when and how environmental testing is an appropriate means of implementing the statutory directives set out above. Although we have not included these provisions in the proposed rule, we request comment on their inclusion in a final rule. If they are

included, what is the appropriate level of specificity? For example, should we simply require the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur? FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying the environmental pathogen or the indicator organism for which the samples must be tested;
- Specifying the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen, such as;
- Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
- Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
- Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated; and
- Conducting finished product testing.
- Specifying the locations within the facility at which samples must be collected;
- Specifying the frequency of collection of environmental samples (e.g., weekly or monthly depending on risk). For example, should the frequency of collection:
  - Be greatest for foods that are likely to be consumed as RTE or consumed after a minimal treatment that may not adequately reduce the environmental pathogen?
  - Be greater for an environmental pathogen that is frequently introduced into a facility (e.g., L. monocytogenes which is ubiquitous in the environment and can be

Moved (insertion) [23]

continually introduced into a facility from many routes, including ingredients, people and objects (Ref. 144) than for an environmental pathogen that is less frequently introduced?

- Be greater for refrigerated or frozen RTE food products that support growth of L. monocytogenes than for those that do not?
- Be greater if there is greater risk of a negative impact on public health (e.g., the product is specifically intended for a sensitive population such as infants) than if there is a lesser risk of a negative impact on public health?
- Be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment?
- Increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction? (Ref. 52) (Ref. 185) (Ref. 184) (Ref. 187).
- Requiring written procedures for conducting environmental testing and, if so, also requiring that procedures for environmental testing be scientifically valid and include the procedures for sampling and the sampling frequency;
- Requiring data analysis to detect trends.

In addition, with respect to environmental testing for L. monocytogenes, FDA requests comment on whether it would be appropriate to distinguish between environmental testing for RTE foods depending on whether the food supports the growth of L. monocytogenes. We also request comment on whether there are appropriate indicator organisms for any environmental pathogen other than L. monocytogenes. We further request comment on whether there is benefit

Formatted: FR Preamble Para Indent Line 1 36 point

Moved (insertion) [6]

Moved (insertion) [22]

in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.

4. Supplier Approval and Verification Program

Moved (insertion) [24]

Section 418(c) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented; and
- The food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Section 418(o)(3)(G) of the FD&C Act indicates that the procedures, practices, and processes described in the definition of preventive controls may include supplier verification activities that relate to the safety of food. While FSMA refers only to supplier verification activities, supplier approval, together with supplier verification, is widely accepted in the domestic and international food safety community. The development of a supplier approval and verification program can be part of a preventive approach. The NACMCF HACCP guidelines describe supplier controls as one of the common prerequisite programs for the safe production of food products and recommend that each facility assure that its suppliers have in place effective CGMP and food safety programs (Ref. 34). Likewise, Codex addresses the safety of ingredients in the GPFH and recommends that, where appropriate, specifications for raw materials be identified and applied and laboratory tests be conducted to establish fitness for use (Ref. 44).

Moved (insertion) [25]

Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

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

The statute does not indicate the specific circumstances where supplier verification would be required or the specific manner in which supplier verification should be performed, and FDA is not including provisions for such verification in this proposed rule. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to determine the specific circumstances and manner where it would be appropriate to perform supplier verification. FDA believes that factors to consider include:

- The nature of the adverse consequences associated with the hazard, such as whether consumption of food containing the hazard may result in serious adverse health consequences or death; and

- The establishment that would be controlling the hazard associated with the raw material or ingredient (e.g., the facility that receives the raw material or ingredient, the supplier of that raw material or ingredient, or even a supplier to the supplier of the raw material or ingredient).

The vast majority of costs related to a supplier approval and verification program are due to verification activities such as audits and testing of raw materials and ingredients, which would likely be selected based on the hazard associated with the raw material or ingredient and where the hazard is controlled. Although we are not including a provision for such a program in this proposed rule, we estimate that a requirement for a supplier approval and verification program, if implemented as part of a preventive approach, could impose an incremental annual cost of $0 – $5,000 per supplier facility based on size (number of employees) that undergoes an annual audit. This would result in an estimated aggregate cost of $11,000,000 for domestic facilities and an estimated aggregate cost of $12,000,000 for foreign facilities. (As described in the PRIA, foreign costs are estimated by multiplying the domestic per facility cost by the total number of foreign facilities. See section XIX of this document for a discussion of the PRIA.). We estimate that a requirement for a supplier approval and verification program could impose an incremental annual cost of $7,000 – $90,000 per facility based on size (number of employees) for testing of raw materials and ingredients. This would result in an estimated aggregate cost of $5,000,000 for domestic facilities and an estimated aggregate cost of $5,400,000 for foreign facilities. This estimate excludes facilities that would be exempt under this proposed rule (using a definition of $250,000 for a very small business) and facilities that are already doing such supplier verification activities. Further details are provided in the “Consideration of Other Provisions” section of the PRIA.

FDA requests comment on when and how supplier approval and verification is an appropriate means of implementing the statutory directives set out above. Although we have not included these provisions in the proposed rule, we request comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? Should the requirement be very general, for example, requiring a supplier approval and verification program as appropriate to the facility and the food, when appropriate based on risk? FDA also requests comment on who a supplier approval and verification program should apply to - e.g., should it apply to all facilities that manufacture, process, pack or hold food, or be limited (such as to facilities that manufacture or process food)?

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

- Requiring that the supplier approval and verification program include a written list of approved suppliers;
- Requiring that, in determining appropriate verification activities, the owner, operator, or agent in charge of a facility consider relevant regulatory information regarding the supplier, including whether the raw material or ingredient is the subject of an FDA warning letter or import alert relating to the safety of the food.
- Specifying circumstances when a supplier approval and verification program would not be required - e.g., when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur; or when the receiving facility obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the hazard.

- Specifying that the type of verification activity be linked to the seriousness of the hazard - e.g., whether to:
    - Require an onsite audit when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans;
    - Provide more flexibility with respect to hazards for which there is not a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans - e.g., periodic onsite audits, periodic or lot-by-lot sampling and testing of the raw material or ingredient, and periodic review of the supplier's food safety records;
- Specifying requirements for audits - e.g., the qualifications (including training, experience, and conflict of interest) for persons who conduct audits; content of an audit (such as compliance with applicable food safety regulations and, when applicable, compliance with a facility's food safety plan);
- Specifying the frequency of verification activities (e.g., initially, annually, or periodically);
- Specifying whether, for some hazards, it will be necessary to conduct more than one verification activity to provide adequate assurances that the hazard is significantly minimized or prevented;
- Providing for alternative requirements if a supplier is a qualified facility - e.g., documenting that the supplier is a qualified facility and obtaining written assurance that the supplier is producing the raw material or ingredient in compliance with sections 402 and 403(w) of the FD&C Act;

- Specifying those records that would be appropriate for a supplier approval and verification program.
- Providing for substitution of a regulatory inspection (e.g., by FDA or a comparable State regulatory agency or foreign food safety authority), for an onsite audit; and
- Specifying that a receiving facility take appropriate action (e.g., discontinuing use of a supplier) if the facility determines that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur.

FDA is aware that many firms that could be affected by supplier verification may be importing their ingredients. We believe that these firms are interested in how a supplier verification component of preventive controls will interface with the regulations FDA is required to issue to implement foreign supplier verification under new section 805 of the FD&C Act. Section 805 requires FDA to issue regulations to require importers to implement foreign supplier verification programs (FSVPs) that are adequate to provide assurances that the importer's foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under sections 418 (concerning hazard analysis and preventive controls) and 419 (concerning produce safety) of the FD&C Act, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act.

FDA intends to issue proposed regulations implementing section 805 in the near future. FDA intends to align regulations implementing supplier verification under section 418 and regulations implementing FSVP under section 805 to the fullest extent so we do not impose duplicative or unjustified requirements under those two regulations. For example, if a facility

imports ingredients, we would not want to subject it to duplicative requirements under a supplier verification provision and an FSVP regulation.

Likewise, FDA is aware that there is great interest from our trading partners on, among other things, the potential overlap between the supplier verification requirements in preventive controls and in FSVP. FDA believes that the approach to harmonization between supplier verification and FSVP described above would adequately address this and comports with our obligations under the World Trade Organization (WTO) trade agreements, including adherence to the principles of the Sanitary and Phytosanitary (SPS) Agreement.

FDA is committed to meeting the requirements of the SPS Agreement and to complying with our obligations under that Agreement as we implement FSMA. In enacting FSMA, Congress explicitly recognized the importance of compliance with international agreements by providing in section 404 of FSMA that "[n]othing in [FSMA] shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party." While the statutory provisions in FSMA governing supplier verification by domestic facilities and foreign supplier verification by importers differ in some respects, they are based on common risk-based principles. Implementation of these risk-based principles will assure a general consistency of approach with respect to foreign and domestic facilities regarding, for example, when on-site audits are required. Implementation of FSMA's risk-based principles will also ensure that measures applicable to imports are not more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection of the United States, taking into account technical and economic feasibility, as required by paragraph 6 of Article 5 of the SPS Agreement.

FDA intends to publish in the very near future a proposed rule to implement FSMA's foreign supplier verification program requirement. FDA will align the comment periods on that proposed rule and the preventive controls rule addressed in this document so that interested parties in the United States and other countries will be able to assess how they will work together in practice. We invite comments to assist FDA in issuing final rules that protect public health and satisfy both FSMA and our international obligations.

K. Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act

1. Overview

This section discusses two measures (review of consumer, customer, and other complaints, and submission of a food safety profile) that FDA is not proposing as specific provisions in proposed part 117, subpart C. Although these measures are not explicitly included in section 418, we believe that the preventive controls and verification measures discussed in this section are an important part of a modern food safety system.

2. Complaints

The role of consumer complaints in evaluating the effectiveness of a food safety plan is reflected in our HACCP regulations for seafood and juice. Our HACCP regulation for seafood (§ 123.8(a)(2)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points. Our HACCP regulation for juice (§ 120.11(a)(1)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether the complaints relate to the performance of the HACCP plan or reveal the

Moved (insertion) [13]

Formatted: FR Preamble Para Indent Line 1 36 point

existence of unidentified critical control points. FDA notes that the role of consumer complaints is not discussed in the NACMCF guidelines or the Codex guidelines, and their review is not required by the FSIS HACCP regulation for meat and poultry. However, as we discussed in the seafood HACCP proposed rule (59 FR 4142 at 4157), no system is foolproof, and consumer complaints may be the first alert for a processor that deviations are occurring and are not being prevented or uncovered by the processor's HACCP controls.

Further, although most consumer complaints will be related to quality issues, recent experience has demonstrated the value that consumer and customer complaints can provide in bringing attention to possible problems within a facility's preventive controls activities. FDA has received a number of submissions to the Reportable Food Registry (Ref. 60) that have suggested that environmental pathogens or food allergen hazards were not adequately addressed in a supplier's food safety plan. Some of these were identified through customer verification testing and others through complaints from consumers to a facility. A facility may also receive alerts as a result of state surveillance and testing programs. (For a discussion of such programs, see section II.A.6.e of this document). Many recall notices identify the results of a state surveillance and testing program as the trigger for a recall (Ref. 188) (Ref. 189) (Ref. 190).

Moved (insertion) [14]

Although this proposed rule does not include a provision regarding a review of complaints, we estimate that a requirement that facility personnel review consumer, customer or other complaints could impose an incremental annual cost of $0– $6,000 per facility based on size (number of employees). This would result in an estimated aggregate annual cost of $11,500,000 for domestic facilities and an estimated aggregate cost of $12,500,000 for foreign facilities.

We request comment on whether and how a facility's review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards.

3. Submission of a Facility Profile to FDA

Proposed § 117.126 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, preventive controls, and other records. Currently, information of this type is not reviewed by FDA investigators until they are physically present at a facility and have begun an inspection. In light of the large number of facilities that would be covered by this proposal, FDA recognizes several potential benefits to having a facility's food safety plan in advance of an inspection, if we were to require facilities to do so. Having such plans could aid in the efficient oversight of preventive controls by allowing FDA to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly with biological hazards) and to improve on-site inspections by focusing attention on hazards and preventive controls for which the facility appears to have deficiencies. Facilities would benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. We could also more quickly identify facilities that had not established preventive controls for specific hazards of concern to the agency and advise them to fill such gaps to prevent a problem before it occurs. Also, FDA could use the plans in evaluating the need for guidance on specific hazards or controls and prioritizing guidance to areas where it is needed most.

Formatted: FR Preamble 3rd Level Heading Flush Left

Deleted: 110

Deleted: Traditionally

Deleted: has

Deleted: been

Deleted: required to have food safety plans under

Deleted: .

FDA believes that there are significant obstacles to realizing these benefits from submission of food safety plans, however. The agency would expect to receive a very large number of plans. Further, these plans would be expected to vary significantly in content and format. Assimilating the underlying information in a way that would be useful to the agency would be an immense challenge. Moreover, not all of the information in such plans may be essential to realizing the potential benefits described above. Therefore, to most efficiently realize the potential benefits of having certain information prior to an inspection, we request comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan. This information, which could be referred to as a "facility profile," could be submitted through an electronic form using a menu selection approach. The use of an electronic form would enhance our ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that we could target inspections to facilities that manufacture, process, or pack, foods that are at increased risk for a food safety problem; to facilities that appear to have insufficient controls to prevent a problem; or to facilities using a control we conclude is ineffective at controlling hazards. The data elements for a facility profile could include some or all of the following:

- Contact information;
- Facility type;
- Products;
- Hazards identified for each product;
- Preventive controls established for each of the identified hazards;
- Third-party audit information (have you had one and which audit firm(s));

Deleted: tentatively has determined

Deleted: FDA is considering

- Preventive control employee training conducted;
- Facility size (square footage);
- Full time operation or seasonal;
- Operations schedule;

This information could be submitted at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration. FDA requests comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. We also request comment on any additional benefits that might be obtained from using such an approach and any potential concerns with this approach.

We have previously announced an opportunity for public comment on the proposed collection of additional food facility profile information on a voluntary basis from firms that complete the FDA food facility registration process (Federal Register of May 11, 2012, 77 FR 27779). In that notice, we noted that FSMA added section 421 of the FD&C Act (21 U.S.C. 350j), which directed FDA to allocate resources to inspect facilities according to the known safety risks of the facilities. We also noted that food facility profile information voluntarily provided to FDA will help us to determine whether a firm is high-risk or non-high-risk and that we will use the profile information to assist us in determining the frequency at which we will inspect the firm. In contrast to the voluntary submission of food facility profile information described in that notice, in this document we are requesting comment on whether the submission of such information should be required.

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

Formatted: FR Preamble Para Indent Line 1 36 point

Formatted: Level 1

Deleted: Subpart D--

FSMA provides for the establishment of modified requirements for certain facilities under certain circumstances. In this section of this document, we propose such modified requirements.

A. Proposed § 117.201--Modified Requirements That Apply to a Qualified Facility

1. Requirements of Section 418(l) of the FD&C Act

Section 418(l) of the FD&C Act establishes modified requirements for "qualified facilities." As discussed in section II.B.1.b of this document, section 418(l)(1) of the FD&C Act establishes the conditions for a facility to be a "qualified facility" based on either business size (section 418(l)(1)(B) of the FD&C Act) or a combination of the average monetary value of the food sold and the value of food sold to qualified end users as compared to all other purchasers (section 418(l)(1)(C) of the FD&C Act), and proposed § 117.3 would establish a definition for "qualified facility" based on section 418(l)(1).

Sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility is exempt from the requirements of sections 418(a) through (i) and (n) of the FD&C Act (i.e., the requirements for hazard analysis and risk-based preventive controls), but must instead submit two types of documentation to the Secretary of HHS. The first type of required documentation relates to food safety practices at the facility, and section 418(l)(2)(B)(i) provides two options for satisfying this documentation requirement. Under section 418(l)(2)(B)(i)(I), the qualified facility may choose to submit documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective. Alternatively, under section 418(l)(2)(B)(i)(II), the qualified facility may choose to submit documentation (which may

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: "

Deleted: ."

Deleted: "

include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary of HHS, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law.

The second type of required documentation relates to whether the facility satisfies the definition of a qualified facility. Under section 418(l)(2)(B)(ii) of the FD&C Act, the facility must submit documentation, as specified by the Secretary of HHS in a guidance document, that the facility is a qualified facility under section 418(l)(1)(B) of the FD&C Act or section 418(l)(1)(C) of the FD&C Act.

Section 418(l)(7)(A) of the FD&C Act requires that a qualified facility that is exempt from the requirements under sections 418 (a) through (i) and subsection (n), and that does not prepare documentation under section 418(l)(2)(B)(i)(I), provide notification to consumers by one of two procedures, depending on whether a food packaging label is required on the food. With respect to a food for which a food packaging label is required by the Secretary of HHS under any other provision of the FD&C Act, section 418(l)(7)(A)(i) of the FD&C Act requires that a qualified facility include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed. With respect to a food for which a food packaging label is not required by the Secretary of HHS under any other provisions of the FD&C Act, section 418(l)(7)(A)(ii) of the FD&C Act requires that a qualified facility prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

Deleted: [
Deleted:],
Deleted: ."
Deleted: "
Deleted: [
Deleted:]
Deleted: [
Deleted:]."
Deleted: "
Deleted: ".
Deleted: "
Deleted: ."

2. Proposed § 117.201(a)--Documentation to be Submitted

a. Proposed § 117.201(a)(1)--Documentation that the facility is a qualified facility.

Proposed § 117.201(a)(1) would require that a qualified facility submit to FDA documentation that the facility is a qualified facility. Consistent with the conditions in section 418(l)(1) of the FD&C Act for a facility to be a qualified facility, and our proposed definition (proposed § 117.3) of "qualified facility," the documentation would be directed to either the status of the facility as a very small business (as would be defined in proposed § 117.3) or the applicability of conditions for average annual monetary value and the value of food sold to qualified end users as compared to other purchasers (as would be included in the definition of qualified facility in proposed § 117.3). As discussed further in section XIII.A.5, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility is a very small business, otherwise meets the definition of a qualified facility under proposed § 117.3, or both, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 117.201(a)(1). We would not, for example, require that a facility submit financial information to FDA demonstrating its total sales or to the proportion of sales to qualified end users.

Proposed § 117.201(a)(1) also would establish that, for the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011. The conditions related to average annual monetary value established in section 418(l)(1)(C) of the FD&C Act, and the definition of very small business in proposed § 117.3, allow adjustment for inflation. To establish a level playing field for all facilities that may satisfy definition of a qualified facility, we are proposing to establish the baseline year for the calculation in proposed § 117.201(a)(1). We are proposing to establish

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted:

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law. We tentatively conclude that because Congress provided a specific dollar amount in section 418(l)(1)(C)(ii)(II) – i.e., $500,000 – and it provided that the dollar amount should be adjusted for inflation, it is reasonable to establish the baseline year as the year that the law was enacted.

b. Proposed § 117.201(a)(2)--Documentation related to food safety practices at a facility. Proposed § 117.201(a)(2) would provide two options for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility. Proposed § 117.201(a)(2)(i) would allow qualified facilities to submit documentation to demonstrate that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective to satisfy this requirement.

Proposed § 117.201(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(I) of the FD&C Act, except that proposed § 117.201(a)(2)(i) would specify monitoring the performance of the preventive controls to ensure that such controls are effective (emphasis added). As discussed in section II.B.1.a of this document, under the overall framework of the proposed requirements that would be established in subpart C, monitoring is directed to performance of preventive controls. Thus, proposed § 117.201(a)(2)(i) is consistent with the statute and the overall framework of this proposed rule.

Proposed § 117.201(a)(2)(ii) would provide another option for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility by allowing qualified facilities to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Proposed § 117.201(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(II) of the FD&C Act.

As discussed further in section XIII.A.5 of this document, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility (1) has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or (2) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 117.201(a)(2). We would not, for example, require that a facility submit documentation to FDA demonstrating the content of their hazard identification, preventive controls, or monitoring of the implementation of preventive controls; or copies of their non-Federal licenses, inspection reports, certificates, permits, credentials, or certifications.

3. Proposed § 117.201(b)--Procedure for Submission

Proposed § 117.201(b) would require that qualified facilities submit the documentation that would be required by proposed § 117.201(a) by one of two procedures. Proposed § 117.201(b)(1) would provide an option to submit documentation electronically at http://www.access.fda.gov by following the instructions to be provided on that web page. Proposed § 117.201(b)(1) would inform facilities that this website is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. Although

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

electronic submission is not required, proposed § 117.201(b)(1) would encourage electronic submission, which is efficient for FDA and should also be efficient for facilities. Electronic submission generally would be available 24 hours a day, 7 days a week, unless the website is experiencing technical difficulties or is undergoing maintenance.

Proposed § 117.201(b)(1) would provide an option to submit documentation by mail. A qualified facility would have the option to submit documents in a paper format or in an electronic format on a CD-ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. "Mail" would include the U.S. mail and businesses that can deliver documents to the address provided. We would recommend that an owner, operator or agent in charge of a qualified facility submit by mail only if the qualified facility does not have reasonable access to the Internet. It is not efficient for FDA to receive such documents by mail.

We are not proposing to provide for submission by fax. We expect that there may be technical difficulties or loss or mix-up of some submitted information if we were to allow for submission by fax.

In section XIII.A.5 of this document, we discuss the information that would be submitted.

4. Proposed § 117.201(c)--Frequency of Submission

Proposed § 117.201(c)(1) would require that the documentation that would be required by section § 117.201(a) be submitted to FDA initially within 90 days of the applicable compliance date of the rule. As discussed in section VII of this document, the compliance date for a small business would be 2 years after the date of publication of the final rule and the compliance date for a very small business would be 3 years after the date of publication of the final rule.

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: six months

Deleted: effective

Deleted: 18 months

Deleted: effective

Proposed § 117.201(c)(2) would require that the documentation that would be required by proposed § 117.201(a) also must be resubmitted to FDA at least every 2 years, or whenever there is a material change to the information that would be described in proposed § 117.201(a). For the purposes of proposed § 117.201, a material change would be one that changes whether or not a facility is a "qualified facility." The status of a facility as a qualified facility has the potential to change materially on an annual basis. For example, if a facility reports that it is a very small business (e.g., under one option identified in proposed § 117.3, has less than $250,000 in total annual sales of food, adjusted for inflation), its total annual sales of food likely would change on an annual basis, and could change so as to exceed $ 250,000. Likewise, if a facility reports that it otherwise satisfies the definition of a qualified facility, its total annual sales of food and value of food sold to qualified end users as compared to other purchasers likely would change on an annual basis, and could change so as to no longer satisfy the definition of a qualified facility.

Deleted: 110
Deleted: 110
Deleted: two
Deleted: 110
Deleted: 110
Deleted: i.
Deleted: 110
Deleted: is

5. Information That Would Be Submitted

Consistent with section 418(l)(2)(B)(ii) of the FD&C Act, we intend to issue guidance regarding documentation that would be submitted under proposed § 117.201(a)(1) to demonstrate that a facility is a qualified facility. As discussed in sections XIII.A.2.a and XIII.A.2.b of this document, we tentatively conclude that certified statements from the owner, operator, or agent in charge of a qualified facility would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 117.201(a)(1) and (2).

Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110

To inform the guidance required under section 418(l)(2)(B)(ii) of the FD&C Act and any other guidance that may be useful in addressing questions regarding submission of documentation under this subpart, in this document we request comment on an option we are

considering regarding the submission of documentation. Specifically, we request comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility. A facility that does not identify itself as a qualified facility would not be prompted to provide additional information under proposed § 117.201(a).

Deleted: 110

A facility that identifies itself as a qualified facility would be prompted to provide the following information by checking items that apply. Such items could include:

- Whether the facility satisfies the conditions for a qualified facility:
  - As a very small business as that term would be defined in proposed § 117.3;

Deleted: 110

  - As a facility that otherwise satisfies the definition of qualified facility in proposed § 117.3 based on average monetary value of sales and value of food sold to qualified end users as compared to other purchasers; or

Deleted: 110

  - Both of the above.
- Whether the facility :
  - Has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective;
  - Is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries; or
  - Both of the above.

In essence, such a system would provide for self-certification that the facility has appropriate information demonstrating that the facility is a qualified facility and either has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Such a system may include a statement reminding submitters that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. Using such a system, a qualified facility could update the documentation required by proposed § 117.201(a) during the biennial registration required by section 415(a)(3) of the FD&C Act.

6. Proposed § 117.201(d)--Notification to Consumers

Proposed § 117.201(d) would require that a qualified facility that does not submit the type of documentation directed to food safety practices described in § 117.201(a)(2)(i) provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) consistent with section 418(l)(7) of the FD&C Act. If a food packaging label is required, proposed § 117.201(d)(1) would require that the required notification appear prominently and conspicuously on the label of the food. If a food packaging label is not required, proposed § 117.201(d)(2) would require that the required notification appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

Proposed § 117.201(d) would enable consumers to contact the facility where a food was manufactured or processed (e.g., if the consumer identifies or suspects a food safety problem with a product) irrespective of whether the food product bears a label. The use of the term "business address" in section 418(l)(7) of the FD&C Act contrasts with Congress' use of a different term, "place of business," in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. Our regulations interpret "place of business" as requiring only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 C.F.R. 101.5(d)). We tentatively conclude that the use of the term "business address" in section 418(l)(7) demonstrates Congress' intent to require the facility's full address, including the street address or P.O. box, to appear on labels or other required notifications when the facility has opted to not submit documentation directed to food safety practices under section 418(l)(2)(B)(i)(I) of the FD&C Act. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the "place of business" labeling regulation (§ 101.5(d)) to be adequate for notification to consumers for foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 418(l)(7) for the facility's "business address" to appear on the food label. Requiring the complete business address for this purpose is consistent with our guidance to industry on the labeling of dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Ref. 130). When proposed § 117.201(d) would

Deleted: 110

Deleted: to 2009 guidance

Deleted: 110

apply to a food for which a food packaging label is required under any other provision of the FD&C Act, the complete business address would substitute for the "place of business" required under section 403(e)(1) of the FD&C Act and 21 C.F.R. 101.5(d) and would not impose any requirement for a label that would be in addition to any label required under any other provision of the FD&C Act. We seek comment on this interpretation.

7. Records

Proposed § 117.201(e)(1) would require that a qualified facility maintain records relied upon to support the documentation that would be required by § 117.201(a). Proposed § 117.201(a) would not require that a qualified facility establish any new records, but merely retain those that the facility relied upon to support the documentation that would required by proposed § 117.201(a). Proposed § 117.201(e)(2) would establish that the records that a qualified facility must maintain are subject to the requirements of subpart F of part 117. As discussed in section XV of this document, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by proposed part 117, including provisions for retention of records and for making records available for official review. Together, proposed § 117.201(a) and (b) would make the underlying records qualified facilities would rely on to support their self-certifications available to FDA upon request. We tentatively conclude that it is appropriate to require that the records relied upon to support a self-certified statement be retained and made available to FDA upon request.

Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted:
Deleted: 110

B. Proposed § 117.206--Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

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

Briefly, as relevant to proposed § 117.206, specific provisions of section 418 of the FD&C Act require, in relevant part, that the owner, operator, or agent in charge of a facility:

- Identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility and develop a written analysis of the hazards (section 418(b) of the FD&C Act);
- Identify and implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act (section 418(c) of the FD&C Act);
- Monitor the effectiveness of the preventive controls implemented under section 418 (c) of the FD&C Act to provide assurances that the outcomes described in section 418 (c) shall be achieved (section 418(d) of the FD&C Act);
- Establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective … appropriate action is taken to reduce the likelihood of recurrence of the implementation failure; all affected food is evaluated for safety; and all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (section 418(e) of the FD&C Act);

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: "[I]dentify
Deleted: … [
Deleted:]
Deleted: ."
Deleted: "[I]dentify
Deleted: …
Deleted: …
Deleted: …
Deleted: … [
Deleted:]
Deleted: [
Deleted:] …"
Deleted: "[M]onitor
Deleted: [
Deleted:]
Deleted: [
Deleted:)]
Deleted: ."
Deleted: "[E]stablish
Deleted: [
Deleted:]
Deleted: …
Deleted: …
Deleted: [
Deleted:] …"

- Verify that the preventive controls are adequate to control the hazards the owner, operator, or agent is conducting monitoring and is making appropriate decisions about corrective actions and the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards and there is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f) of the FD&C Act);

- Maintain, for not less than 2 years, records documenting the monitoring of the preventive controls instances of nonconformance material to food safety and instances when corrective actions were implemented (section 418(g) of the FD&C Act);

- Prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards and identifying the preventive controls adopted to address those hazards (section 418(h) of the FD&C Act);

- Conduct a reanalysis under section 418 (b) of the FD&C Act whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier (section 418(i) of the FD&C Act).

In addition to these requirements directed to the owner, operator, or agent in charge of a facility, section 418(m) of the FD&C Act provides, in relevant part, that the Secretary may, by regulation, exempt or modify the requirements for compliance under section 418 of the FD&C

Deleted: "[V]erify
Deleted: …
Deleted: …
Deleted: …
Deleted: … [
Deleted:]
Deleted: … [
Deleted:]
Deleted: …
Deleted: … [
Deleted:]
Deleted: [
Deleted:]
Deleted: .”
Deleted: “[M]aintain
Deleted: …
Deleted: … [
Deleted:]
Deleted: …”
Deleted: “[P]repare
Deleted: this
Deleted: …
Deleted: …
Deleted: .”
Deleted: “[C]onduct
Deleted: [
Deleted:]
Deleted: .”
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: “[t]he
Deleted: [

Act with respect to facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment.

2. Approach to Modified Requirements under Section 418(m) of the FD&C Act

As discussed in section X.D.4 of this document, proposed § 117.7 would both provide that subpart C does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment (proposed § 117.7(a)) and establish that such a facility is subject to modified requirements in proposed § 117.206 (proposed § 117.7(a)). In the remainder of our discussion of these modified requirements, we refer to "packaged food that is not exposed to the environment" as "unexposed packaged food," and we refer to "unexposed refrigerated packaged food that requires time/temperature control for safety" as "unexposed refrigerated packaged TCS food." As noted in section X.D.2 of this document, we consider "not exposed to the environment" and "unexposed" to mean that the food is in a form that prevents any direct human contact with the food. The modified requirements in proposed § 117.206 would apply to unexposed refrigerated packaged TCS food. In essence, proposed § 117.7 distinguishes between unexposed packaged food and unexposed refrigerated packaged TCS food. This distinction is based on hazards that are reasonably likely to occur during the storage of unexposed refrigerated packaged TCS food, but are not reasonably likely to occur during the storage of unexposed packaged food that does not require time/temperature control for safety.

When an unexposed packaged food is a refrigerated TCS food, the principal hazard for the unexposed refrigerated packaged TCS food is the potential for the growth of, or toxin production by, microorganisms of public health significance. Information about this hazard for TCS foods in general (i.e., not limited to unexposed packaged food) is widely available (Ref. 137) (Ref. 138) (Ref. 139) (Ref. 140). In brief, the need for time/temperature control is primarily

Deleted:]
Deleted: ...
Deleted: ."
Formatted: Level 1
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110.5
Deleted: 110.5
Deleted: 110
Deleted: 110.5
Deleted: 110
Deleted: 110.5
Deleted: Food Code Chapter 1 and Annex 3, Chapter 1; IFT report on PHF).

determined by (1) the potential for contamination with microorganisms of public health significance and (2) the potential for subsequent growth and/or toxin production. Refrigeration has long been used to retard deterioration of the flavor, color, and texture of foods. More importantly, refrigeration helps maintain the microbiological safety of potentially hazardous foods (62 FR 8248, February 24, 1997).

Failure to maintain foods at appropriate temperatures may result in the growth of microorganisms that may have contaminated the foods before, or at the time of, harvest or during processing, handling, or storage. The rate of growth of these microorganisms is reduced as the storage temperature is lowered. Proper refrigeration, therefore, prevents or slows the growth of human pathogens and spoilage microorganisms and reduces the likelihood of foodborne illness (62 FR 8248). A review of the factors that influence microbial growth and an analysis of microbial hazards related to time/temperature control of foods for safety can be found in a report (issued by the Institute of Food Technologists (IFT) under contract to FDA) on the Evaluation and Definition of Potentially Hazardous Foods (Ref. 140) (the IFT report). The IFT report describes properties of common food commodities and the microbiological hazards that may occur from consuming particular food commodities, emphasizing microbial concerns that would be associated with temperature abuse of the products. The IFT report discusses foods for which time/temperature control may be necessary for safety (Ref. 140). Most foods that are stored refrigerated have not been processed to eliminate pathogenic sporeformers, including Clostridium botulinum, Bacillus cereus and C. perfringens. If refrigerated foods are exposed to high enough temperatures for sufficient time, these sporeformers may begin to grow and produce toxins. Some strains of C. botulinum and B. cereus can grow at refrigeration temperatures, e.g.,

Deleted: ;

Deleted: IFT 2001 report

Deleted: IFT 2001

some strains of B. cereus grow at 39ºF (4ºC) and some strains of C. botulinum grow at 38ºF (3.3ºC) (Ref. 173).

Deleted: FDA Seafood Hazards and Controls Guide, Appendix 4).

Examples of refrigerated foods that are capable of supporting the growth of pathogenic sporeformers such as B. cereus, C. botulinum and C. perfringens include many prepared soups, filled pastas, and sauces. In addition, some foods may be contaminated with L. monocytogenes, which, as described in section II.D.2.a, can also grow at refrigeration temperatures. Examples of foods that support the growth of L. monocytogenes include milk and soft cheese. Producers of refrigerated foods minimize the contamination of foods with pathogens to the extent possible, particularly if the pathogen can grow under refrigeration conditions. Growth of pathogens is very slow under refrigeration, and the lower the temperature the longer the time for growth (Ref. 140). Conversely, as refrigeration temperature increases, the growth rate of strains of pathogens that grow slowly under refrigeration increases and food temperatures may get high enough that pathogens that cannot grow at normal refrigeration temperatures (generally in the range of 41-45ºF (5ºC-7ºC)) begin to grow (Ref. 140). For example, the strains of C. botulinum that have caused most of the outbreaks in the United States do not grow and produce toxin until the temperature reaches 50ºF (10ºC) (Ref. 3). Additional information about the time/temperature control of food to address the potential for microorganisms of public health significance to grow or produce toxins is available in books on food microbiology that are available for purchase.

Deleted: IFT 2001

Deleted: IFT 2001

Deleted: FDA seafood hazards guide).

Such information is sufficiently well-known and accepted that we tentatively conclude that the outcome of each individual hazard analysis for an unexposed refrigerated packaged TCS food, conducted by the owner, operator, or agent in charge of each individual facility solely engaged in the storage of unexposed packaged food, would be the same. That outcome would be that the potential for the growth of, or toxin production by, microorganisms of public health

significance is a hazard reasonably likely to occur in any unexposed refrigerated packaged TCS food. Likewise, information about appropriate preventive controls for this hazard is widely available (Ref. 191) (Ref. 139). Such information is sufficiently well-known and accepted that we tentatively conclude that the appropriate preventive control selected by each individual facility solely engaged in the storage of unexposed packaged food would be adequate controls on the temperature of any unexposed refrigerated packaged TCS food.

Deleted: Food Code Chapter 3 and Annex 3 Chapter 3).

In light of the general recognition of the hazard that is reasonably likely to occur in a refrigerated packaged TCS food and the appropriate preventive control for that hazard, we tentatively conclude that it is appropriate to specify the hazard and appropriate preventive control in the regulation. Under this approach, it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged food to conduct its own hazard analysis and reach its own conclusion about the hazard and the appropriateness of temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. Instead, what would remain for the facility to do to comply with section 418 of the FD&C Act for the activity of storing an unexposed refrigerated packaged TCS food would be a subset of the requirements for hazard analysis and risk-based preventive controls that would be established in proposed subpart C to implement section 418 of the FD&C Act. None of these requirements would require a qualified individual. This subset of requirements would be to:

- Implement temperature controls (section 418(c) of the FD&C Act);
- Monitor temperature (section 418(d) of the FD&C Act);
- Take appropriate corrective actions when there is a problem with temperature control (section 418(e) of the FD&C Act);

- Conduct applicable verification activities (review of records) (section 418(f) of the FD&C Act); and
- Establish and maintain certain records (section 418(g) of the FD&C Act).

We seek comment on the proposed list of modified requirements.

We also tentatively conclude that it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged food to conduct the reanalysis specified in section 418(i) of the FD&C Act with respect to storing an unexposed refrigerated packaged TCS food. As discussed in section XII.G.6 of this document, reanalysis would apply in determining whether to apply any additional preventive controls and in determining whether to update the written plan. Under our approach, it is FDA who has identified the preventive control, and it would be FDA's responsibility, through rulemaking, to require any additional preventive control. Likewise, under our approach, the facility would not be required to develop a food safety plan and, therefore, would not need to update the plan. If, for example, the facility changes its procedures for temperature control, the specific activities that the facility would be required to conduct (monitoring temperature; taking appropriate corrective actions if there is a problem with temperature control; conducting applicable verification activities; and establishing and maintaining appropriate records) would be adequate to address the change in procedure for temperature control.

Formatted: FR Preamble Para Indent Line 1 36 point

3. Proposed § 117.206--Modified Requirements that Apply to a Facility Solely Engaged in the Storage of Packaged Food that Is Not Exposed to the Environment

Formatted: Level 1

Deleted: 110

Proposed § 117.206(a) would require that the owner, operator or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment conduct certain activities for any such refrigerated packaged food that requires time/temperature

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. Briefly, those activities would encompass:

- Establishing and implementing temperature controls (proposed § 117.206(a)(1));
- Monitoring the temperature controls (proposed § 117.206(a)(2));
- If there is a problem with the temperature controls for such refrigerated packaged food, taking appropriate corrective actions (proposed § 117.206(a)(3));
- Verifying that temperature controls are consistently implemented (proposed § 117.206(a)(4)); and
- Establishing and maintaining certain records (proposed § 117.206(a)(5)).

More specifically, proposed § 117.206(a)(1) would require that the owner, operator, or agent in charge of a facility subject to proposed § 117.206 establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food. There are two fundamental questions that the owner, operator, or agent in charge of a facility subject to proposed § 117.206 would need to know the answers to in order to comply with proposed § 117.206 for any given unexposed refrigerated packaged food:

- Is the food a TCS food?
- If the food is a TCS food, what is the appropriate temperature for storage of the food?

The two primary ways in which the owner, operator, or agent in charge of a facility subject to proposed § 117.206 can obtain the answers to these questions are: (1) through information provided by the manufacturer, processor, or packer of the food, either in documents exchanged between the parties in the course of business or by label statements placed on the food

Deleted: 110
Deleted:
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: No underline
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110

by the manufacturer, processor, or packer of the food; and (2) through applicable scientific and technical support literature.

As discussed in section X.D.2 of this document, a citizen petition submitted to FDA (Docket No. FDA-2011-P-0561) asserted that facilities work closely with the food manufacturers to understand the conditions and controls that need to be utilized to ensure the quality of the foods they store and distribute and, in many cases, those conditions and controls are formalized in written contracts. If the conditions for storage are not formalized in written contracts or by other means (e.g., through documents of the trade that travel with a food product when it moves within the supply chain), information relevant to safe storage of the food may be provided by the manufacturer, processor, or packer of the food on the food label. For example, in 1997 FDA published guidelines for labeling food that needs refrigeration by consumers due to the potential for the food to be rendered unsafe due to the growth of infectious or toxigenic microorganisms if "temperature abused" (62 FR 8248, February 24, 1997). FDA recommended that foods requiring refrigeration by the consumer for safety be labeled "IMPORTANT Must be Kept Refrigerated to Maintain Safety" (62 FR 8248 at 8251) and that foods that are intended to be refrigerated but that do not pose a safety hazard if temperature abused be labeled more simply – e.g.; "Keep refrigerated." Such labeling can provide facilities with the information to identify TCS foods. We tentatively conclude that it would be rare for a facility solely engaged in the storage of unexposed packaged food to not have information regarding whether a refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food. We request comment on this tentative conclusion.

In a situation where the owner, operator or agent in charge of a facility does not have information from the manufacturer, processor, or packer of the food about whether an unexposed

refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food, the owner, operator, or agent in charge of the facility could either consult the scientific and technical literature to determine whether a particular food is a TCS food or assume that any unexposed refrigerated packaged food is a TCS food. Information about foods that are TCS foods, and about the appropriate temperatures to address the potential for microorganisms of public health significance to grow, or produce toxin, in food are well-established in the scientific literature. Documents prepared by or on behalf of FDA regarding appropriate time/temperature controls for safety (Ref. 173) (Ref. 140) provide numerous references to the primary scientific literature and serve as the basis for time/temperature controls for a variety of foods. The two temperatures commonly cited in these documents as maximum temperatures for safe storage of refrigerated food are 41 ºF (5 ºC) and 45 ºF (7 ºC). The cited maximum temperature depends on the food; in some cases, a maximum storage temperature is established through rulemaking in a regulation. For example:

- Our regulations for the prevention of Salmonella Enteritidis in shell eggs during production, storage, and transportation (§ 118.4(e)) and for refrigeration of shell eggs held for retail distribution (§ 115.50(b)(2)) require that eggs be held and transported at a temperature not to exceed 45ºF (7ºC).
- The PMO provides for pasteurized Grade "A" milk and milk products to be held at 45ºF (7ºC) (Ref. 37).
- The FDA Food Code, which has been widely adopted in state laws, recommends holding most potentially hazardous (TCS) food at 41ºF (7ºC) or lower (Ref. 191).

Storage of refrigerated food at or below one of these two temperatures (i.e., 41 ºF (5 ºC) or 45 ºF (7 ºC)) consistent with storage temperatures required by regulation or recommended in

Deleted: Refs. to Food Code Annex 3, Chapter 3; Seafood Hazards Guide Appendix 4; and IFT 2001 report

Deleted: FDA PMO

Deleted: Food Code, Chapter 3).

Formatted: FR Preamble Para Indent Line 1 36 point

widely adopted documents such as the PMO and the FDA Food Code would satisfy proposed § 117.206(a).

We consider frozen food to be a subset of refrigerated food. The temperature and time required for a frozen food to become unsafe would result in significant quality issues for such food. Although there have been occasional problems with frozen food being subject to temperatures that allow some thawing in storage and distribution, we are not aware of situations in which frozen foods have been associated with the food becoming unsafe. Thus, we tentatively conclude that it would be rare for an unexposed frozen packaged food to be a TCS food.

Proposed § 117.206(a)(2) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food monitor the temperature controls established for unexposed refrigerated packaged TCS food with sufficient frequency to provide assurance that they are consistently performed. Monitoring can be done by use of a continuous temperature-recording device (e.g., a recording thermometer) that indicates and records the temperature accurately within the refrigeration compartment with a visual check of the recorded data at least once per day. Monitoring as would be required by proposed § 117.206(a)(2) would provide the owner, operator, or agent in charge of the facility with factual information with which to judge whether the temperature control is operating as intended. Proposed § 117.206(a)(2) is modified relative to the analogous monitoring requirement that would be established in proposed § 117.140(a) in subpart C in that proposed § 117.206(a)(2) would not require written procedures for monitoring. The records of monitoring (which would be required by proposed § 117.206(a)(5)(i)) would demonstrate the frequency of monitoring. We request comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

Deleted: 110

Deleted: with frozen food

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Proposed § 117.206(a)(3) would require that, if there is a problem with the temperature controls for unexposed refrigerated packaged TCS food, the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food take appropriate corrective actions to correct a problem with the control of temperature for any refrigerated packaged food and reduce the likelihood that the problem will recur (proposed § 117.206(a)(3)(i)); evaluate all affected food for safety (proposed § 117.206(a)(3)(ii)); and prevent the food from entering commerce, if the owner, operator, or agent in charge of a facility cannot ensure the affected food is not adulterated under section 402 of the FD&C Act (proposed § 117.206(a)(3)(iii)). Such corrective actions would be necessary if, for example, there was a failure to maintain adequate temperature control. Proposed § 117.206(a)(3) is modified relative to the analogous proposed requirement for corrective actions that would be established in proposed § 117.145(a) in subpart C in that proposed § 117.206(a)(3) would not require written procedures for corrective actions. In essence, there is a single action to correct the problem (i.e., to restore temperature control), followed by the need to evaluate the food for safety and to prevent food from entering commerce when appropriate. The corrective actions taken, including information to document that product was not exposed to temperatures and times that would compromise the safety of the product, would be documented in records subject to agency review. It may be necessary for the owner, operator, or agent in charge of the facility to consult with the applicable manufacturer, processor, or packer of the food to determine the appropriate disposition of the food.

Proposed § 117.206(a)(4)(i) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food verify that temperature controls are consistently implemented by calibrating temperature monitoring and recording

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

devices. As discussed in section XII.G.5.a of this document, calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance temperatures are adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food. Proposed § 117.206(a)(4)(i) is analogous to proposed § 117.150(d)(2) in subpart C, which would establish a verification requirement for calibration of process monitoring instruments and verification instruments.

Proposed § 117.206(a)(4)(ii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food verify that temperature controls are consistently implemented by reviewing records of calibration within a reasonable time after the records are made. As discussed in section XII.G.5.b of this document, the purpose of the review of records would be to ensure that the records are complete and that the preventive controls are effective. If temperature monitoring and recording devices are not properly calibrated, the temperature controls may not be effective. As discussed in section XII.G.5.b of this document, the review of calibration records will depend in part on the frequency with which calibrations occur.

Proposed § 117.206(a)(4)(iii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food verify that temperature controls are consistently implemented by reviewing the records of monitoring and actions taken to correct a problem with the control of temperature within a week after the records are made. As discussed in section XII.G.5.b of this document, the purpose of the review of records would be to ensure that the records are complete, that the temperatures recorded were adequate to

Deleted: b

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: f

Deleted: f

Deleted: 110

Deleted: f

significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food, and that appropriate actions were taken to correct any problem with the control of temperature for any unexposed refrigerated packaged TCS food. A weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records. Proposed § 117.206(a)(4)(iii) is analogous to proposed § 117.150(d)(2)(ii) in subpart C, which would establish a verification requirement for review of records of monitoring and corrective action records within a week after the records are made.

Proposed § 117.206(a)(4) is modified relative to the analogous proposed verification requirements in proposed § 117.150 in that proposed § 117.206(a)(4) would not require validation or reanalysis. There is a single control to verify, which limits the need for many of the verification procedures that might otherwise apply. As noted above, the temperatures to control growth of microbial pathogens are well documented and do not require validation that they are effective in controlling the potential for microorganisms of public health significance to grow, or produce toxin, in food. The reasons for not requiring reanalysis were discussed in section XIII.B.2. Proposed § 117.206(a)(4) also is modified relative to the analogous proposed verification requirements in proposed § 117.150 in that proposed § 117.206(a)(4) would not require that a qualified individual perform or oversee the review of records of calibration or records of monitoring and actions taken to correct a problem with the control of temperature. The nature of these records does not require the qualifications that would be required under proposed § 117.155(b).

Deleted: 110

Deleted: 110

Deleted: 5

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: , review of consumer, customer or other complaints, product testing,

Deleted: Under §

Moved down [27]: 101.

Deleted: 5, complaints would go to the manufacturer, packer, or distributor of food as identified on the label of the food rather than to a warehouse solely engaged in storage of the food. .Product testing is not a useful verification procedure for this control measure since monitoring provides sufficient information that microbial growth is being controlled.

Deleted:

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Proposed § 117.206(a)(5) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food establish and maintain records documenting the monitoring of temperature controls for any unexposed refrigerated packaged TCS food (proposed § 117.206(a)(5)(i)); records of corrective actions taken when there is a problem with the control of temperature for any unexposed refrigerated packaged TCS food (proposed § 117.206(a)(5)(ii)); and records documenting verification activities (proposed § 117.206(a)(5)(iii)). The records that document monitoring would be used to verify that the temperature controls are effectively and significantly minimizing or preventing the growth of, or toxin production by, microorganisms of public health significance. The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken. The records that document verification activities would be used to document that this key element of a food safety plan has been implemented. These records would be necessary to demonstrate compliance with the requirements and as such would be useful to inspectors and auditors. Proposed § 117.206(a)(5) is analogous to provisions in proposed §§ 117.140(c), 117.145(d), and 117.150(f) in subpart C, which would require documentation of monitoring, corrective actions, and verification activities, respectively.

Proposed § 117.206(b) would establish that the records that a facility must establish and maintain under proposed § 117.206(a)(5) are subject to the requirements of proposed subpart F. Proposed subpart F would establish requirements that would apply to all records that would be required under proposed part 117. We describe the requirements of proposed subpart F in section XV of this document. Proposed § 117.206(b) is analogous to proposed § 117.175(b) in subpart C.

Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110

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

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

Section 418(l)(3)(A) of the FD&C Act specifies that, in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under section 418(l) of the FD&C Act, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under section 418(l) of the FD&C Act. Section 418 does not expressly prescribe the procedures for withdrawing an exemption provided to a qualified facility under section 418(l). We tentatively conclude that it is appropriate to be transparent about the process we would use to withdraw an exemption and that we should include the process in the proposed rule.

B. Proposed § 117.251--Circumstances That May Lead FDA to Withdraw an Exemption Applicable to a Qualified Facility

1. Proposed § 117.251(a)--Withdrawal of an Exemption in the Event of an Active Investigation of a Foodborne Illness Outbreak

Proposed § 117.251(a) would provide that FDA may withdraw the exemption that would be applicable to a qualified facility under proposed § 117.5(a) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility. Proposed § 117.251(a) would implement the statutory language of section 418(l)(3)(A) of the FD&C Act. As discussed in section II.A.6.c of this document, an outbreak of foodborne illness

Deleted: Subpart E--
Formatted: Level 1
Deleted: "[i]n
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: [
Deleted:],
Deleted: [
Deleted:]."
Formatted: Level 1
Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110.2
Deleted: 110

is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. Food can become contaminated at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. When foodborne illness is associated with food, a traceback investigation may enable us to directly link the illness to the facility or facilities that manufactured, processed, packed, and/or held the food.

For example, in February 2007, CDC notified FDA of a multi-state outbreak of Salmonella Tennessee infections associated with the consumption of peanut butter (73 FR 55115 at 55118, September 24, 2008). Peanut butter is a non-perishable packaged food, sold in jars. Consumers who became ill had open jars of peanut butter available for testing. Investigators were able to test samples of peanut butter taken from the jars and confirm the presence of Salmonella Tennessee in the peanut butter. Investigators were able to identify the manufacturer through information required to be on the label of the jars (21 CFR 101.5(a)) and through a product code the manufacturer had voluntarily placed on the jars. This information made it possible for FDA to visit the manufacturing facility the day after we learned of the outbreak from CDC. Investigators were able to use the product code to look in the manufacturing facility for unopened jars of peanut butter manufactured at the same time as the jars available from consumers. Investigators took samples of peanut butter from these unopened jars and confirmed the presence of Salmonella Tennessee in those samples. Because investigators uncovered conditions at the manufacturer's facility that were likely to have caused the contamination and obtained a positive environmental sample, investigators saw no need to further trace the peanuts back to the farm where the peanuts were grown (73 FR 55115 at 55118). In circumstances such

Deleted: the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (

Deleted:)

as the 2007 peanut butter outbreak, the available data and information from the investigation directly linked the outbreak of foodborne illness to the manufacturing facility.

2. Proposed § 117.251(b)--Withdrawal of an Exemption Based on Conduct or Conditions Associated with a Qualified Facility

Proposed § 117.251(b) would provide that FDA may withdraw the exemption applicable to a qualified facility under proposed § 117.5(a) if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. As an example, we may receive reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a qualified facility that manufactured, processed, packed or held the food. If our investigation finds conduct or conditions associated with the facility that are material to the safety of the food (for example, conduct or conditions that likely led to the contamination of the food), we would consider withdrawing the exemption applicable to the facility under proposed § 117.5(a) if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a qualified facility, we discover conditions and practices that are likely to lead to contamination of food with microorganisms of public health significance, we would consider withdrawing the exemption provided to the facility under proposed § 117.5(a) if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110.2
Deleted: 110.2
Deleted: 110.2

C. Proposed § 117.254--Issuance of an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.254(a) would provide that, if FDA determines that an exemption applicable to a qualified facility under proposed § 117.5(a) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption. We intend to create and maintain a written record of a determination that the withdrawal of an exemption is warranted and to include the basis for the determination in the written record.

Proposed § 117.254(b) would require that an FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption as part of the withdrawal determination procedure before the order is issued. A Regional Food and Drug Director is an example of an FDA official senior to a District Director. The Deputy Director and Director of the Center for Food Safety and Applied Nutrition are examples of an FDA official senior to the Director of the Office of Compliance. Requiring prior approval of a withdrawal order by a District Director or an FDA official senior to a District Director is consistent with the approval requirement for a detention order in part 1, subpart K (Administrative Detention of Food for Human or Animal Consumption). Requiring prior approval of a withdrawal order by the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition is consistent with current FDA practices when dealing with foreign firms.

Proposed § 117.254(c) would require that FDA issue an order to withdraw the exemption to the owner, operator, or agent in charge of the qualified facility. The requirements of section 418 of the FD&C Act are directed to the owner, operator, or agent in charge of a facility. We

Formatted: Level 1
Deleted: 110
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: § 110.2
Deleted: 110
Deleted:
Deleted: 110
Deleted:

tentatively conclude that the statutory language of section 418 enables FDA to issue an exemption withdrawal order to any of these persons.

Proposed § 117.254(d) would require that FDA issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

D. Proposed 117.257--Contents of an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.257(a) through (i) would require that an order to withdraw an exemption applicable to a qualified facility under § 117.5(a) include the following information:

- (a) The date of the order (proposed § 117.257(a));
- (b) The name, address and location of the qualified facility (proposed § 117.257(b));
- (c) A brief, general statement of the reasons for the order, including information relevant to:
  - (1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or
  - (2) Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility (proposed § 117.257(c)).
- (d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order (proposed § 117.257(d));
- (e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E (proposed § 117.257(e));

Deleted: 110

Formatted: Level 1

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110.2

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

- (f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter (21 CFR Part 16), with certain exceptions described in proposed § 117.270 (proposed § 117.257(f));
- (g) The mailing address, telephone number, e-mail address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); (proposed § 117.257(g)); and
- (h) The name and the title of the FDA representative who approved the order (proposed § 117.257(i)).

FDA tentatively concludes that the requirements that we propose in § 117.257 would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal with adequate notice of the basis for our determination to withdraw the exemption and of their opportunity to appeal our determination and to request an informal hearing. The proposed notification procedures are similar to and consistent with the notification requirements in other regulations involving administrative action, such as administrative detention of food under § 1.393 orders for diversion or destruction of shell eggs under the PHS Act under § 118.12(a)(i), and with procedures for an informal hearing in part 16.

E. Proposed § 117.260--Compliance With, or Appeal of, an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.260(a) would require that 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) either comply with applicable requirements of this part within 60

Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Formatted: Level 1
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110.2

calendar days of the date of the order; or appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 117.264. We tentatively conclude that either of the two circumstances that could result in our determination that an exemption should be withdrawn (as described in proposed § 117.251) warrant prompt compliance with the rule in the interest of public health. We tentatively conclude that ten calendar days for the submission of an appeal from the date of the receipt of a withdrawal order is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that comes to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 117.260(b) would establish that submission of an appeal, including submission of a request for an informal hearing, will not delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. For example, the submission of an appeal of a withdrawal order with a request for an informal hearing under proposed § 117.260(b) would not prevent FDA from simultaneously detaining food from the facility under section 304(h) of the FD&C Act, seizing food from the facility under section 304(a) of the FD&C Act, or seeking or enforcing an injunction under section 302 of the FD&C Act.

Proposed § 117.260(c) would require that, if the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order. Proposed § 117.260(c) would make clear that the 60 calendar day time frame for compliance applies regardless of whether the owner, operator, or

Deleted: 110

Deleted: 110

Deleted:

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: Not Highlight

Deleted: 110

agent in charge of a facility requests, and FDA grants, a hearing. As already discussed, FDA tentatively concludes that the circumstances that lead to a determination that an exemption should be withdrawn warrant prompt compliance in the interest of public health.

F. Proposed § 117.264--Procedure for Submitting an Appeal

Proposed § 117.264(a) would require that, 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 same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, e-mail address, or facsimile number identified in the order within 10 calendar days of the date of the order; and (2) respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

Allowing the owner, operator, or agent in charge of the facility to submit an appeal in person, by mail, e-mail, or fax would provide for flexibility as well as speed. For example, submitting in person would give the owner, operator, or agent in charge direct knowledge that the request for appeal had been delivered and received. E-mail and fax are instantaneous, and overnight mail delivery services are readily available to those who choose to use them; however, the ten day time frame for appeal of the order would not require the use of overnight mail delivery. For clarity, proposed § 117.264(a) would repeat the 10 calendar day time frame that would be established in proposed § 117.260(a)(2) and would not establish any new requirement. Any appeal would need to be written in order for FDA to evaluate the basis for the appeal. We are proposing that a written appeal would need to address with particularity all of the issues

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110.2
Deleted: 110
Deleted: 110

raised in the withdrawal order and include all supporting documentation so that we would be able to issue a final determination as to the disposition of the appeal solely on the basis of the materials submitted as part of the written appeal.

Proposed § 117.264(b) would provide that, 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. Requesting an informal hearing does not mean that a hearing will be held, because we may deny the request (see discussion of proposed § 117.267(b) in the next section of this document). However, if the owner, operator, or agent in charge of the facility does not request an informal hearing at the time the written appeal is submitted, the owner, operator, or agent in charge of the facility will not be entitled to an informal hearing. Instead, FDA will make a final decision based on the written appeal and its supporting materials.

G. Proposed § 117.267--Procedure for Requesting an Informal Hearing

Proposed § 117.267(a)(1) would provide that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility may request an informal hearing. Proposed § 117.267(a)(1) would restate an option that would be included in proposed § 117.264(b) to highlight the opportunity to request an informal hearing. Proposed § 117.267(a)(2) would require that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility must submit any request for an informal hearing together with its written appeal submitted in accordance with § 117.264 within 10 calendar days of the date of the order. We tentatively conclude that requiring submission of a request for an informal hearing in writing at the time that the owner, operator, or agent in charge of the facility would be required to submit a written appeal is appropriate for purposes of the

Deleted: 110

Deleted: 110.2

Deleted: 110

Deleted: 110

Formatted: Level 1

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 117.267(b) would establish that a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. Proposed § 117.267(b) would also provide that if the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial. Under proposed § 117.264(a), a written appeal would be required to respond with particularity to the facts and issues contained in the withdrawal order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies. If the materials submitted do not directly address the facts and issues contained in the withdrawal order in a manner that suggests that there is a dispute regarding the material facts contained in the order, the presiding officer may determine that an informal hearing is not warranted. The presiding officer may include written notice of the determination that a hearing is not justified as part of the final decision on the appeal.

H. Proposed § 117.270--Requirements Applicable to an Informal Hearing

Proposed § 117.270(a) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA. We tentatively conclude that, if we grant a request for an informal hearing, holding the hearing within 10 calendar days, or within an alternative time frame as agreed upon in writing, is

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: Level 1

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: except as provided by proposed § 110.270(b),

appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed 117.270(b) would establish that the presiding officer may require that a hearing conducted under this subpart E be completed within 1 calendar day, if appropriate. We tentatively conclude that, if we grant a request for an informal hearing, limiting the time for the hearing itself to be completed within 1 calendar day is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Deleted: 110

Proposed § 117.270(c)(1) through (7) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, FDA must conduct the hearing in accordance with part 16, except that:

Deleted: 110

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

Deleted: 110

Deleted: 110

- (2) A request for a hearing under this subpart E must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

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

Deleted: 110

- (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.

Deleted: 110

- (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, 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 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.

Deleted: pursuant to

Deleted: 110

Under § 16.1(b), the procedures in part 16 apply when a regulation provides a person with an opportunity for a hearing on a regulatory action under part 16. Section 418 of the FD&C Act does not expressly provide for a hearing if circumstances lead FDA to determine that an exemption provided to a qualified facility under proposed § 117.5(a) should be withdrawn. However, we tentatively conclude as a matter of agency discretion that providing an opportunity for a hearing by regulation in this subpart of the proposed rule would provide appropriate process to the owner, operator, or agent in charge of a qualified facility subject to withdrawal of the facility's exemption. We also tentatively conclude that the modified part 16 procedures contained in this proposed rule would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order sufficient fairness and due process while enabling FDA to expeditiously adjudicate an appeal of a withdrawal order for which an informal hearing has been granted.

Section 16.119 provides that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35. Proposed § 117.270(c)(6) would specify that these procedures for reconsideration and stay would not apply to the process of withdrawing an exemption provided under proposed § 117.5(a). The circumstances that may lead FDA to withdraw an exemption include an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility, or our determination that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. Such circumstances require prompt action. Under § 16.120, a qualified facility that disagrees with

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110.2

Deleted:

Deleted: 110

Deleted: 110.2

FDA's decision to withdraw an exemption provided under § 117.5(a) has an opportunity for judicial review in accordance with § 10.45.

I. Proposed § 117.274--Presiding Officer for an Appeal and for an Informal Hearing

Proposed § 117.274 would require that the presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director. Under § 16.42(b), an officer presiding over an informal hearing is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action. An order for the withdrawal of an exemption applicable to a qualified facility must be approved by a District Director or an official senior to a District Director. It is therefore necessary that appeals of a decision to issue a withdrawal order should be handled by persons in positions senior to the District Directors. The Regional Food and Drug Director is such a person and could be from the same region where the facility is located, provided that the Regional Food and Drug Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice. Alternatively, the Regional Food and Drug Director could be from a different region than the region where the facility is located, for example in the event the Regional Food and Drug Director for the region in which the facility is located is the FDA official who approved the withdrawal order. Any Office Director of FDA's Office of Regulatory Affairs could preside at a hearing, provided that the Office Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice.

Deleted: 110.2

Formatted: Level 1

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

J. Proposed § 117.277--Time Frame for Issuing a Decision on an Appeal

Proposed § 117.277(a) would require that, if the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed. Under proposed § 117.251, FDA would issue a withdrawal order either in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility or if we determine that an exemption withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food located at the facility. We tentatively conclude that we will need 10 calendar days to review the written appeal and the materials submitted with the written appeal, and that a final decision confirming or revoking a withdrawal order should be issued as quickly as possible in the interest of the public health and to provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 117.277(b)(1) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and, if FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.270(c)(4), and must issue a final decision within the 10-calendar day period after the hearing is held. We tentatively conclude that it is appropriate to grant the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order the opportunity to review and submit comments to the presiding officer's report because the report is part of the record of a final

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110

agency action (see discussion of proposed § 117.284 in section XIV.L of this document) that is not subject to further reconsideration by FDA. The presiding officer would have discretion to determine whether to revise the report of the hearing in light of any comments that might be submitted by any of the hearing participants.

Proposed § 117.277(b)(2) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and if FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed. We tentatively conclude that ten calendar days for the presiding officer to issue a final decision is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order, would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal, and is in the interest of public health.

K. Proposed § 117.280--Revocation of an Order to Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.280(a) through (c) would establish that an order to withdraw an exemption applicable to a qualified facility under § 117.5(a) is revoked if:

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

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110.2

confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

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

We tentatively conclude that an order to withdraw an exemption may be revoked in one of two manners. First, we are proposing that the FDA officer responsible for adjudicating the appeal and presiding over a hearing, if one is granted, may expressly issue a written decision revoking the order within the specified 10 calendar day time frames. Second, we are proposing that the failure of the FDA officer responsible for adjudicating an appeal to issue a final decision expressly confirming the order within the specified time frames will also serve to revoke the order. We tentatively conclude that fairness would warrant the revocation of a withdrawal order if FDA is unable to meet the proposed deadlines for expressly confirming an order.

L. Proposed § 117.284--Final Agency Action

Proposed § 117.284 would establish that confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of section 702 of title 5 of the United States Code (5 U.S.C. 702). A confirmation of an order withdrawing an exemption therefore would be reviewable by the courts under section 702 of title 5 and in accordance with § 10.45 (21 CFR § 10.45).

M. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(2) to include part 117, subpart E, relating to the withdrawal of an exemption applicable to a qualified facility, to the list of regulatory provisions under which regulatory hearings are available.

Formatted: Not Highlight

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

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

A. Relevant Statutory Provisions

FDA is proposing to create a new Subpart F to establish requirements applying to records that must be established and maintained according to the requirements of this proposed rule. As discussed in section XII.J of this document, section 418 of the FD&C Act prescribes several requirements relevant to recordkeeping. The statutory provisions that are most relevant to proposed subpart F are:

- Section 418(a) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records of monitoring the performance of preventive controls as a matter of routine practice;
- Section 418(b)(3) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility develop a written analysis of the hazards;
- Section 418(g) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain certain records for not less than 2 years. The records identified in section 418(g) include records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions; and
- Section 418(h) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section and that such written plan, together with documentation described in section 418(g) of the FD&C Act, shall be

Formatted: Level 1
Deleted: Subpart F--
Deleted: Applying to Records That Must Be Established and Maintained
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: J
Deleted: Section 418(a
Deleted: "maintain records of [monitoring the performance of preventive controls] as a matter of routine practice";¶
<#>Section 418(b)(3) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility "develop a written analysis of the hazards";¶
Section 418(g) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility
Deleted: "
Deleted: [
Deleted:],
Deleted: [
Deleted:],
Deleted: ";
Deleted: "
Deleted: …"
Deleted: "[s]uch
Deleted: [
Deleted:],

made promptly available to a duly authorized representative of the Secretary upon oral or written request;

- Section 418(n)(1)(A) of the FD&C Act, which provides, in relevant part, that FDA shall promulgate regulations to establish science-based minimum standards for documenting hazards and documenting the implementation of the preventive controls under this section;
- Section 402(a)(4) of the FD&C Act, which provides that food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- Section 701(a) of the FD&C Act [21 U.S.C. 371(a)], which provides FDA with authority to promulgate regulations for the efficient enforcement of the FD&C Act; and
- Section 361(a) of the Public Health Service Act [42 U.S.C. 264(a)], which provides FDA with authority to make and enforce such regulations as in FDA's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.
- Section 418(l)(2)(B) of the FD&C Act, which requires a qualified facility to submit documentation to the Secretary related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws.

B. Proposed § 117.301 - Records Subject to the Requirements of this Subpart F

Proposed § 117.301(a) would establish that, except as provided by proposed § 117.301(b) and (c), all records required by proposed part 117 would be subject to all requirements of

Deleted: ";
Deleted: "
Deleted: …
Deleted: …
Deleted: …
Deleted: ";
Deleted: "
Deleted: "
Deleted: "
Deleted: [
Deleted:]";
Deleted: "
Deleted: his
Deleted: ."
Deleted: 110
Formatted: Level 1
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110

proposed subpart F. FDA tentatively concludes that the requirements in subpart F describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts aid plants and facilities in compliance with the requirements of proposed part 117; and allow plants and facilities to show, and FDA to determine, compliance with the requirements of part 110.

Proposed § 117.301(b) would establish that the requirements of proposed § 117.310 apply only to the written food safety plan and is discussed in more detail in Part D of this section.

Proposed § 117.301(c) would provide that the requirements of § 117.305(b), (d), (e), and (f) do not apply to the records required by § 117.201(e). As discussed in section XIII.A.7 of this document, proposed § 117.201(e) would require that a qualified facility maintain records relied upon to support the self-certification that would be required by § 117.201(a). Such documentation would be directed to the financial basis (and, when applicable, percentage of sales to qualified end users) as well as to food safety practices at the qualified facility, and could range from invoices to a food safety plan to an operating license issued by a state or local authority. Such records would not be expected to satisfy the provisions of proposed § 117.305(b), (d), (e), and (f) (which we discuss in the next section of this document). To make clear that a qualified facility need not comply with provisions that do not apply to its records, we are proposing to specify that those provisions do not apply to such records.

C. Proposed § 117.305--General Requirements Applying to Records

Proposed § 117.305 contains general requirements that would apply to records that would be required under proposed part 117, including the format for required records, the recording of

Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110

actual values and observations obtained during monitoring, when records must be created, and information that must be included in each record.

1. Proposed § 117.305(a)

Proposed § 117.305(a) would require that the records be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. True copies of records should be of sufficient quality to detect whether the original record was changed or corrected in a manner that obscured the original entry (e.g., through the use of white-out). Proposed § 117.305(a) would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system. The proposed requirement allowing true copies is consistent with other regulations such as our Good Manufacturing Practices (GMPs) regulation for dietary supplements (§ 111.605(b)) and provides options that may be compatible with the way records are currently being kept in plants and facilities.

Proposed § 117.305(a) also would require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by proposed part 117 may be retained electronically, provided that they comply with part 11.

FDA tentatively concludes that it is appropriate to apply the requirements of part 11 to the records that would be required to be kept under proposed part 117. However, we request comment on whether there are any circumstances that would warrant not applying part 11 to records that would be kept under proposed part 117. For example, would a requirement that

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted:
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: ..
Deleted: 110
Deleted: 110

electronic records be kept according to part 11 mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which we determined to be the case in the regulation Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (69 FR 71562, December 9, 2004 (the BT records regulation)) For the purposes of the records requirements in the BT records regulation, we concluded that it was not necessary for new recordkeeping systems to be established as long as current practices would satisfy the requirements of the Act and, therefore, we exempted the records from the requirements of part 11 (21 CFR § 1.329(b)). We also exempted records related to certain cattle materials prohibited from use in human food and cosmetics from part 11 (21 CFR §§ 189.5(c)(7) and 700.27(c)(7), respectively). We also seek comment on whether we should allow additional time for electronic records to be kept in accordance with part 11. Comments should provide the basis for any view that the requirements of part 11 are not warranted.

2. Proposed § 117.305(b)

Proposed § 117.305(b) would require that records contain the actual values and observations obtained during monitoring. It is neither possible to derive the full benefits of a preventive controls system, nor to verify the operation of the system, without recording actual values and observations to produce an accurate record. Notations that monitoring measurements, such as heat treatment temperatures, are ''satisfactory'' or ''unsatisfactory,'' without recording the actual times and temperatures, are vague and subject to varying interpretations and, thus, will not ensure that controls are working properly. In addition, it is not possible to discern a trend toward loss of control without actual measurement values. Proposed § 117.305(b) is consistent with our HACCP regulations for seafood and juice, specifically § 123.6(c)(7) and §120.12(b)(4),

Deleted: ;

Formatted: Level 1

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

respectively. In addition, our HACCP regulation for juice also requires that records documenting the monitoring of critical control points and their critical limits include recording of actual times, temperatures, or other measurements (§ 120.12(a)(4)(i)). We seek comment on this proposal.

3. Proposed § 117.305(c), (d) and (e)

Proposed § 117.305(c), (d) and (e) would require that records be accurate, indelible, and legible (proposed § 117.305(c)); be created concurrently with performance of the activity documented (proposed § 117.305(d)); and be as detailed as necessary to provide a history of work performed (proposed § 117.305(e)). Proposed § 117.305(c) and (d) would ensure that the records are useful to the owner, operator, or agent in charge of a plant or facility in complying with the requirements of proposed part 117, for example, in documenting compliance with monitoring requirements and verifying compliance with the food safety plan. These proposed requirements would also ensure that the records would be useful to FDA in determining compliance with the requirements of proposed part 117. Proposed § 117.305(e) would provide flexibility to plants and facilities to tailor the amount of detail to the nature of the record. These proposed requirements are consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and our HACCP regulations for seafood and juice. Consistent with the definition of "monitor" in proposed § 117.3, the NACMCF guidelines assert that monitoring is a planned sequence of observations or measurements to not only assess whether a CCP is under control but to also produce an accurate record for future use in verification (Ref. 34). The Codex guidelines advise that efficient and accurate record keeping is essential to the application of a HACCP system (Ref. 35). Our HACCP regulations for seafood and juice require that processing and

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: 110
Deleted: NACMCF
Deleted: CODEX).

other information be entered on records at the time that it is observed (§§ 123.9(a)(4) and 120.12 (b)(4), respectively).

4. Proposed § 117.305(f)

Proposed § 117.305(f) would require that the records include (1) the name and location of the plant or facility; (2) the date and time of the activity documented; (3) the signature or initials of the person performing the activity; and (4) where appropriate, the identity of the product and the production code, if any. The name and location of the plant or facility and the date and time would allow the owner, operator, or agent in charge of a plant or facility (and, during inspection, an FDA investigator) to assess whether the record is current, to identify when and where any deviation occurred, and to track corrective actions. The signature of the individual who made the observation would ensure responsibility and accountability. In addition, if there is a question about the record, a signature would ensure that the source of the record will be known. Linking a record to a specific product (and, when applicable, the production code) would enable the owner, operator, or agent in charge of a facility to isolate product that has not been processed properly when there has been a problem, thereby limiting the impact of the problem (such as the need to reprocess product or to recall product) to only those lots with the problem.

Proposed § 117.305(f) is consistent with the NACMCF HACCP guidelines and our HACCP regulations for seafood and juice. The NACMCF HACCP guidelines recommend that all records and documents associated with CCP monitoring be dated and signed or initialed by the person doing the monitoring (Ref. 34). Our HACCP regulations for seafood and juice require that all records include the name and location of the processor; the date and time of the activity that the record reflects; the signature or initials of the person performing the operation;

Deleted: 110

Formatted: Level 1

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: NACMCF

and where appropriate, the identity of the product and the production code, if any (§§ 123.9(a) and 120.12 (b), respectively).

D. Proposed § 117.310--Additional Requirements Applying to the Food Safety Plan

Proposed § 117.310 would require that the owner, operator, or agent in charge of a facility sign and date the food safety plan upon initial completion (proposed § 117.310 (a)) and upon any modification (proposed § 117.310(b)). Such a signature would provide direct evidence of the owner, operator, or agent's acceptance of the plan and commitment to implementation of the plan. Additionally, the signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist. The proposed requirement for signing and dating is consistent with our HACCP regulations for seafood and juice, which require that the HACCP plan be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor and be dated and signed upon initial acceptance; upon any modification; and upon verification of the plan (for seafood) or upon verification and validation (for juice) (§§ 123.6(d) and 120.12 (c) for seafood and juice, respectively).

E. Proposed § 117.315--Requirements for Record Retention

Proposed § 117.315 contains requirements on the length of time records that would be required under proposed part 117 must be retained and allowances for offsite storage of records under certain circumstances.

1. Proposed § 117.315(a) and (b)

Proposed § 117.315(a) would require that all records that would be required by proposed part 117 be retained at the plant or facility for at least 2 years after the date they were prepared. Proposed § 117.315(b) would require that records that relate to the general adequacy of the

Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110
Formatted: Level 1
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Formatted: Level 1
Deleted: 110
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: 110
Deleted: 110
Deleted: 110

equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.150(a)). Proposed § 117.315(a) and (b) implement subsection 418(g) of the FD&C Act, which requires certain records to be maintained for not less than 2 years. The 2-year timeframe for all records required by proposed part 117 is consistent with the length of time that nonperishable food products, on average, can be expected to be in commercial distribution plus a reasonable time thereafter to ensure that the records are available for verification activities. As we noted in the proposed BT records regulation (68 FR 25188 at 25198, May 9, 2003), according to information provided to FDA by the food industry, the minimum time for processed food products to clear the food production and distribution/retail system is 3 years. In addition, the average distribution time between harvesting and final retail sale of frozen fruits and vegetables is approximately 3 to 24 months (68 FR 25188 at 25198). In the final BT records regulation, we concluded that 2 years was the minimum time records related to nonperishable foods for the purpose of identifying immediate previous sources and immediate subsequent recipients should be kept (69 FR 71562 at 71602-3). The 2-year record retention requirement is also consistent with our HACCP regulations for seafood and juice, which both require that records be retained for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products (§§ 123.9(b)(1) and 120.12(d)(1), respectively); and with the requirement in the seafood HACCP regulation that records relating to the general adequacy of equipment or processes, including scientific studies and evaluations, be retained for at least 2 years after their applicability to the product being produced at the facility (§ 123.9(b)(2)). While FDA established shorter records retention

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: ;

Deleted: 71561

Deleted: ; December 9, 2004

requirements for records related to perishable foods in the BT records, seafood HACCP, and juice HACCP regulations, in this case Congress determined and specified in section 418(g) of the FD&C Act that the minimum retention period for the majority of the records required under proposed part 117 for all foods, regardless of perishability, is 2 years. Therefore, FDA tentatively concludes that the same requirement should apply to all records required under this section, regardless of the perishability of the food to which the record relates. This would simplify plants' or facilities' duties in compliance because there would only be one 2-year retention period to apply to any record required under proposed part 117. This 2-year retention period would run either from the date the record was prepared, for day-to-day operational records; or from the date at which use of the record is discontinued, for records relating to the general adequacy or equipment or processes (e.g., the written food safety plan and records that document validation of the written food safety plan). We seek comment on this proposal.

Deleted: 110

Deleted: 110

2. Proposed § 117.315(c)

Deleted: 110

Formatted: Level 1

Proposed § 117.315(c) would provide that, except for the food safety plan, use of offsite storage for records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan would be required to remain onsite. FDA realizes that the proposed requirements for recordkeeping could require some plants or facilities to store a significant quantity of records, and that there may not be adequate storage space in the plant or facility for all of these records. Providing for offsite storage of most records after 6 months would enable a facility to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available.

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Proposed § 117.315(c) also would provide that electronic records are considered to be onsite if they are accessible from an onsite location. Computerized systems within corporations can be networked, allowing for the sending and receiving of information in a secure fashion to all of the different food processing facilities of that corporation worldwide. This type of system can be used to provide access at multiple locations to records from multiple plants or facilities.

Proposed § 117.315(c) is consistent with our HACCP regulations for seafood and juice. Our HACCP regulation for seafood provides for transfer of records if record storage capacity is limited on a processing vessel or at a remote processing site, if the records could be immediately returned for official review upon request (§ 123.9(b)(3)). Our HACCP regulation for juice permits offsite storage of processing records after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review and considers electronic records to be onsite if they are accessible from an onsite location (§ 120.12(d)(2)).

3. Proposed § 117.315(d)

Proposed § 117.315(d) would provide that if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request. Allowing for transfer of records will give practical storage relief to seasonal operations or those closed for other reasons for prolonged periods. Proposed § 117.315(d) is consistent with our HACCP regulations for seafood and juice, which provide for transfer of records for facilities closed for prolonged periods (between seasonal packs, in the case of juice) if the records could be immediately returned for official review upon request (§ 123.9(b)(3) and 120.12(d)(3) for seafood and juice, respectively).

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

F. Proposed § 117.320--Requirements for Official Review

Proposed § 117.320 would require that all records required by proposed part 117 be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request. Proposed § 117.320 implements subsection 418(h) of the FD&C Act and is necessary in order for FDA to determine compliance with the requirements of proposed part 117. Proposed § 117.320 is consistent with our HACCP regulations for seafood and juice, which require that all records required under those rulemakings be available for review and copying at reasonable times (§§ 123.9(c) and 120.12(e), respectively).

Proposed § 117.320 does not explicitly require a facility to send records to the agency rather than making the records available for review at a facility's place of business. FDA requests comment on whether proposed § 117.320 should be modified to explicitly address this circumstance, and if so, whether FDA should require that the records be submitted electronically. Obtaining a facility's food safety plan without going to a facility could be useful to FDA in a number of different circumstances, such as to determine whether a recently identified hazard is being addressed by affected facilities.

G. Proposed § 117.325--Public Disclosure

Proposed § 117.325 would establish that all records required by proposed part 117 are subject to the disclosure requirements under part 20 of this chapter. FDA's regulations in 21 CFR part 20, the Freedom of Information Act (FOIA) [5 U.S.C. 552], the Trade Secrets Act [18 U.S.C. 1905], and the FD&C Act govern FDA's disclosures of information, including treatment of commercial confidential information (CCI) and trade secret information. Our general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule.

Proposed § 117.325 is consistent with, but framed differently than, the disclosure provisions of the HACCP regulations for seafood and juice (§§123.9(d) and 120.12(f), respectively). Proposed § 117.325 is framed similarly to the disclosure provisions for records that must be kept under part 118 (Prevention of Salmonella Enteritidis in Shell Eggs During Production) (the shell egg production rule). Under § 118.10(f), records required by part 118 are subject to the disclosure requirements under part 20.

Deleted: 110

Deleted:

Deleted: 110

XVI. FSMA's Rulemaking Provisions

Formatted: Level 1

A. Requirements in Section 418(n)(3) of the FD&C Act Regarding Content

Deleted: Content (

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

Section 418(n)(3) of the FD&C Act specifies that the regulations promulgated under section 418(n)(1)(A) shall:

Formatted: FR Preamble Para Indent Line 1 36 point

- "(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm;"
- "(B) comply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the facility, and collection of information (as defined in section 3502(3) of such Act), associated with such regulations;"
- "(C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and"
- "(D) not require a facility to hire a consultant or other third party to identify, implement, certify, or audit prevent[ive] controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party."

2. Section 418(n)(3)(A)

Implementing section 418 through this proposed rule would provide sufficient flexibility to be practicable for all sizes and types of facilities. As discussed in sections II.C and XII of this document, subpart C of the proposed rule (and related requirements) are consistent with HACCP principles. Like HACCP, the preventive controls system proposed in this document would provide flexibility for facilities to tailor their food safety plans to their specific foods and operating conditions. This proposal would allow facilities to establish only those preventive controls that are applicable to their circumstances, and to choose among multiple options wherever there are different ways to significantly minimize or prevent a hazard that is reasonably likely to occur.

In addition, the specific provisions of proposed subpart C (and related requirements) have been designed to maximize their flexibility and practicability wherever it is possible to do so consistently with the requirements of section 418 of the FD&C Act. For example:

- As discussed in section XII.A.2 of this document, proposed § 117.126(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf.
- As discussed in section XII.A.3 of this document, proposed § 117.126 would allow facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical and, thus, would provide flexibility for facilities in the development of their food safety plans.
- As discussed in section XII.C of this document, proposed § 117.135 would provide flexibility with regard to preventive controls by allowing flexibility to establish the parameters and the maximum/minimum values for the selected control.

Deleted:
Formatted: Level 1
Formatted: FR Preamble Para Indent Line 1 36 point
Deleted: section
Deleted: 110
Deleted: 110
Deleted: 110

- As discussed in section XII.C.2 of this document, for process controls, food allergen controls, sanitation controls, and other controls, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes available to it that would provide the assurances that would be required by proposed § 117.135(a).

- As discussed in section XII.H of this document, proposed § 117.155(b) would provide flexibility for the qualified individual to be either an employee of the facility or an individual not employed by the facility (such as individuals associated with universities, trade associations, and consulting companies). Proposed § 117.155(b) would also provide flexibility for the qualified individual to be qualified either through training or job experience.

- As discussed in section XV.C.1 of this document, proposed § 117.305(a) would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system.

- As discussed in section XV.C.3 of this document, proposed § 117.305(e) would provide flexibility to facilities to tailor the amount of detail in their records to the amount necessary to provide a history of the work performed.

Section 418(m) of the FD&C act also provides us with the authority to exempt certain facilities from the requirements of section 418, or to modify those requirements. As discussed in section X.C.9 of this document, we propose to use this authority to exempt facilities that solely engage in the storage or raw agricultural commodities, other than fruits and vegetables, intended for further distribution or processing (§ 117.5(j)). As discussed in sections X.D and XII.B of this document, we also propose to establish modified requirements for facilities solely engaged in the storage of packaged food that is not exposed to the environment under this authority (proposed

Deleted: 110

Deleted: <#>As discussed in section XII.F.4 of this document, proposed § 110.145(c) would not specify how corrective actions for environmental monitoring must be performed, such as the number of sites to test when the test organism is found in a facility, or how to clean and sanitize the surfaces on which the test organism was detected, to provide facilities with sufficient flexibility to develop and implement aggressive and appropriate corrective actions to find and eliminate the source of the contamination in the environment.¶
<#>As discussed in section XII.G.5.c of this document, proposed § 110.150(d)(3) would provide flexibility with respect to verification testing of product by not specifying specific products that must be tested, the hazards to test for, the frequency of testing, or the number of samples.¶
<#>As discussed in section XII.H.3 of this document, proposed § 110.152(b) would provide flexibility for the owner, operator, or agent in charge of a receiving facility to either conduct audits or obtain documentation of an audit that has been conducted at the supplier by a third party auditor. This would allow for consolidation of audits such that a supplier would be able to use the results of one audit as documentation for multiple receiving facilities.¶
<#>As discussed in section XII.H.5 of this document, proposed § 110.152(c) would provide that, for supplier verification programs, facilities would have the flexibility to choose appropriate verification activities when the hazard is not controlled at the supplier's establishment under a designated food safety regulation. ¶
As discussed in section XII.G of this document, proposed § 110

Deleted: 110

Deleted: 110

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: B

Deleted: 110.2

Deleted: section

Deleted: (§§ 110.5

§§ 117.7 and 117.206). These proposed modified requirements are specifically designed to be targeted to the specific circumstances of such facilities and therefore to be practicable for such facilities.

We are also proposing to define the terms "small business" and "very small business" in proposed § 117.3. As discussed in sections VII, X.C.1, and X.C.6 of this document, the proposed rule provides flexibility for small and very small businesses in multiple ways. These special provisions based on business size enhance the flexibility of the proposed rule for businesses of all sizes. First, FDA proposes to allow small and very small businesses more time to come into compliance with Section 418 after the effective date of the rule (2 years and 3 years after the date of publication of the final rule, respectively). FDA expects that this would assist small and very small businesses in making changes that would be required for compliance.

Second, FDA is proposing two exemptions from proposed subpart C that would be available in part based on business size. The proposed exemption for qualified facilities in § 117.5(a) would be available to very small businesses, and to certain other businesses based in part on business size, as set forth in that proposed section. Qualified facilities would be subject instead to the modified requirements in proposed § 117.201, which themselves provide significant flexibility. For example, proposed § 117.201(a) would not specify the form of documentation required for a qualified facility to show that it is in fact a qualified facility, or to demonstrate its own hazard analysis and preventive control system or compliance with state, local, county, or other applicable non-Federal law. Instead, FDA is proposing to accept self-certification of compliance with these requirements, provided that facilities retain the documentation on which they rely and make such documentation available to FDA upon request (§ 117.201(e) and related requirements in proposed subpart F).

Deleted: 110
Deleted: 110
Deleted: B.6
Deleted: B.1
Deleted: 6 months
Deleted: 18 months
Deleted: 110.2
Deleted: 110
Deleted: 110
Deleted: 110

In addition, under section 103(c) of FSMA, we have conducted a qualitative risk assessment of certain on-farm activities. Based on that qualitative risk assessment, as discussed in section X.C.6 of this document, we are proposing to exempt facilities that are small or very small businesses engaged only in certain low-risk activity/food combinations from the requirements of section 418. We have identified a significant number of activity/food combinations that we would consider to be low-risk when conducted on-farm by small and very small businesses, set forth in the proposed exemption in § 117.5(g) and (h).

Finally, as discussed in section VII of this document, FDA is proposing to begin enforcement of section 418 of the FD&C Act for all facilities subject to that section only after providing a sufficient time period following publication of the final rule for facilities to come into compliance. Specifically, FDA is proposing that businesses would be required to comply with the final rule 1 year after its publication in the Federal Register. Further, FDA is proposing to allow one additional year for small businesses and two additional years for very small businesses to come into compliance with the final rule. Providing additional time for businesses to comply, with the most time given to the smallest businesses, helps to make the regulation practicable for all sizes of facilities.

3. Section 418(n)(3)(B)

In implementing section 418 through this proposed rule, FDA has complied with chapter 35 of title 44, United States code (commonly known as the 'Paperwork Reduction Act' (PRA)), with special attention to minimizing the burden (as defined in section 3502(2) of such Act (44 U.S.C. 3502(2))) on the facility, and collection of information (as defined in section 3502(3) of such Act (44 U.S.C. 3502(3))), associated with the proposed rule. Under section 3502(2) of the PRA, "burden" means "time, effort, or financial resources expended by persons to generate,

Deleted: science-based

Deleted: evaluation

Deleted: evaluation

Deleted: B

Deleted: 110.2

Deleted: an

Deleted: 6 months

Deleted: an

Deleted: 18 months

Formatted: Level 1

Deleted:

Formatted: FR Preamble Para Indent Line 1 36 point

maintain, or provide information to or for a Federal agency." Under section 3502(3) of the PRA, "collection of information" means, in relevant part, "the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for … answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons…."

In section XVII of this document, we discuss how this proposed rule complies with the requirements of the PRA. In addition, in implementing section 418 of the FD&C Act, we have paid special attention to minimizing burden and collection of information associated with the proposed rule.

Deleted: XXI

As discussed immediately above in section XVI.A.2, we are proposing requirements that provide significant flexibility for different sizes and types of facilities. By making these requirements flexible enough to be practicable for different sizes and types of facilities, the proposed rule also avoids creating unnecessary information collection burden for facilities, because facilities should be able to tailor their recordkeeping to their specific circumstances while still complying with the requirements of the proposed rule.

In addition, the only requirements we are proposing that constitute collections of information are those that are necessary to meet the requirements of section 418 of the FD&C Act and to efficiently enforce that section. Section 418 requires facilities to establish and maintain certain records, such as the written food safety plan (sections 418(b)(3) and 418(h)), records of monitoring of preventive controls (section 418(g)), records of instances of nonconformance material to food safety (section 418(g)), records of the results of testing and other appropriate means of verification (section 418(g)), records of implementation of corrective actions (section 418(g)), and records of the efficacy of preventive controls and corrective actions

(section 418(g)). Section 418(h) also requires facilities to make those records promptly available to FDA upon request. In this proposed rule, FDA has interpreted these requirements in a manner calculated to minimize the associated burden and to minimize recordkeeping requirements beyond those explicitly provided for by the statute to those that are essential to implementation and enforcement of section 418. For example:

- As discussed in section XII.A.3 of this document, FDA is proposing to interpret section 418(h) not to require written procedures for conducting a hazard analysis or written procedures for establishing preventive controls, thereby avoiding unnecessary recordkeeping burden.
- As discussed in section XII.A.2 of this document, proposed § 117.126 would allow facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical and, thus, would minimize the number of different documents that need to be included in the food safety plan and the recordkeeping burden associated with that plan.
- As discussed in section XII.C.7 of this document, FDA is proposing that written corrective action procedures would not be required for sanitation deviations when the owner, operator, or agent in charge of a facility takes corrective action in accordance with proposed § 117.135(d)(3)(iii), because there would be little benefit in requiring written corrective action procedures for the many sanitation deviations that could occur for which the corrective actions that would need to be taken are very general.
- As discussed in section XII.D.2 of this document, proposed § 117.137 would require facilities to establish recall plans only for foods in which there is a hazard reasonably likely to occur, not for all foods, thereby avoiding unnecessary recordkeeping burden.

Deleted: 4
Deleted: 110
Deleted: 110
Deleted: 110

- As discussed in section XII.G.6 of this document, FDA is proposing to require written verification procedures only for the frequency of calibration.

4. Section 418(n)(3)(C)

In implementing section 418 through this proposed rule, FDA is proposing to acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.

As discussed in section XII.B.2.a of this document, proposed § 117.130(a)(1) would identify the purpose of the hazard analysis - i.e., to determine whether there are hazards that are reasonably likely to occur. As such, there is a single standard that applies to all covered foods when determining whether preventive controls are required. Proposed § 117.130(a)(1) would require that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. If a food presents no hazard reasonably likely to occur, no preventive controls would need to be established. For foods that present hazards reasonably likely to occur, facilities would be required to establish preventive controls in keeping with one general set of requirements set forth in proposed § 117.135. Thus, proposed subpart C simultaneously acknowledges differences in risk among foods and applies a single standard to all foods subject to that subpart.

In addition, the proposed rule acknowledges differences in risk by establishing exemptions and modified requirements in certain cases. We discuss these proposed exemptions and modified requirements in sections X.C and X.D of this document. The proposed rule would exempt all of the following from proposed subpart C: qualified facilities; activities subject to part 123 (seafood HACCP) and in compliance with that part; activities subject to part 120 (juice

Deleted: finished product testing and environmental monitoring. FDA is not proposing to require written verification procedures for validation; verification of monitoring and corrective actions; review of consumer, customer, or other complaints; or calibration of process monitoring instruments and verification instruments, other than for

Deleted:). ¶
As discussed in section XII.H.3.e of this document, FDA is not proposing to require written procedures for supplier approval and verification activities.

Deleted:

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: B

HACCP) and in compliance with that part; activities subject to part 113 (LACF) and in compliance with that part with respect to microbiological hazards addressed in that part; manufacturing, processing, packing, or holding of dietary supplements in compliance with part 111 (dietary supplement CGMPs) and section 761 of the FD&C Act (serious adverse event reporting); activities subject to section 419 of the FD&C Act (standards for produce safety); on-farm low-risk activity/food combinations conducted by small or very small businesses engaging only in such activities; alcoholic beverages and limited amounts of non-alcohol prepackaged food at alcohol-related facilities; and facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. In addition, the proposed rule includes modified requirements for facilities solely engaged in the storage of packaged food that is not exposed to the environment. The proposed exemptions and modified requirements implement specific statutory authorities allowing for those exemptions and modifications, indicating that Congress intended that there should be some differences in the requirements for certain foods, certain facilities, and certain activities, depending on risk and on other aspects of the regulatory environment. This proposed rule strikes what FDA considers to be an appropriate balance between acknowledging differences in risk and minimizing the number of separate standards applied to separate foods. We seek comments on our approach.

5. Section 418(n)(3)(D)

This proposed rule would not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventive controls. As discussed in section XII.H of this document, proposed § 117.155(a) would require that a qualified individual conduct (or oversee) certain required activities, and proposed § 117.155(b) would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities

Formatted: Not Highlight

Formatted: Level 1

Deleted:

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: G

Deleted: 110

Deleted: 110

may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. The option in proposed § 117.155(b) would provide flexibility to facilities subject to the rule. Providing an option to use a consultant or other third party as the qualified individual to conduct specific functions would not require using a consultant or other third party. These proposed provisions are merely permissive and FDA tentatively concludes that they are consistent with the requirements of section 418(n)(3)(D) of the FD&C Act.

B. Requirements in Section 418(n)(5) of the FD&C Act Regarding Review of Hazard Analysis and Preventive Controls Programs in Existence on the Date of Enactment of FSMA

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

Section 418(n)(5) of the FD&C Act specifies that, "[i]n promulgating the regulations [required by section 418(n)(1)(A) of the FD&C Act], the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of [FSMA], including the Grade 'A' Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date."

2. Overview of FDA's Review of Hazard Analysis and Preventive Controls Programs

FDA has conducted the review of regulatory hazard analysis and preventive control programs and internationally-recognized standards required by section 418(n)(5) of the FD&C Act. To do so, we reviewed the following domestically recognized standards:

- NACMCF's "Hazard Analysis and Critical Control Point Principles and Application Guidelines" (Ref. 34);

Deleted: 110

Deleted:

Deleted: Consistency With HACCP

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Formatted: Level 1

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: NACMCF

- FDA's regulation in part 120 (Hazard Analysis and Critical Control Points (HACCP) Systems) for juice ;
- FDA's regulation in part 123 (Fish and Fishery Products);
- FSIS' regulation in 9 CFR 417 (Hazard Analysis and Critical and Control Point (HACCP) systems) for meat and poultry products; and
- The Grade "A" Pasteurized Milk Ordinance (PMO), specifically the National Conference on Interstate Milk Shipments HACCP alternative found in Appendix K (the PMO HACCP Appendix) (Ref. 37) (Ref. 192).

We also reviewed the following internationally recognized standards:

- The Codex Annex to the Recommended International Code of Practice - General Principles of Food Hygiene on the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Ref. 35);
- The European Parliament and Council of the European Union Regulation (EC) No 852/2004 on the Hygiene of Foodstuffs (the EU regulation) (Ref. 38);
- The requirements for food safety programs in the Australia New Zealand Food Standards Code (the FSANZ Code) (Ref. 39); and
- The Canadian Food Inspection Agency's Food Safety Enhancement Program (the CFIA FSEP) (Ref. 40).

We compared the key features of our proposed requirements to implement section 418 of the FD&C Act (i.e., the proposed requirements that would be established in subpart C of proposed part 117) to the listed domestic and international food safety standards. The key features we compared are:

- Requirement for a food safety plan;

Deleted: PMO

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: Codex

Deleted: EU 852/2004

Deleted: FSANZ Code

Deleted: CFIA

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: 110

- Requirement for a hazard analysis;
- Requirement for preventive controls, including a requirement for control parameters and maximum or minimum values;
- Requirement for a recall plan;
- Requirement for monitoring procedures;
- Requirement for corrective actions;
- Requirement for verification procedures;
- Requirements applicable to a qualified individual; and
- Requirement for records.

Deleted: <#>Requirements for a supplier approval and verification program;¶

Formatted: FR Preamble Para Indent Line 1 36 point

The two most widely applied guidelines are the NACMCF HACCP guidelines and the Codex HACCP Annex. As discussed in section II.C.1 of this document, the NACMCF HACCP guidelines and the Codex HACCP Annex evolved over time, and revisions that NACMCF made to its recommendations in 1992 and 1997 were patterned after changes made in Codex HACCP documents. Thus, the NACMCF HACCP guidelines and the Codex HACCP Annex are similar in their recommendations, although the specific wording is not always identical. In general, domestic standards are patterned after the NACMCF HACCP guidelines and the international standards are patterned after the Codex HACCP Annex.

As noted in section II.C.2 of this document, throughout this document we identify the sections of FSMA applicable to specific proposed provisions and describe how the proposed provisions relate to HACCP principles as established in the NACMCF HACCP guidelines, the Codex HACCP Annex and Federal HACCP regulations for seafood, juice, and meat and poultry. We do not elaborate throughout the document on how the proposed provisions relate to the PMO HACCP Appendix or international standards other than the Codex HACCP Annex (i.e., the EU

regulation, the FSANZ Code, and the CFIA FSEP). However, for the purpose of the review required by section 418(n)(5) of the FD&C Act, we discuss all of these standards. We also developed a table showing how the proposed requirements of subpart C compare to the listed domestic and international food safety standards; that table is a reference to this document (Ref. 193).

In other sections of this document, we refer to "Federal HACCP regulations for seafood, juice, and meat and poultry." For the purpose of the review required by section 418(n)(5) of the FD&C Act, we refer to "domestic" regulations rather than "Federal" regulations.

3. Comparison of Preventive Control Programs

a. Requirement for a food safety plan. Proposed § 117.126 would require that the owner, operator or agent in charge of a facility prepare (or have prepared) and implement a written food safety plan. As discussed in section II.C.3 of this document, NACMCF describes five preliminary tasks in the development of a HACCP plan and seven HACCP principles that apply in implementing a HACCP plan (Ref. 34). The Codex HACCP Annex also describes these five preliminary tasks and seven HACCP principles, although the specific descriptions are not always identical to those in the NACMCF HACCP guidelines (Ref. 35). The domestically recognized standards and all international standards except the FSANZ Code focus on "HACCP systems" to control hazards; the FSANZ Code uses the term "food safety program."

Consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex, all domestic HACCP regulations and the PMO HACCP Appendix require that food establishments as specified in the regulation or standard operate in accordance with the seven HACCP principles. All domestic regulations and the PMO HACCP Appendix require a written HACCP plan (which in this proposed regulation is a food safety plan) whenever the hazard analysis

Deleted: Table

Formatted: Level 1

Deleted: 110

Formatted: FR Preamble Para Indent Line 1 36 point

Deleted: NACMCF, 1998

Deleted: Codex 2003

identifies hazards that are reasonably likely to occur. The international standards require, in general, that food establishments as specified in the regulation or standard operate in accordance with the seven HACCP principles as described by Codex. FSANZ requires the food safety program to be written, and CFIA FSEP requires the HACCP plan to be written, but the EU regulation has no explicit requirement that HACCP plans be written.

Proposed § 117.126 would require a written "food safety plan," the term used by FSMA in section 418(h), rather than require a "HACCP plan." Proposed § 117.126 would specify the contents of the food safety plan, including the (1) written hazard analysis; (2) written preventive controls; (3) written monitoring procedures; (4) written corrective action procedures; (5) written verification procedures; and (6) written recall plan. The contents of a written HACCP plan in domestic HACCP regulations are similar but not identical, and include the (1) list of hazards; (2) CCPs; (3) critical limits; (4) monitoring procedures; (5) corrective action procedures; (5) verification procedures; and (6) record-keeping procedures. The PMO HACCP Appendix requires that the HACCP plan include process flow diagrams (also a requirement in the FSIS HACCP regulation for meat and poultry, but not included in the contents of the HACCP plan). FSANZ requires that the food safety program (1) identify hazards; (2) identify where hazards can be controlled and the means: (3) provide for monitoring; (4) provide for corrective actions; (5) provide for regular review for adequacy; and (6) provide for appropriate records of compliance. The CFIA FSEP requires that the HACCP plan include all relevant information needed to conduct the five preliminary steps in addition to the seven HACCP principles. The EU regulation has no explicit requirement for the contents of a HACCP plan other than requiring food business operators to put in place procedures based on the HACCP principles.

Deleted: 110

Deleted: 110

Deleted: (6) written recall plan; and (7) written list of approved suppliers and written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient.

b. Requirement for a hazard analysis. Proposed § 117.130 would require that a hazard analysis be conducted to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine those hazards reasonably likely to occur. As discussed in section XII.B of this document, proposed § 117.130 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex, all domestic HACCP regulations, the PMO HACCP Appendix, and international standards require that a hazard analysis be conducted. Domestic HACCP regulations specify that the outcome is to determine the hazards reasonably likely to occur for the product being produced, which is consistent with the FSANZ requirement that a food business identify the potential hazards that may be reasonably expected to occur in all food handling operations. This outcome is implied by the EU regulation, which requires identifying any hazards that must be prevented, eliminated or reduced to acceptable levels.

c. Requirement for preventive controls, including a requirement for control parameters and maximum or minimum values. Proposed § 117.135 would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented. Proposed § 117.135 also would require that preventive controls include, as appropriate to the facility and the food, parameters associated with the control of the hazard and the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

As discussed in section XII.C of this document, proposed § 117.135 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix require the inclusion of CCPs and critical limits in the HACCP plan to control hazards that are identified as reasonably likely to occur. Consistent with the Codex HACCP Annex, the CFIA FSEP and the EU regulation also require the inclusion of CCPs and critical limits in the HACCP plan. FSANZ requires the identification of where, in a food handling operation, each hazard can be controlled, without referring to these as CCPs, and the means of control, but does not specify the establishment of critical limits.

Deleted: 110

d. Requirement for a recall plan. Proposed § 117.137 would require that a recall plan be established for food in which there is a hazard that is reasonably likely to occur. The CFIA FSEP provides for recall plans as a prerequisite program in the HACCP system. None of the other domestic or international standards include a provision for a recall plan as part of HACCP requirements. Although not part of the Codex HACCP Annex, the Codex GPFH specify that managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market (Ref. 44).

Deleted: 110

Deleted: Codex GPFH, 2003

e. Requirement for monitoring procedures. Proposed § 117.140 would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. As discussed in section XII.E of this document, proposed § 117.140 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP

Deleted: 110

Deleted: 110

Appendix require monitoring procedures (and the frequency) for CCPs to ensure compliance with critical limits. Consistent with the Codex HACCP Annex, international standards require monitoring, although Codex does not specify that the monitoring system include the frequency of monitoring. The EU regulation requires establishing and implementing effective monitoring procedures at CCPs. The CFIA FSEP requires documented monitoring procedures for each CCP and these must specify any tests, measurements or observations to assess whether the control measure is functioning as intended and the critical limits are met. FSANZ requires that the food safety program provide for the systematic monitoring of controls.

f. Requirement for corrective actions. Proposed § 117.145 would require that the owner, operator, or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. As discussed in section XII.F of this document, proposed § 117.145 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix require establishing corrective actions (or corrective action plans) for deviations from established critical limits. Proposed § 117.145 also would require that corrective actions be taken if a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective. This provision of proposed § 117.145 is consistent with corresponding requirements in domestic HACCP regulations for corrective actions when there is no corrective action plan for a specific deviation.

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: 110

Consistent with the Codex HACCP Annex, international standards require corrective actions. The EU regulation and the CFIA FSEP require establishing corrective actions when monitoring indicates that a critical control point is not under control. FSANZ requires that the

food safety program provide for appropriate corrective action when the hazard is found not to be under control. However, only the CFIA FSEP requires that documented deviation procedures specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that the control measure is not functioning as intended or; the critical limits are not met.

g. Requirement for verification procedures. Proposed § 117.150 would require that the owner, operator, or agent in charge of a facility establish specific verification and validation procedures and activities. As discussed in section XII.G of this document, proposed § 117.150 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, domestic HACCP regulations and the PMO HACCP Appendix require a list of the verification procedures (including validation in the HACCP regulation for juice and the PMO HACCP Appendix), and the frequency of performing these procedures. Consistent with the Codex HACCP Annex, international standards (except FSANZ) require the establishment of verification procedures. The EU regulation requires procedures to verify that the HACCP system is working effectively and the CFIA FSEP requires documentation of verification procedures. FSANZ does not specifically require verification procedures but requires that the food safety program provide for the regular review of the program by the food business to ensure its adequacy.

In addition to validation, proposed § 117.150 would require specific verification activities, i.e., calibration of process monitoring instruments and verification instruments; records review; and reanalysis. Several of these requirements are found in domestic standards. All domestic HACCP regulations and the PMO HACCP Annex require calibration of monitoring instruments. All domestic HACCP regulations and the PMO HACCP Appendix require record

Deleted: 110

Deleted: 110

Deleted: 110

Deleted: including a review of any consumer, customer, or other complaints to determine whether a complaint relates to the effectiveness of the food safety plan;

Deleted: performance of scientifically valid finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur; performance of environmental monitoring for any environmental pathogens that are reasonably likely to occur;

Deleted: For example, the HACCP regulations for seafood and juice require a review of any consumer complaints to determine whether a complaint relates to the effectiveness of the food safety plan.

Deleted: The HACCP regulations for seafood and juice and the PMO HACCP Annex provide for optional in-process or end-product testing as a verification activity.

review as a verification activity, and all provide for an annual reanalysis; both of these are specified by the NACMCF guidelines as verification activities. Other than the FSANZ requirement that the food safety program provide for the regular review of the program to ensure its adequacy, the only international standard that provides specific verification activities is the CFIA FSEP, which requires observation of monitoring and corrective actions (which is also a requirement of the FSIS HACCP regulation for meat and poultry) and records review.

h. Requirements applicable to a qualified individual. Proposed § 117.155 would establish the requirements applicable to a qualified individual. We use the term "qualified individual" to refer to an individual who is qualified by training or job experience to conduct certain food safety activities as would be specified in proposed subpart C. As discussed in section XII.H of this document, proposed § 117.155 is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Proposed § 117.155 is also consistent with the PMO HACCP Appendix, in which only a person who has met certain qualifications (i.e., through specific training) can carry out certain requirements related to the HACCP system. The NACMCF HACCP guidelines stress the importance of ensuring that individuals have appropriate training to develop and maintain the HACCP system. Similarly, the Codex HACCP Annex emphasizes that training is essential for effective implementation of HACCP. The EU regulation requires "food business operators" to ensure that those responsible for the development and maintenance of procedures based on the HACCP principles have received adequate training in the application of the HACCP principles. The CFIA FSEP requires that the individuals responsible for monitoring, deviation and verification procedures have received adequate training.

Deleted:),

Deleted: and, when applicable, product testing

Deleted: h. Requirement for a supplier approval and verification program. Proposed § 110.152 would require that the owner, operator, or agent in charge of a facility establish and implement a supplier approval and verification program for raw materials and other ingredients for which the receiving facility has identified hazards that are reasonably likely to occur. The specific details of when such a program would be required and the activities associated with such a program are described in section XII.H of this document. There are no explicit requirements for such a program in any of the domestic or international standards. However, all standards require the identification of hazards, the implementation of controls for those hazards, and verification activities to ensure hazards are controlled. Proposed § 110.152 is consistent with these requirements; we have simply segregated this program in order to better focus the specific activities that would apply.¶
i

Deleted: 110

Deleted: I

Deleted: 110

Deleted: 110

j. Requirement for records. Proposed § 117.175 would list the records that would required for proposed subpart C, including the food safety plan, records that document the monitoring of preventive controls, records that document corrective actions, records that document verification activities, and records that document applicable training for the qualified individual. Proposed § 117.175 is consistent with the requirements for records in the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix, which require records to include the hazard analysis, HACCP plan, and records of monitoring, corrective actions and verification activities. The Codex HACCP Annex also specifies documentation, including the hazard analysis and CCP and critical limit determination, and records for monitoring, corrective actions and verification procedures. The EU regulation requires records to demonstrate the effective application of the HACCP measures. Similarly, FSANZ requires that the food safety program provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program. The CFIA FSEP requires record keeping to demonstrate the effective application of the critical control points and to facilitate official verifications by the CFIA or other competent authority.

Deleted: j

Deleted: 110

Deleted: 110

Proposed subpart F would establish requirements that apply to the required records, including requirements for records to be accurate and to include specific information and for record retention. These record-keeping requirements are consistent with the requirements for records in all domestic HACCP regulations, but such details are not found in international standards other than the CFIA FSEP.

XVII. Proposed Removal of 21 CFR Part 110 - Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food

Proposed part 117 would replace current part 110. Therefore, we are proposing to remove current part 110 after the compliance date for all businesses to be in compliance with the requirements of new part 117. As discussed in section VII of this document, we are proposing that businesses would be required to comply with new part 117 1, 2, or 3 years after the date of publication of the final rule establishing part 117, depending on the size of the business. Thus, we are proposing to remove part 110, 3 years after the date of publication of the final rule.

XVIII. Proposed Conforming Amendments

Several current regulations refer to the requirements of part 110. FDA is proposing a series of amendments so that these current regulations would refer to part 117 as well as part 110. We also are proposing that when part 110 is removed, all references to part 110 be removed from our regulations. The affected regulations are:

- §§ 106.100(j) and (n) (infant formula records);
- § 114.5 (current good manufacturing practice for acidified foods);
- §§ 120.3, 120.5, and 120.6(b) (definitions, current good manufacturing practice, and sanitation standard operating procedures for juice products subject to the HACCP regulation for juice);
- §§ 123.3, 123.5(a), and 123.11(b) (definitions, current good manufacturing practice, and sanitation control procedures for fish and fishery products subject to the HACCP regulation for seafood);
- § 129.1 (current good manufacturing practice for the processing and bottling of bottled drinking water);

Formatted: Not Highlight

Deleted: Analysis of Economic Impacts

Formatted: FR Preamble 1st Level Outline Heading Normal Double space + Centered, Level 1

Formatted: Not Highlight

Deleted: A. Benefit-Cost

Moved (insertion) [28]

Formatted: Not Highlight

- § 179.25(a) (general provisions for food irradiation); and
- § 211.1(c) (scope of current good manufacturing practice for finished pharmaceuticals).

XIX. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 194). FDA believes that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 194) which is available at http://www.regulations.gov (enter Docket No. FDA-2011-N-0920), and is also available on FDA's Web site at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new preventive controls, FDA acknowledges that the final rules

Formatted: Not Highlight

Formatted: FR Preamble 1st Level Heading Normal Double space + Centered, Level 1

Moved up [28]: XVIII.

Formatted: Not Highlight

Deleted: Initial Regulatory Flexibility Analysis ¶ XIX. Unfunded Mandates¶

resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

Moved down [29]: XX.

Formatted: FR Preamble 2nd Level Heading Normal Double space + Underline Centered, Level 1

Deleted: (SBREFA)

Formatted: Not Highlight

Formatted: Not Highlight

Deleted: XXI

E. Paperwork Reduction Act of 1995

Formatted: FR Preamble 2nd Level Heading Normal Double space + Underline Centered, Level 1

Formatted: Not Highlight

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the proposed rule have been submitted to OMB for review under Section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

F. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) are available to the public in the docket for this proposed rule (Ref. 194).

XX. Analysis of Environmental Impact

FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XXII. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www/regulations.gov. It is only necessary to send one set of comments. Identify

Moved (insertion) [29]
Moved down [30]: XXII.
Formatted: Not Highlight
Formatted: FR Preamble 1st Level Heading Normal Double space + Centered, Level 1
Deleted: XXIII
Formatted: FR Preamble 1st Level Heading Normal Double space + Centered, Level 1
Formatted: Not Highlight
Deleted: XXIV.
Moved (insertion) [30]
Formatted: Not Highlight
Formatted: FR Preamble 1st Level Heading Normal Double space + Centered, Level 1
Deleted: XXV

comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www/regulations.gov.

XXIII. References

Formatted: FR Preamble 1st Level Heading Normal Double space + Centered, Level 1

Formatted: Not Highlight

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.)

1. FDA, "Food CGMP Modernization — A Focus on Food Safety," (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/ucm207458.htm), November 2, 2005. Accessed and printed on October 14, 2011.

2. Shapiro, R. L., C. Hatheway, and D. L. Swerdlow, "Botulism in the United States: A Clinical and Epidemiologic Review," Annals of Internal Medicine, 129:221-228, 1998.

3. FDA, "Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition," 2011.

4. FDA, "Guidance for Industry: Juice HACCP Hazards and Controls Guidance First Edition; Final Guidance," 2004.

5. FDA, "Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy," 2006.

6. 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.

7. FDA, "Compliance Policy Guide Sec. 527.300 Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity," 2010.

8. FDA, "Compliance Policy Guide Sec. 555.300 Foods, Except Dairy Products - Adulteration with Salmonella," 1995.

9. FDA, "Establishment Inspection Report (EIR)," (http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061430.htm), June 7, 2007. Accessed and printed on October 17, 2011.

10. FDA, "Regulatory Procedures Manual, Chapter 4. Advisory Actions," 2010.

11. FDA, "Regulatory Procedures Manual, Chapter 5. Administrative Actions," 2011.

12. FDA, "Regulatory Procedures Manual, Chapter 6. Judicial Actions," 2011.

13. CDC, "Foodborne Disease Outbreak Surveillance," (http://www.cdc.gov/outbreaknet/surveillance_data.html), September, 2011. Accessed and printed on July 19, 2012.

14. CDC, "Frequently Asked Questions About CDC's Foodborne Outbreak Online Database," (http://www.cdc.gov/outbreaknet/pdf/FAQsonFOOD.pdf), December, 2009. Accessed and printed on October 14, 2011.

15. CDC, "FoodNet - Foodborne Diseases Active Surveillance Network," (http://www.cdc.gov/foodnet/), 2012. Accessed and printed on July 27, 2012.

16. CDC, "Questions and Answers About Vital Signs: FoodNet MMWR, 2010," (http://www.cdc.gov/foodsafety/vitalsigns_questions.html), June 8, 2011. Accessed and printed on October 17, 201.

17. "Food Emergency Response Network," (http://www.fernlab.org/), 2012. Accessed and printed on July 27, 2012.

18. Electronic Laboratory Exchange Network, "Welcome to ELEXNET," (https://www.elexnet.com/portal/server.pt), 2012. Accessed and printed on July 27, 2012.

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

20. 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.

21. 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.

22. 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.

23. 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.

24. FDA, "Recall: Products Containing Hydrolyzed Vegetable Protein," (http://www.accessdata.fda.gov/scripts/HVPCP/), April 1, 2010. Accessed and printed on September 9, 2011.

25. Council to Improve Foodborne Outbreak Response, "Guidelines for Foodborne Disease Outbreak Response," 2009.

26. FDA, "State Contracts," (http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/StateContracts/default.htm), 2012. Accessed and printed on July 27, 2012.

27. "FoodSafety.Gov," (http://www.foodsafety.gov/index.html), 2011. Accessed and printed on July 27, 2012.

28. Partnership for Food Safety Education, "Fight Bac!" (http://www.fightbac.org/), 2012. Accessed and printed on July 27, 2012.

29. FDA, "Consumers. Food Safety, Nutrition Information, and Campaigns," (http://www.fda.gov/Food/ResourcesForYou/Consumers/default.htm), 2012. Accessed and printed on July 27, 2012.

30. FDA, "Health Educators. Food Safety & Nutrition Education Campaigns," (http://www.fda.gov/Food/ResourcesForYou/HealthEducators/default.htm), 2012. Accessed and printed on July 27, 2012.

31. FDA Memorandum, "Consultation with USDA on Food Processing Sector Study," 2011.

32. FDA, "Food Processing Sector Study," 2011.

33. FSIS, "National Advisory Committee on Microbiological Criteria for Foods. About NACMCF," (http://www.fsis.usda.gov/About_FSIS/NACMCF_Background/index.asp), 2010. Accessed and printed on December 12, 2011.

34. 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.

35. Codex Alimentarius Commission, "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application. Annex to CAC/RCP 1-1969 (Rev. 4 - 2003)," 2003.

36. National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point System," International Journal of Food Microbiology, 16:1-23, 1992.

37. FDA, "Grade "A" Pasteurized Milk Ordinance (2011 Revision)," 2012.

38. European Parliament and the Council of the European Union, "Regulation (EC) No 852/2004 of the European Parliament and of the Council," (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0001:0054:en:PDF), April 29, 2004. Accessed and printed on December 13, 2011.

39. Food Standards Australia New Zealand, "Standard 3.2.1 - Food Safety Programs," 2007.

40. Canadian Food Inspection Agency, "Food Safety Enhancement Program / Hazard Analysis Critical Control Points," (http://www.inspection.gc.ca/food/fsep-haccp/eng/1299855874288/1299859914238), September 10, 2011. Accessed and printed on July 31, 2012.

41. Global Food Safety Initiative, "Enhancing Food Safety Through Third Party Certification," 2011.

42. World Health Organization, "Hazard Analysis Critical Control Point System (HACCP)," 2007.

43. Food and Agriculture Organization, "Manual on the Application of the HACCP System in Mycotoxin Prevention and Control,"

(http://www.fao.org/docrep/005/y1390e/y1390e00.htm), 2001. Accessed and printed on October 14, 2011.

44. Codex Alimentarius Commission, "General Principles of Food Hygiene, CAC/RCP 1-1969 (Rev. 4-2003)," 2003.

45. Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M. A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin, "Foodborne Illness Acquired in the United States--Major Pathogens," Emerging Infectious Diseases, 17:7-15, 2011.

46. Scallan, E., P. M. Griffin, F. J. Angulo, R. V. Tauxe, and R. M. Hoekstra, "Foodborne Illness Acquired in the United States--Unspecified Agents," Emerging Infectious Diseases, 17:16-22, 2011.

47. CDC, "CDC 2011 Estimates: Method," (http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_E_2011ESTIMATES.pdf), 2011. Accessed and printed on October 14, 2011.

48. Scheutz, F., E. Moller Nielsen, J. Frimodt-Moller, N. Boisen, S. Morabito, R. Tozzoli, J. P. Nataro, and A. Caprioli, "Characteristics of the Enteroaggregative Shiga Toxin/Verotoxin-Producing Escherichia coli O104:H4 Strain Causing the Outbreak of Haemolytic Uraemic Syndrome in Germany, May to June 2011," Eurosurveillance, 16:6, 2011.

49. FDA, "Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. Second Edition," 2012.

50. CDC, "Vital Signs: Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food - Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996-2010," MMWR, 60:749-755, 2011.

Moved (insertion) [7]

Formatted: No underline

51. CDC, "What Is Salmonellosis?" (http://www.cdc.gov/Salmonella/general/), April 5, 2012. Accessed and printed on July 27, 2012.

52. 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.

53. FDA and USDA, "Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods," (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm), September, 2003. Accessed and printed on July 24, 2012.

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

55. FDA and USDA, "Listeria monocytogenes Risk Assessment: Executive Summary," (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm185292.htm), 2003. Accessed and printed on December 12, 2011.

56. 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.

57. CDC, "Norovirus: Clinical Overview," (http://www.cdc.gov/norovirus/hcp/clinical-overview.html), April 12, 2012. Accessed and printed on July 19, 2012.

58. FDA Memorandum, "Food GMP Modernization Working Group: Summary of Food Recalls, 1999-2003," 2004.

59. FDA Memorandum, "Analysis of Food Recalls Initiated in 2008-2009 by an FDA CGMP Working Group," 2012.

60. 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.

61. FDA, "FDA Foods Program, The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration. Second Annual Report: September 8, 2010 - September 7, 2011," (http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/ucm200958.htm), 2012.

62. 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.

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

64. FDA, "Establishment Inspection Report Conagra Grocery Products 02/14/2007," 2007.

65. FDA, "Establishment Inspection Report Conagra Foods 08/20/2007," 2007.

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

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

68. 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.

69. 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.

70. CDC, "Foodborne Outbreak Online Database (FOOD). Search Results Highlighted for 2007 Salmonella Wandsworth and Salmonella Typhimurium Outbreak in Puffed Snacks.," 2011. Accessed and printed on November 18, 2011.

71. CDC, "Foodborne Outbreak Online Database (FOOD). Search Results Highlighted for 2008-2009 Listeria Outbreak in Mexican-Style Cheese," 2011. Accessed and printed on October 18, 2011.

72. 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.

73. California Department of Public Health, "Outbreak of Salmonella Rissen Associated with Ground White Pepper," (http://www.cdph.ca.gov/programs/DFDRS/Documents/QSS_Presentation_SRissen_and_%20white%20pepper_010611.pdf), 2011. Accessed and printed on October 17, 2011.

74. CDC, "Foodborne Outbreak Online Database (FOOD). Search Results Highlighted for 2008 Salmonella Rissen Outbreak in Ground White Pepper," 2011. Accessed and printed on November 23, 2011.

75. FDA, "Warning Letter to U.F. Union International Food Company, 11/24/1009," (http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm192435.htm), November 24, 2009. Accessed and printed on October 17, 2011.

76. CDC, "Multistate Outbreak of E. coli O157:H7 Infections Linked to Eating Raw Refrigerated, Prepackaged Cookie Dough," (http://www.cdc.gov/ecoli/2009/0630.html), June 30, 2009. Accessed and printed on October 17, 2011.

77. FDA Public Health Focus Document, "E. coli in Nestlé Toll House Cookie Dough," (http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm169858.htm), July 13, 2009. Accessed and printed on October 17, 2011.

78. FDA, "Nestlé USA's Baking Division Initiates Voluntary Recall," (http://www.fda.gov/Safety/Recalls/ucm167954.htm), 2009. Accessed and printed on October 19, 2011.

79. 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.

80. CDC, "Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado," (http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/120811/index.html), December 8, 2011. Accessed and printed on July 31, 2012.

81. FDA, "Pesticide Monitoring Program - FY 2008," (http://www.fda.gov/downloads/Food/FoodSafety/FoodContaminantsAdulteration/Pesticides/ResidueMonitoringReports/UCM230537.pdf), December 9, 2010. Accessed and printed on October 14, 2011.

82. FDA, "CPG Sec. 570.375 Aflatoxin in Peanuts and Peanut Products," 2005.

83. FDA, "CPG Sec. 570.200 Brazil Nuts - Adulteration with Aflatoxin," 2005.

84. FDA, "CPG Sec. 570.500 Pistachio Nuts - Aflatoxin Adulteration," 2005.

85. FDA, "CPG Sec.510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin," 2005.

86. Taylor, S. L. and World Health Organization (WHO), "Histamine Poisoning Associated with Fish, Cheese, and Other Foods," (http://whqlibdoc.who.int/hq/1985-86/VPH_FOS_85.1.pdf), 1985. Accessed and printed on October 17, 2011.

87. Stratton, J. E., R. W. Hutkins, and S. L. Taylor, "Biogenic Amines in Cheese and Other Fermented Foods: A Review," Journal of Food Protection, 54:460-469, 1991.

88. FDA, "Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children,"

Moved (insertion) [8]

Formatted: No underline

(http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/Metals/Lead/ucm172050.htm), November, 2006. Accessed and printed on October 14, 2011.

89. Williams, J. H., T. D. Phillips, P. E. Jolly, J. K. Stiles, C. M. Jolly, and D. Aggarwal, "Human Aflatoxicosis in Developing Countries: a Review of Toxicology, Exposure, Potential Health Consequences, and Interventions," American Journal of Clinical Nutrition, 80:1106-1122, 2004.

90. Shephard, G. S., "Risk Assessment of Aflatoxins in Food in Africa," Food Additives and Contaminants: Part A -- Chemistry, Analysis, Control, Exposure and Risk Assessment, 25:1246-1256, 2008.

91. Sampson, H. A., "Update on Food Allergy," Journal of Allergy and Clinical Immunology, 113:805-819, 2004.

92. Sampson, H. A., "Food Allergy--Accurately Identifying Clinical Reactivity," Allergy, 60 Suppl 79:19-24, 2005.

93. Sicherer, S. H. and H. A. Sampson, "Food Allergy," Journal of Allergy and Clinical Immunology, 125:S116-S125, 2010.

94. Branum, A. M. and S. L. Lukacs, "Food Allergy Among Children in the United States," Pediatrics, 124:1549-1555, 2009.

95. Bindslev-Jensen, C., D. Briggs, and M. Osterballe, "Can We Determine a Threshold Level for Allergenic Foods by Statistical Analysis of Published Data in the Literature?" Allergy, 57:741-746, 2002.

96. Taylor, S. L., J. A. Nordlee, L. M. Niemann, and D. M. Lambrecht, "Allergen Immunoassays - Considerations for Use of Naturally Incurred Standards," Analytical and Bioanalytical Chemistry, 395:83-92, 2009.

Moved (insertion) [9]

Formatted: No underline

97. Taylor, S. L., D. A. Moneret-Vautrin, R. W. R. Crevel, D. Sheffield, M. Morisset, P. Dumont, B. C. Remington, and J. L. Baumert, "Threshold Dose for Peanut: Risk Characterization Based upon Diagnostic Oral Challenge of a Series of 286 Peanut-Allergic Individuals," Food and Chemical Toxicology, 48:814-819, 2010.

98. Ross, M. P., M. Ferguson, D. Street, K. Klontz, T. Schroeder, and S. Luccioli, "Analysis of Food-Allergic and Anaphylactic Events in the National Electronic Injury Surveillance System," Journal of Allergy and Clinical Immunology, 121:166-171, 2008.

99. Simon, M. R. and Z. D. Mulla, "A Population-Based Epidemiologic Analysis of Deaths from Anaphylaxis in Florida," Allergy, 63:1077-1083, 2008.

100. Yocum, M. W., J. H. Butterfield, J. S. Klein, G. W. Volcheck, D. R. Schroeder, and M. D. Silverstein, "Epidemiology of Anaphylaxis in Olmsted County: A Population-Based Study," Journal of Allergy and Clinical Immunology, 104:452-456, 1999.

101. Branum, A. M. and S. L. Lukacs, "Food Allergy Among U.S. Children: Trends in Prevalence and Hospitalizations," NCHS Date Brief, 10, 2008.

102. Jackson, W. F., Food Allergy, Belgium, ILSI Press, 2003.

103. FDA, "Nationwide Milk Allergen Recall of Kroger 'Meals Made Simple Shrimp Linguini'," (http://www.fda.gov/Safety/Recalls/ucm222663.htm), August 14, 2010. Accessed and printed on October 17, 2011.

104. FDA, "Brand Castle, LLC Issues Allergy Alert on Undeclared Egg in Icing of Licensed Rice Krispies Treats Holiday Village Kit Distributed Through Michaels Retail Stores Only," (http://www.fda.gov/Safety/Recalls/ucm238089.htm), December 23, 2010. Accessed and printed on October 17, 2011.

Moved (insertion) [10]
Formatted: No underline
Moved (insertion) [27]
Moved (insertion) [11]
Formatted: No underline

105. FDA, "The Pictsweet Company Announces a Voluntary Recall of Frozen Green Peas Due to Possible Health Risk," (http://www.fda.gov/Safety/Recalls/ucm229838.htm), October 15, 2010. Accessed and printed on October 17, 2011.

106. FDA, "Flowers Foods Issues Voluntary Recall on Certain English Muffins and One Bread Item," (http://www.fda.gov/Safety/Recalls/ucm254434.htm), May 3, 2011. Accessed and printed on October 17, 2011.

107. Ayotte, J. D., S. M. Flanagan, and W. S. Morrow, "Occurrence of Uranium and ^{222}Radon in Glacial and Bedrock Aquifers in the Northern United States, 1993-2003. U.S. Geological Survey Scientific Investigations Report 2007-5037," (http://pubs.usgs.gov/sir/2007/5037/), October 17, 2007. Accessed and printed on November 14, 2011.

108. Focazio, M. J., Z. Szabo, T. F. Kraemer, A. H. Mullin, T. H. Barringer, and V. T. dePaul, "Occurrence of Selected Radionuclides in Ground Water Used for Drinking Water in the United States: A Targeted Reconnaissance Survey, 1998. U.S. Geological Survey Water-Resources Investigations Report 00-4273," (http://pubs.usgs.gov/wri/wri004273/pdf/wri004273.pdf), 2001. Accessed and printed on October 14, 2011.

109. World Health Organization, "FAQs: Japan Nuclear Concerns," (http://www.who.int/hac/crises/jpn/faqs/en/index.html), September 20, 2011. Accessed and printed on October 17, 2011.

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

111. 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.

112. 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.

113. FDA, "Transcript: Public Meeting on the Food Safety Modernization Act: Focus on Preventive Controls for Facilities," (http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM253612.pdf), April 20, 2011. Accessed and printed on October 14, 2011.

114. FDA, "Webcast Videos: Public Meeting on the Food Safety Modernization Act: Focus on Preventive Controls for Facilities," (http://www.fda.gov/Food/FoodSafety/FSMA/ucm250377.htm#webcast), April 20, 2011. Accessed and printed on October 14, 2011.

115. FDA, "Draft Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2012.

116. FDA, "Guidance for Industry: Questions and Answers Regarding Registration of Food Facilities (Edition 4); Final Guidance," 2004.

117. FDA, "Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)," 2012.

118. FDA, "Guidance for Industry: Antimicrobial Food Additives," 1999.

119. Codex Alimentarius Commission, "Codex Alimentarius Commission Procedural Manual, Twentieth Edition," 2011.

120. FDA, "FDA Allergy Warning Letter. Notice to Manufacturers Label Declaration of Allergenic Substances in Foods," 1996.

121. Deibel, K., T. Trautman, T. DeBoom, W. H. Sveum, G. Dunaif, V. N. Scott, and D. T. Bernard, "A Comprehensive Approach to Reducing the Risk of Allergens in Foods," Journal of Food Protection, 60:436-441, 1997.

122. Taylor, S. L. and J. L. Baumert, "Cross-Contamination of Foods and Implications for Food Allergic Patients," Current Allergy and Asthma Reports, 10:265-270, 2010.

123. Food Allergy Research and Resource Program, "Components of an Effective Allergen Control Plan. A Framework for Food Processors," (http://farrp.unl.edu/c/document_library/get_file?p_l_id=4070800&folderId=2103644&name=DLFE-22219.pdf), 2011. Accessed and printed on October 17, 2011.

124. Jackson, L. S., F. M. Al-Taher, M. Moorman, J. W. DeVries, R. Tippett, K. M. J. Swanson, F. Tong-Jen, R. Salter, G. Dunaif, S. Estes, S. Albillos, and S. M. Gendel, "Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-Contact in Food-Processing Operations," Journal of Food Protection, 71:445-458, 2008.

125. Troller, J. A., "Sanitizing," In: Sanitation in Food Processing, edited by S. Taylor, 2nd edition, San Diego, Chapter 5, pp. 52-70, Academic Press, Inc., 1993.

126. FDA, "Draft Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods," 2008.

127. Codex Alimentarius Commission, "Guideline for the Validation of Food Safety Control Measures, CAC/GL 69-2008," 2008.

128. Anderson, J. E., R. R. Beelman, and S. Doores, "Persistence of Serological and Biological Activities of Staphylococcal Enterotoxin A in Canned Mushrooms," Journal of Food Protection, 59:1292-1299, 1996.

129. Bennett, M. R. and R. W. Berry, "Serological Reactivity and in Vivo Toxicity of Staphylococcus aureus Enterotoxins A and D in Selected Canned Foods," Journal of Food Science, 52:416-419, 1987.

130. FDA, "Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act," 2009.

131. FDA and BATF, "MOU 225-88-2000 Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms," (http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm), November 20, 1987. Accessed and printed on October 17, 2011.

132. FDA, "Guide to Produce Farm Investigations (11/05)," 2005.

133. FDA, "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," 1998.

134. Tauxe, R. V., "Emerging Foodborne Diseases: an Evolving Public Health Challenge," Emerging Infectious Diseases, 3:425-434, 1997.

135. FDA, "Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis," (http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm), October 19, 2011. Accessed and printed on October 20, 2011.

136. CDC, "Multistate Outbreaks of Salmonella Infections Associated with Raw Tomatoes Eaten in Restaurants --- United States, 2005--2006," MMWR, 56:909-911, 2007.

137. FDA, "Food Code 2009: Chapter 1 - Purpose and Definitions," 2009.

138. FDA, "Food Code 2009: Annex 3 - Public Health Reasons / Administrative Guidelines - Chapter 1, Purpose and Definitions," 2009.

139. FDA, "Food Code 2009: Annex 3 - Public Health Reasons / Administrative Guidelines - Chapter 3, Food," 2009.

140. Institute of Food Technologists, "Evaluation and Definition of Potentially Hazardous Foods," (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm094141), December 31, 2001. Accessed and printed on December 14, 2011.

141. FDA, "Defect Levels Handbook," 2005.

142. FDA, "Safe Food Handling. What You Need to Know," (http://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM257049.pdf), June, 2011. Accessed and printed on October 17, 2011.

143. Bernard, D. T., K. E. Stevenson, and V. N. Scott, "Hazard Analysis," In: HACCP: A Systematic Approach to Food Safety, edited by V. N. Scott and K. E. Stevenson, 4th edition, Washington, D.C., Chapter 8, pp. 57-68, The Food Products Association, 2006.

144. 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.

145. 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.

146. National Conference on Interstate Milk Shipments, "M-I-05-5: Tolerance and/or Safe Levels of Animal Drug Residues in Milk (Replaces M-I-03-9 (June 30, 2003) and Identifies It as "INACTIVE") and also Identifies M-I-92-1 as "INACTIVE"," (http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/CodedMemoranda/MemorandaofInformation/ucm077350.htm), September 27, 2005. Accessed and printed on October 17, 2011.

147. FDA, "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food," 2006.

148. FDA, "CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects," 2005.

149. Olsen, A. R., "Regulatory Action Criteria for Filth and Other Extraneous Materials. 1. Review of Hard or Sharp Foreign Objects as Physical Hazards in Foods," Regulatory Toxicology and Pharmacology, 28:181-189, 1998.

150. FDA, "Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies,"

(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM094513.pdf), August 13, 1998. Accessed and printed on October 17, 2011.

151. FDA, "CPG Sec. 560.750 Radionuclides in Imported Foods - Levels of Concern," 2005.

152. 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.

153. 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.

154. FDA, "Pacific Coast Fruit Company Voluntarily Recalls Spinach Salad Products and Pizza Because of Possible Health Risk," (http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2006/ucm112048.htm), September 22, 2006. Accessed and printed on October 17, 2011.

155. 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.

156. 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. Accessed and printed on July 20, 2012.

157. Wojtala, G., "Interstate Food Transportation Assessment Project," (http://www.michigan.gov/documents/mda/truckproj_224450_7.pdf), 2007.

Moved (insertion) [26]

Deleted: ¶
¶
¶

158. FDA, "Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory," 2010. Accessed and printed on October 18, 2011.

159. FSIS, "Meat and Poultry Hazards and Controls Guide," 2005.

160. Food and Agriculture Organization and World Health Organization, "Risk Assessment of Listeria monocytogenes in Ready-to-Eat Foods, Technical Report, Part 5. Risk Characterization: Response to Codex Questions," 2004.

161. International Commission on Microbiological Specifications for Foods, "Staphylococcus aureus," In: Microorganisms in Foods 5. Characteristics of Microbial Pathogens, edited by T. A. Roberts, A. C. Baird-Parker, and R. B. Tompkin, London, Chapter 17, pp. 299-333, Blackie Academic & Professional, 1996.

162. Greig, J. D., E. C. D. Todd, C. A. Bartleson, and B. S. Michaels, "Outbreaks Where Food Workers Have Been Implicated in the Spread of Foodborne Disease. Part 1. Description of the Problem, Methods and Agents Involved," Journal of Food Protection, 70:1752-1761, 2007.

163. Todd, E. C. D., J. D. Greig, C. A. Bartleson, and B. S. Michaels, "Outbreaks Where Food Workers Have Been Implicated in the Spread of Foodborne Disease. Part 3. Factors Contributing to Outbreaks and Description of Outbreak Categories," Journal of Food Protection, 70:2199-2217, 2007.

164. FDA, "Industry Guidance. Information on Recalls of FDA Regulated Products," (http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm), December 14, 2011. Accessed and printed on July 27, 2012.

165. FDA, "Model Recall Letter (Generic, All Centers)," (http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214960.pdf), March, 2009. Accessed and printed on October 17, 2011.

166. FDA, "Recalls, Market Withdrawals, & Safety Alerts," (http://www.fda.gov/Safety/Recalls/default.htm), 2012. Accessed and printed on July 31, 2012.

167. FDA, "Allergens Model Press Release," (http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm), May 31, 2009. Accessed and printed on October 17, 2011.

168. FDA, "Listeria monocytogenes Model Press Release," (http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm), May 31, 2009. Accessed and printed on October 17, 2011.

169. FDA, "Salmonella Model Press Release (All Serotypes)," (http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129275.htm), May 31, 2009. Accessed and printed on October 17, 2011.

170. FDA, "Model Effectiveness Check Letter (Industry)," (http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214958.pdf), 2009. Accessed and printed on October 17, 2011.

171. FDA, "Model Effectiveness Check Response Format (Industry)," (http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214963.pdf), 2009. Accessed and printed on October 17, 2011.

172. FDA, "Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry),"

(http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214971.pdf), 2009. Accessed and printed on October 17, 2011.

173. FDA, "Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition. Appendix 4: Bacterial Pathogen Growth and Inactivation," 2011.

174. FDA, "Food Code 2009," 2009.

175. National Advisory Committee on Microbiological Criteria for Foods, "Parameters for Determining Inoculated Pack/Challenge Study Protocols," Journal of Food Protection, 73:140-202, 2010.

176. National Advisory Committee on Microbiological Criteria for Foods, "Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization," Journal of Food Protection, 69:1190-1216, 2006.

177. EPA, "Pesticide Registration Manual: Chapter 4 - Additional Considerations for Antimicrobial Products," 2011.

178. FDA and USDA, "Listeria monocytogenes Risk Assessment: I. Introduction," (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm184052.htm), September, 2003. Accessed and printed on October 17, 2011.

179. 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.

180. International Commission on Microbiological Specifications for Foods, "Sampling Considerations and Statistical Aspects of Sampling Plans.," 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, Appendix A, pp. 355-364, Springer, 2011.

181. International Commission on Microbiological Specifications for Foods, "Selection of Cases and Attributes Plans," 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 8, pp. 145-172, Kluwer Academic / Plenum Publishers, 2002.

182. International Commission on Microbiological Specifications for Foods, "Sampling Plans," 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 7, pp. 123-143, Kluwer Academic / Plenum Publishers, 2002.

183. Codex Alimentarius Commission, "Codex Standard for Natural Mineral Waters, CODEX STAN 108-1981," 1981.

184. 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.

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

186. 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.

187. 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.

188. 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.

189. 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.

190. 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.

191. FDA, "Food Code 2009: Chapter 3 - Food," 2009.

192. FDA, "Grade "A" Pasteurized Milk Ordinance (2011 Revision): Appendix K. HACCP Program," 2012.

193. FDA Memorandum, "Comparison of Proposed Subpart C (Hazard Analysis and Risk-Based Preventive Controls) to Various Existing Domestic and International HACCP Based Standards," 2012.

194. FDA, "Preliminary Regulatory Impact Analysis," 2012.