FDA FOOD SAFETY MODERNIZATION ACT

Frequently Asked Questions and Answers

Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

March, 2013

A. General

A1. Who would be covered by the proposed rule?

In general, with some exceptions the new preventive controls provisions would apply to facilities that are required to register with FDA under FDA's current food facility registration regulations. (78 FR 3648) The proposed exemptions for the preventive control provisions are summarized in the following table.

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

Who or What Would Be Exempt From the Requirements for Hazard Analysis and Risk-Based Preventive Controls	**Notes**

"Qualified Facility" as defined by FSMA:
 	
• Business with average annual sales of < $500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or
 	
• Very small business
  • Option 1: Average annual sales of < $250,000
  • Option 2: Average annual sales of < $500,000
  • Option 3: Average annual sales of <$1,000,000
	FDA is proposing three options for defining "very small business" and requests comment on which to adopt in a final rule.
	
	Modified requirements would apply - i.e., a qualified facility would be required to:
	• Notify FDA about its status; and
	• Either:
	  o Notify FDA that it is addressing hazards through preventive controls and monitoring; or
	  o Notify FDA that it complies with applicable local regulations, and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.

• Low risk, on farm activities performed by small business (< 500 employees)
 	
-or-
 	
• Low-risk, on-farm activities performed by a very small business
  o Option 1: very small = <$250,000
  o Option 2: very small = <$500,000
  o Option 3: very small = <$1,000,000
	Small and very small on-farm businesses conducting these low risk activities would be exempt from most of the rule's requirements.
	
	We would define the low-risk activities that qualify for the exemption, including the specific foods to which they relate (such as re-packing intact fruits and vegetables, or grinding/milling/cracking/crushing grains)

Who or What Would Be Exempt From the Requirements for Hazard Analysis and Risk-Based Preventive Controls	Notes
Activities that are subject to the seafood HACCP requirements of part 123 (21 CFR part 123)	The facility must be in compliance with part 123.
Activities that are subject to the juice HACCP requirements of part 120 (21 CFR part 120)	The facility must be in compliance with part 120.
Activities that are subject to the "low-acid canned food" requirements of part 113 (21 CFR part 113)	• The exemption applies only with respect to microbiological hazards. • The facility must be in compliance with part 113.
The manufacturing, processing, packing, or holding of a dietary supplement that is subject to the CGMP requirements of part 111 (21 CFR part 111)	• The facility must be in compliance with part 111. • The facility must be in compliance with requirements for serious adverse event reporting for dietary supplements
Activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety)	Elsewhere in this issue of the Federal Register, FDA is proposing standards for produce safety.
Alcoholic beverages at a facility that is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States	The exemption also would apply to food other than alcoholic beverages at such a facility, provided that the food is in prepackaged form and constitutes not more than 5 percent of the overall sales of the facility.
Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	A facility that stores raw agricultural commodities that are fruits and vegetables would not be exempt.
A facility solely engaged in the storage of packaged food that is not exposed to the environment	Modified requirements would apply for the storage of refrigerated packaged food.

In addition, the modernized CGMP (proposed subpart B) would apply to persons who manufacture, process, pack or hold food for human consumption except as provided in proposed § 117.5(k). Proposed § 117.5(k) would provide that Subpart B does not apply to "farms," activities of farm mixed-type facilities that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities" (RACs). (78 FR 3710, 3802)

A2. Does this proposed rule address "hazards that may be intentionally introduced, including by acts of terrorism"?

FDA tentatively concluded that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. (78 FR 3659)

However, FDA requests comment on whether to include potential hazards that may be intentionally introduced for economic reasons and when an economically motivated adulterant can be considered reasonably likely to occur. (78 FR 3659)

A3. Would the proposed requirements for hazard analysis and risk-based preventive controls apply to foods in intrastate commerce?

Yes. FDA tentatively concluded that the proposed requirements for hazard analysis and risk-based preventive controls should be applicable to activities that are intrastate in character. (78 FR 3669)

A4. How would the proposed requirements for hazard analysis and risk-based preventive controls relate to Hazard Analysis and Critical Control Points (HACCP) systems?

The hazard analysis and preventive control systems in existence are all based on HACCP principles. Section 418 of the FD&C Act uses HACCP terminology throughout (e.g., hazard analysis, monitoring, corrective actions, and verification). However, not every provision in section 418 of the FD&C Act is identical to the provisions of HACCP systems such as those established in guidelines issued by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the Codex Alimentarius Commission (Codex), and Federal HACCP regulations for seafood (part 123), juice (part 120), and meat and poultry (9 CFR 417). (78 FR 3660)

A5. How would the proposed rule modernize the CGMPs in current part 110?

The proposed rule would:

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

- Proposing that provisions directed to preventing contamination of food and food-contact substances be directed to preventing contamination of food-packaging materials as well. (78 FR 3672)

A6. How would the proposed new requirements for hazard analysis and risk-based preventive controls relate to the current CGMP requirements in part 110?

The proposed new requirements for hazard analysis and risk-based preventive controls would be included in new part 117 of our regulations together with the revised umbrella CGMP requirements that are currently in part 110 of our regulations. (78 FR 3672)

A7. What would happen to current part 110 after a final rule establishes updated CGMPs in new part 117?

FDA is proposing to remove current part 110 after the compliance date for all businesses to be in compliance with the requirements of new part 117. (78 FR 3672)

A8. When would I need to comply with a final rule?

FDA is proposing that the final rule would be effective 60 days after publication in the *Federal Register*, with staggered compliance dates. However, we recognize that businesses of all sizes may need more time to comply with the new requirements established under FSMA. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. FDA also believes that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements established under FSMA, and 3 years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements established under FSMA. (78 FR 3674)

A9. Would the current CGMP requirements in part 110 be reorganized in the proposed new part 117?

Yes. FDA also is proposing a general reorganization and redesignation of the provisions currently in part 110 as they would be established in proposed part 117. The proposed revisions are intended to enhance the clarity of proposed part 117 as a whole. (78 FR 3692 and Table 6)

Proposed Rearrangement of Provisions and Subparts of Current Part 110

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

B. Proposed § 117.3--Definitions

B1. What definitions in current § 110.3 would the proposed rule revise? (Proposed § 117.3)

The proposed rule would revise the following definitions in current § 110.3:

- Critical control point;
- Food-contact surfaces;
- Microorganisms;
- Plant;
- Safe-moisture level; and
- Sanitize.

(78FR 3695 - 3697)

B2. What new definitions would the proposed rule establish? (Proposed § 117.3)

The proposed rule would establish new definitions for the following terms:

- Affiliate;
- Calendar day;
- Cross-contact;
- Environmental pathogen;
- Facility;
- Farm;
- Food allergen;
- FDA;
- Harvesting;
- Hazard;
- Hazard that is reasonably likely to occur;
- Holding;
- Manufacturing/processing;
- Mixed-type facility;
- Monitor;
- Packaging (when used as a verb);
- Packing;
- Preventive controls;
- Qualified end-user;
- Qualified facility;
- Qualified individual;
- Ready-to-eat food (RTE food);
- Reasonably foreseeable hazard;
- Significantly minimize;

- Small business;
- Subsidiary;
- Validation;
- Verification; and
- Very small business.

(78 FR 3697 -3700)

B3. Why would the proposed rule revise the definition of "critical control point"? (Proposed § 117.3)

The current definition of "critical control point" (CCP) was established in 1986 and preceded various currently used definitions of CCP. The proposed revision would match the statutory definition in FSMA and be consistent with definitions in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. (78 FR 3695).

B4. How would the proposed rule define "cross-contact"? (Proposed § 117.3)

The proposed rule would define "cross-contact" to mean the unintentional incorporation of a food allergen into a food. In the past, inadvertent incorporation of an allergen into a food was referred to as "contamination" or "cross contamination", and in many instances these terms are still used. More recently, the term "cross-contact" (rather than "contamination" or "cross contamination") has been applied with respect to unintentional transfer of allergenic proteins from a food containing the proteins to one that does not, because an allergen is a normal component of food, and not itself a contaminant. Given this shift in the scientific literature distinguishing "cross-contact" from "contamination" and "cross contamination," FDA tentatively concluded that it should begin using the term "cross-contact" to describe inadvertent incorporation of an allergen into food, rather than the general term "contamination," for purposes of clarity. (78 FR 3693)

B5. How would the proposed rule define the term "environmental pathogen"? (Proposed § 117.3)

The proposed rule would define the term "environmental pathogen" to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment (78 FR 3697).

B6. How would the proposed definition of “food allergen” relate to the major food allergens as defined in section 201(qq) of the FD&C Act? (Proposed § 117.3)

The proposed rule would define “food allergen” to mean a major food allergen as defined in section 201(qq) of the FD&C Act. Section 201(qq) defines the term “major food allergen” to mean any of the following: milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans, or a food ingredient that contains protein derived from one of these foods, with certain exceptions. (78 FR 3697)

B7. How would the proposed rule define the term “hazard”? (Proposed § 117.3)

The proposed rule would define “hazard” to mean” any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. (78 FR 3697)

B8. Why would the proposed definition of “hazard” include a radiological agent? (Proposed § 117.3)

The proposed rule would include a radiological agent in the definition of “hazard” because FSMA includes radiological hazards as an example of known or reasonably foreseeable hazards that may be associated with the facility. (78 FR 3698)

B9. How would the proposed rule define the term “hazard that is reasonably likely to occur”? (Proposed § 117.3)

The proposed rule would define the term “hazard that is reasonably likely to occur” to mean a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls. The proposed definition is consistent with Federal HACCP regulations for seafood, juice, and meat and poultry. (78 FR 3698)

B10. How would the proposed rule define the term "preventive controls"? (Proposed § 117.3)

The proposed rule would define the term "preventive controls" to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. The proposed definition would incorporate the definition in section 418(o)(3) of the FD&C Act. (78 FR 3699)

B11. How would the proposed rule define the term "qualified-end-user"? (Proposed § 117.3)

The proposed rule would define the term "qualified end-user" to mean, with respect to a food, the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that (1) is located (a) in the same State as the qualified facility that sold the food to such restaurant or establishment; or (b) not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. The proposed definition would incorporate the definition in section 418(l)(4)(B) of the FD&C Act. (78 FR 3699)

B12. How would the proposed rule define the term "qualified facility"? (Proposed § 117.3)

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

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

The proposed definition would incorporate the description of "qualified facility" in section 418(l)(1) of the FD&C Act with editorial changes to improve clarity. (78 FR 3699)

B13. Why would the proposed definition of "ready-to-eat food" (RTE food) include food for which "it is reasonably foreseeable that the food would be eaten" without further processing to significantly minimize biological hazards? (Proposed § 117.3)

The proposed definition of ready-to-eat food would address both foods commonly recognized as RTE (e.g., cheese, peanut butter, and breakfast cereal) and foods that usually receive a heat treatment (e.g., cooking) before consumption but in some circumstances are eaten without such treatment (e.g., raw cookie dough and dried soup mix). For example, it is well known that consumers eat raw cookie dough; an outbreak of foodborne illness caused by *E. coli* O157:H7 has been linked to consumption of raw cookie dough. It also is well known that consumers use dried soup mix in RTE form as a component of a dip; multiple dried soup mix products were recalled due to the potential for contamination with *Salmonella* spp. from an ingredient (hydrolyzed vegetable protein). (78 FR 3700)

B14. How would the proposed rule define the term "reasonably foreseeable hazards"? (Proposed § 117.3)

The proposed rule would define the term "reasonably foreseeable hazard" to mean a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food. The term "reasonably foreseeable hazard" is not used in NACMCF HACCP guidelines, the Codex HACCP Annex, or Federal HACCP regulations for seafood, juice, or meat and poultry. However, the term is used in FSMA and the concept is grounded in the hazard evaluation process in HACCP systems. (78 FR 3700)

B15. Would a business fit the proposed definition of "small business" if it has two facilities and each facility has about 300 employees? (Proposed § 117.3)

No. The business would not fit the definition of a "small business" because it employs about 600 people. The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. (78 FR 3701)

B16. What year would be the baseline year to calculate the adjustment for inflation for purpose of the proposed definitions of "qualified facility" and "very small business"? (Proposed §§ 117.3 and 117.401(a)(1))

We are proposing to establish 2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law. (78 FR 3769)

B17. How would the proposed rule define the term "validation"? (Proposed § 117.3)

The proposed rule would define the term "validation" to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and our HACCP regulation for juice. (78 FR 3700)

B18. How would the proposed rule define the term "verification"? (Proposed § 117.3)

The proposed rule would define the term "verification" to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex and validation guidelines, and our HACCP regulation for juice. (78 FR 3700)

B19. Why would the proposed rule revise the definition of "farm" in the section 415 food facility registration regulations? (Proposed part 1, subpart H, § 1.227)

As a conforming change to the proposed definition of "harvesting," FDA is proposing to revise the definition of "Farm" in current §§ 1.227(b)(3) and § 1.328 to delete examples of harvesting that currently appear in that definition. With the proposed new, separate definition of harvesting, it would be redundant to retain the examples of harvesting within the definition of "Farm." (78 FR 3683)

B20. How would the proposed rule define the terms "mixed-type facility" and "farm mixed-type facility"? (Proposed §§ 1.227 and 117.3)

The proposed rule would define "mixed-type facility" to mean an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. (78 FR 3797, 3799)

B21. Would activities described in the proposed definition of "harvesting" apply only to activities conducted on a farm and a farm mixed-type facility? (Proposed §§ 1.227 and 117.3)

Yes. "Harvesting" is a category of activities that is only applicable to farms and farm mixed-type facilities. (78 FR 3681)

B22. Would activities described in the proposed definition of "harvesting" apply only to RACs that are produce? (Proposed §§ 1.227 and 117.3)

No. The activities in the proposed definition of "harvesting" would apply to any of a farm's own RACs, not just "produce." For example, unpasteurized shell eggs are RACs, and washing such eggs on the farm on which the eggs were produced would be part of harvesting the eggs. (78 FR 3681)

B23. Would activities described in the proposed definition of "harvesting" apply to activities conducted on RACs other than those grown or raised on that farm or on another farm under the same ownership? (Proposed §§ 1.227 and 117.3)

No. Activities that would be included in the proposed definition of "harvesting" would be limited to activities performed on RACs on the farm on which they were grown or raised, or another farm under the same ownership. For example, at an off-farm processing facility that pasteurizes eggs, washing the unpasteurized shell eggs after they are received would not be "harvesting" because it is not being performed on the farm that produced the eggs (or another farm under the same ownership). Instead, washing eggs at the off-farm processing facility would be "manufacturing/processing," because it involves preparing, treating, modifying or manipulating food. (78 FR 3681)

B24. What activities would be included under the proposed definition of "holding" for a farm and a farm mixed-type facility? (Proposed §§ 1.227 and 117.3)

For a farm and a farm mixed-type facility, the proposed definition of "holding" would include storage of food and activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just storage of food would be classified as "holding" when a farm or farm mixed-type facility performs those activities on its own RACs. For example, fumigating or otherwise treating a farm's own RACs against pests for the purpose of safe and effective storage would be "holding" under this proposed definition.

However, fumigating or otherwise treating food against pests under other circumstances (such as off-farm or by a farm handling others' RACs) would not be "holding" food because it would not be performed by a farm or farm mixed-type facility for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership. (78 FR 3681)

B25. What activities would be included under the proposed definition of "packing" for a farm and a farm mixed-type facility? (Proposed §§ 1.227 and 117.3)

For a farm and a farm mixed-type facility, the proposed definition of "packing" would include activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on the same farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just placing food into a container other than packaging would be classified as "packing" when a farm or farm mixed-type facility performs those activities on its own RACs. For example, packaging (placing food into a container that directly contacts the food and that the consumer receives) a farm's own RACs would be "packing" under this definition because farms traditionally do this to provide greater protection for fragile RACs than would be possible if the RACs were placed in containers other than the consumer container, and because this activity does not transform a RAC into a processed food. However, packaging food under other circumstances would not be "packing" food because packaging is explicitly excluded from the definition of packing applicable to most circumstances (placing food into a container other than packaging). Other examples of activities that could be packing when performed by a farm or a farm mixed-type facility on its own RACs include packaging or packing a mix of RACs together (e.g., in a bag containing three different colored bell peppers, or a box of mixed produce for a community sponsored agriculture program farm share); coating RACs with wax, oil, or resin coatings used for the purposes of storage or transport; placing stickers on RACs; labeling packages containing RACs; sorting, grading, or culling RACs; and drying RACs for the purpose of storage or transport. (78 FR 3681 - 3682)

B26. What is FDA's current interpretation of activities that transform a RAC into a processed food?

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

EPA/FDA Policy Interpretation") (63 FR 54532, October 9, 1998). In 1999, FDA issued guidance addressing several of the issues discussed in the 1998 Joint EPA/FDA Policy Interpretation (See Guidance for Industry: Antimicrobial Food Additives, July 1999). The table below summarizes activities that cause food RACs to become processed foods and activities that do not change the status of a food RAC, as provided in the FD&C Act and addressed in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance. (78 FR 3678-79, Table 2)

The Effect of Activities on RACs That Are Foods

Activities That Change a RAC into a Processed Food	Activities That Do Not Change the Status of a RAC
Canning	Application of pesticides (including by washing, waxing, fumigation, or packing)
Chopping	Coloring
Cooking	Drying for the purpose of storage or transportation
Cutting	Hydro-cooling
Drying that creates a distinct commodity	Otherwise treating fruits in their unpeeled natural form
Freezing	Packing
Grinding	Refrigeration
Homogenization	Removal of leaves, stems, and husks
Irradiation	Shelling of nuts
Milling	Washing
Pasteurization	Waxing
Peeling	Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant
Slaughtering animals for food and activities done to carcasses post-slaughter, including skinning, eviscerating, and quartering	
Slicing	
Activities that alter the general state of the commodity	

B27. How do activities that change the status of a RAC into a processed food relate to the current definition of "manufacturing/processing" in the section 415 food facility registration regulations?

The current definition of "manufacturing/processing" in § 1.227(b)(6) and 1.328 includes most food-handling activities because it is satisfied by any degree of "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food." In contrast, transforming a RAC into a processed food seems to require meeting a threshold of altering the general state of the commodity, sometimes referred to as transformation of the RAC into a new or distinct commodity. This means that a given activity may be manufacturing/processing under the current definition in § 1.227(b)(6) and 1.328 without transforming a RAC into a processed food. Examples of such activities include coloring, washing, and waxing. (78 FR 3679)

C. Proposed § 117.5--Exemptions

C1. What specific exemptions would the proposed rule establish? (Proposed § 117.5)

As required or provided by FSMA, certain facilities, or certain activities conducted by facilities, would be exempt from the proposed requirements for hazard analysis and preventive controls in proposed part 117, subpart C. The proposed exemptions would be consistent with requirements established by FSMA or discretion provided by FSMA. The subjects of the specified exemptions relate to:

- A "qualified" facility;
- Activities subject to our existing HACCP regulations for seafood and juice, our regulations governing microbiological hazards in low acid canned foods, and our dietary supplement CGMP regulations;
- Activities of a facility that are subject to the Standards for Produce Safety in section 419 of the FD&C Act;
- Certain low-risk packing or holding activity/food combinations conducted on a farm by a small or very small business;
- Certain low-risk manufacturing/processing activity/food combinations conducted on a farm by a small or very small business;
- The receipt, manufacturing, processing, packing, holding, and distribution of alcoholic beverages and other prepackaged food sold in conjunction with alcoholic beverages (e.g., gift baskets);
- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing; and
- Facilities solely engaged in the storage of packaged food that is not exposed to the environment, although the storage of such food that requires time/temperature control to prevent the growth of, or toxin formation by, pathogenic microorganisms would be subject to modified requirements.

(78 FR 3672)

In addition, certain types of facilities, or activities conducted by certain types of facilities, would be exempt from the updated CGMP requirements in proposed subpart B. The specified exemptions would relate to:

- "Farms" (as defined in § 1.227);
- Activities of "farm mixed-type facilities" (as defined in as defined in § 1.227) fall within the definition of "farm"; and
- The holding or transportation of one or more "raw agricultural commodities" as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

(78 FR 3802)

C2. Would a facility be exempt from ALL the proposed requirements for hazard analysis and risk-based preventive controls in subpart C if it is required to comply with, and is in compliance with, FDA's regulations for thermally processed low-acid foods (21 CFR part 113)? (Proposed § 117.5(d))

No. The proposed exemption for thermally processed low-acid foods packaged in hermetically sealed containers would apply ONLY with respect to the microbiological hazards that are regulated under part 113. A facility that is required to comply with, and is in compliance with, part 113 would be subject to the requirements in proposed subpart C for hazards such as chemical hazards (e.g., pesticide residues), physical hazards (e.g., metal fragments that could be introduced from equipment) and radiological hazards (e.g., high concentrations of radium-226, radium-228 or uranium in well water used in product). A facility that is required to comply with, and is in compliance with, part 113 also would be subject to the requirements in proposed subpart C for biological hazards not regulated under part 113. For example, the heat-stable toxin produced by the *Staphylococcus aureus* is a biological hazard that would not be inactivated or destroyed by the processing required under part 113. (78 FR 3704)

C3. How would the exemption from the proposed requirements for hazard analysis and risk-based preventive controls in subpart C apply to a facility that produces both thermally processed low-acid food and acidified food and is in compliance with FDA's regulations for these foods (part 113 for low-acid food and part 114 for acidified food)? (Proposed § 117.5(d))

FSMA specified a partial exemption for facilities that produce low-acid food but did not specify any exemption for foods subject to, and produced in compliance with, part 114. The facility would be exempt from the proposed requirements of subpart C with respect to the microbiological hazards for food that is regulated under part 113. The facility would be subject to the proposed requirements in subpart C for chemical, physical and radiological hazards for both the low-acid food and acidified food it produces, as well as for the microbiological hazards that are reasonably likely to occur in the acidified food. (78 FR 3704)

C4. Would ALL activities that a facility conducts be exempt from the proposed requirements for hazard analysis and risk-based preventive controls in subpart C if the facility is required to comply with, and is in compliance with FDA's HACCP regulation for juice [or seafood] but also manufactures, processes, packs, or holds other types of foods that are not subject to FDA's HACCP regulation for juice [or seafood]? (Proposed § 117.5(b) and (c))

No. Proposed § 117.5(b) and (c) would make clear that the exemptions provided would apply to particular activities at a facility rather than to the facility as a whole. For example, a facility producing juice and dairy beverages would be exempt only with respect to juices subject to, and in compliance, with part 120. Such a facility would be subject to subpart C with respect to its dairy beverages, unless it qualified for another exemption. (78 FR 3704)

C5. Would a facility be exempt from the proposed requirements for hazard analysis and risk-based preventive controls in subpart C if it only conducts on-farm, low-risk activities on food types described in the exemptions in proposed § 117.5(g) and (h), but it does not fit the definition of a small or a very small business? (Proposed § 117.5(g) and (h))

No. The facility would not be exempt from the proposed requirements for hazard analysis and risk-based preventive controls in subpart C. The proposed exemptions in proposed § 117.5(g) and (h) would only apply to small and very small businesses. (78 FR 3706)

C6. Would a facility be exempt from the proposed requirements for hazard analysis and risk-based preventive controls in subpart C when it conducts the on-farm, low-risk activities on food types described in the exemptions in proposed § 117.5(g) and (h) if it is a small (or a very small) business and some, but not all, of the activities it conducts are those in these proposed exemptions? (Proposed § 117.5(g) and (h))

No. FDA tentatively concluded that the language in FSMA is unambiguous and means that Congress intended us to exempt a facility from, or modify the requirements of, section 418 of the FD&C Act if the facility only conducts a limited set of low-risk activity/food combinations that would otherwise be subject to section 418. This interpretation would mean that a facility would be required to conduct a hazard analysis and establish and implement risk-based preventive controls for all activities conducted on all foods (including low-risk activity/food

combinations) if a facility conducts a single activity subject to section 418 of the FD&C Act that is not a low-risk activity/food combination, unless the facility qualifies for another exemption from subpart C. (78 FR 3706)

C7. How would the proposed requirements for hazard analysis and risk-based preventive controls in subpart C apply if a facility manufactures, processes, packs, and holds both alcoholic beverages and non-alcoholic beverages? (Proposed § 117.5(i))

The activities related to alcoholic beverages (including the manufacturing, processing, packing, or holding of alcoholic beverages) at facilities within the scope of 117.5(i) would not be subject to the proposed requirements of subpart C. Activities related to food other than alcoholic beverages (including the receiving, manufacturing, processing, packing, holding, and distributing of such foods) at the facility would be subject to the proposed requirements of subpart C (unless they qualify for another exemption or the foods are in prepackaged form and constitute 5 percent or less of your facility's overall sales). (78 FR 3708)

C8. What are examples of facilities that would be exempt from the proposed requirements for hazard analysis and risk-based preventive controls in subpart C under the exemption for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution? (Proposed § 117.5(j))

One example of a facility that would be exempt from the proposed requirements of subpart C under proposed § 117.5(j) is a grain elevator or silo that only stores whole grains (including corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, and soybeans). Other examples of facilities that would be exempt from the proposed requirements of subpart C under proposed § 117.5(j) are facilities that only store unpasteurized shell eggs or unpasteurized milk. The exemption in proposed § 117.5(j) would apply to such facilities provided that the facilities do not conduct other activities subject to section 418 of the FD&C Act. (78 FR 3709)

C9. Why would the exemption for storage of RACs intended for further distribution exclude the storage of those RACs that are fruits and vegetables? (Proposed § 117.5(j))

The exemption in proposed § 117.5(j) would implement a statutory provision in FSMA (section 418(m) of the FD&C Act) which does not apply to the storage of those RACs that are fruits and vegetables.

C10. How would the proposed rule change "the RAC exemption" in current § 110.19(a) regarding establishments engaged solely in the harvesting, storage, or distribution of one or more RACs? (Proposed § 117.5(k))

Proposed § 117.5(k) would adjust and clarify what activities fall within the "RAC exemption" in current § 110.19(a) based on experience and changes in related areas of the law since issuance of the CGMP regulation. For example, proposed § 117.5(k) would provide that Subpart B does not apply to "farms" (as would be defined in proposed § 1.227), activities of farm mixed-type facilities (as would be defined in proposed § 1.227) that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the FD&C Act. (78 FR 3710)

C11. Would an establishment be exempt from the proposed requirements for hazard analysis and risk-based preventive controls in subpart C if it currently is exempt from the requirements of part 110 under the "RAC exemption" in current § 110.19(a)?

An exemption under the RAC exemption in current § 110.19(a) does not determine whether an establishment would be exempt from the proposed requirements of subpart C. Establishments that previously qualified for the RAC exemption would be subject to section 418 of the FD&C Act if they are required to register under section 415 of the FD&C Act, unless they otherwise qualify for an exemption from section 418 (in proposed § 117.5(a) through (j)). (78 R 3710)

C12. Would the current limitation that the RAC exemption in current § 110.19(a) applies only to "establishments engaged solely in" the listed activities still apply under the revised RAC exemption? (Proposed § 117.5(k))

No. FDA tentatively concluded that it would be reasonable to revise the exemption so that it would exempt the specifically identified activities when performed on RACs, regardless of whether the establishment that conducts those activities also conducts other activities that do not qualify for the exemption. (78 FR 3711)

D. Proposed Subpart B—Current Good Manufacturing Practice

D1. What general revisions would the proposed rule make to the current CGMPs in part 110?

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

- Redesignating certain sections to enhance clarify of proposed part 117 as a whole;
- Revising or clarifying certain terms for consistency;
- Clarifying that certain CGMP provisions requiring protection against contamination require protection against cross-contact of food as well;
- Deleting provisions containing recommendations, and;
- Making editorial changes that have no substantive effect on the current requirements of part 110 to modernize the language throughout (e.g., by replacing the word “shall” with the word “must”).

(78 FR 3691-3694)

D2. Why would the proposed rule include “cross-contact” in several provisions of subpart B?

In subpart B, FDA is proposing a number of revisions to address cross-contact. To make it clear that CGMPs require protection against cross-contact, and to ensure that CGMPs continue to address health concerns related to allergens, FDA is proposing to revise several provisions of current part 110 to explicitly address cross-contact in proposed part 117. (78 FR 3693)

E. Proposed Subpart C--Hazard Analysis and Risk-Based Preventive Controls

E1. Proposed § 117.126--Requirements for a Food Safety Plan

E1.1 What would a food safety plan include? (Proposed § 117.126(b)(1) through (7))

The proposed rule would require that the contents of a food safety plan include:

- The written hazard analysis;
- The written preventive controls;
- The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls;
- The written corrective action procedures;
- The written verification procedures; and
- The written recall plan.

(78 FR 3730, 3805-3806)

E1.2 Would the proposed rule require that the food safety plan be written? (Proposed § 117.126(a))

Yes. The proposed rule would require that the plan be written as is expressly required by section 418(h) of the FD&C Act. 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. (78 FR 3730)

E1.3 Who could prepare a food safety plan? (Proposed § 117.126(a) and (c))

The proposed rule 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. (78 FR 3730)

A qualified individual must develop the food safety plan in order to ensure the preventive controls are effective. The plan must be designed to identify and to significantly minimize or prevent hazards in order to prevent illness or injury. Designing a plan requires an individual who is knowledgeable in the concepts of preventive controls, the hazards associated with a product and process, the appropriate preventive controls, with associated monitoring and corrective actions for those hazards, and appropriate verification activities for the applicable

preventive controls. Such knowledge requires scientific and technical expertise developed through training, experience, or both. (78 FR 3731)

E1.4 Would all aspects of the food safety plan need to be prepared by a qualified individual? (Proposed § 117.126(c))

No. 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 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. (78 FR 3731-3732)

E1.5 Could a facility use the same food safety plan to address hazards in multiple foods? (Proposed § 117.126)

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. 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. (78 FR 3732)

E2. Proposed § 117.130--Hazard Analysis

E2.1 Would the proposed rule require that the hazard analysis be written? (Proposed § 117.130(a)(2))

Yes. The proposed rule would require that the hazard analysis be written, as required by section 418(b)(3) of the FD&C Act. (78 FR 3733)

E2.2 What are examples of an "environmental pathogen" as that term would be defined in the proposed rule?

Examples of environmental pathogens include *Salmonella* spp. and *Listeria monocytogenes*. (78 FR 3697)

E2.3 When would a facility be required to evaluate whether environmental pathogens are reasonably likely to occur? (Proposed § 117.130(b)(1) and (c)(2))

The proposed rule 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. 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*. The proposed rule would include environmental pathogens as one of the biological hazards that must be considered in identifying hazards for evaluation. 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 and evaluate whether contamination of RTE food with the environmental pathogen is reasonably likely to occur in the facility. (78 FR 3736)

E3. Proposed § 117.135--Preventive Controls for Hazards That Are Reasonably Likely to Occur

E3.1 Under what circumstances would the proposed rule require a facility to identify and implement preventive controls? (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. (78 FR 3739)

E3.2 What types of preventive controls would a facility develop and implement? (Proposed § 117.135(a))

The types of preventive controls implemented would depend on the facility and the food it produces. Most hazards would be 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). (78 FR 3739)

E3.3 How would the proposed approach for applying preventive controls compare to the approach used in a HACCP system? (Proposed § 117.135)

The proposed hazard analysis and risk-based preventive control requirements are similar to Hazard Analysis and Critical Control Points (HACCP) systems and are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry. 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. (78 FR 3739)

E3.4 Would the proposed rule require that preventive controls be written? (Proposed § 117.135(b))

Yes. Proposed § 117.135(b) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur be written. (78 FR 3806)

E3.5 What types of parameters would have to be included in the preventive controls? (Proposed § 117.135(c)(1))

The proposed rule 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. (78 FR 3739, 3806)

E3.6 Would all preventive controls have associated parameters? (Proposed § 117.135(c)(1))

No. 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. (78 FR 3740)

E3.7 Would all parameters that would have to be included in the preventive controls have associated maximum or minimum values? (Proposed § 117.135(c)(2))

No. The proposed rule 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. (78 FR 3740)

E3.8 What types of controls would be considered preventive controls? (Proposed § 117.135(d))

Preventive controls for hazards identified in the hazard analysis as reasonably likely to occur would include, as appropriate, process controls, food allergen controls, sanitation controls, recall plan, and other controls necessary. (78 FR 3806)

E3.9 What would process controls include? (Proposed § 117.135(d)(1))

The proposed rule would require that process controls include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Examples of process controls include heating a food to adequately reduce pathogens and acidifying a food to prevent pathogen growth. (FR 3740 – 3741)

E3.10 What are specific examples of food allergen control procedures, practices and processes that a facility can use to address cross-contact? (Proposed § 117.135(d)(2)(i))

Examples of food allergen controls 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.

(78 FR 3741)

E3.11 What are specific examples of food allergen control procedures, practices, and processes that a facility can use to address labeling? (Proposed § 117.135(d)(2)(ii))

Examples of specific food allergen control procedures, practices, and processes that a facility can use to address labeling include the following:

- 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).

(78 CFR 3741)

E 3.12 When is sanitation considered to be a preventive control? (Proposed §§ 110.135 and 117.135(d)(3))

Sanitation is considered to be a preventive control 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). (78 FR 3741, 3806)

E3.13 What are examples of sanitation controls for the cleanliness of food-contact surfaces? (Proposed § 117.135(d)(3)(i)(A))

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. (78 FR 3741-3742)

E3.14 What are examples of sanitation controls to prevent cross-contact? (Proposed § 117.135(d)(3)(i)(B))

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). (78 FR 3742)

E3.15 What are examples of sanitation controls to prevent cross-contamination? (Proposed § 117.135(d)(3)(i)(B))

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. (78 FR 3742)

E4. Proposed § 117.137--Recall plan for food with a hazard that is reasonably likely to occur

Reserved.

E5. Proposed § 117.140--Monitoring

Reserved.

E6. Proposed § 117.145--Corrective Actions

Reserved.

E7. Proposed § 117.150--Verification

E7.1 Proposed § 117.150(a)--Validation

E7.1.1 When would validation be conducted relative to implementation of the food safety plan and initial production? (Proposed § 117.150(a)(1)(i))

The proposed rule 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). 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. 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. (78 FR 3753)

E7.1.2 What would constitute validation? (Proposed § 117.150(a)(2))

The proposed rule would require that 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. (78 FR 3753, 3807)

E7.1.3 What preventive controls would not require validation? (Proposed § 117.150(a)(3))

The proposed rule would provide that validation need not address:

- Food allergen controls;
- Sanitation controls; and
- Recall plan.

(78 FR 3755, 3807)

E7.1.4 What types of scientific and technical information could be used for validation?

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. (78 FR 3753 – 3754)

E7.1.5 What would a facility do if scientific and technical information to support the adequacy of a preventive control measure is not available or is insufficient?

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. Information is available in the literature that can assist in the design of studies to support the adequacy of preventive control measures. (78 FR 3753 – 3754)

E7.1.6 What would be the role of a qualified individual when validation studies are conducted?

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 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. (78 FR 3754)

E7.2 Proposed § 117.150(f)--Reanalysis.

E7.2.1 When would the proposed rule require reanalysis of the food safety plan? (Proposed § 117.150(f)(1)(i))

The proposed rule 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;

- Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;
- Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food;
- Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and
- Whenever a preventive control is found to be ineffective.

(78 FR 3759, 3807)

E7.2.2 Would a facility be required to document reanalysis of a food safety plan if the facility concludes that no change or revision is needed? (Proposed § 117.150(f)(1)(iii))

Yes. A facility would be required to document that a reanalysis has been conducted even if no change has been made. 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. (78 FR 3760)

E8. Proposed § 117.155--Requirements Applicable to a Qualified Individual

E8.1 Would the proposed rule require that a qualified individual be an employee of the facility? (Proposed § 117.155(b))

The proposed rule 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. (78 FR 3762)

F. Proposed Subpart D--Modified requirements

F1. Proposed § 117.201-- Modified Requirements that Apply to a Qualified Facility

F1.1 What two types of documentation would a qualified facility be required to submit to FDA? (Proposed § 117.201(a))

A qualified facility would be required to submit two types of documentation to FDA. The first type of required documentation relates to satisfying the definition of a qualified facility. The second type of documentation relates to food safety practices at the facility. (78 FR 3769, 3808)

F1.2 How could a qualified facility satisfy the proposed requirement to submit documentation regarding its status as a qualified facility? (Proposed § 117.201(a)(1))

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).

FDA tentatively concluded 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. 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. (78 FR 3769)

F1.3 How could a qualified facility satisfy the proposed requirement to document the food safety practices at the facility? (Proposed § 117.201(a)(2)(i) and (ii) and Proposed § 117.201(d))

A qualified facility would have two options to satisfy the documentation requirement with respect to the food safety practices at the facility:

- Option 1. A statement from the owner, operator, or agent in charge of a qualified facility certifying that 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; or

- Option 2. A statement from the owner, operator, or agent in charge of a qualified facility certifying 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.
  (78 FR 3770)

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. (78 FR 3770)

The 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 Option 1 (proposed § 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). 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 contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales. (78 FR 3771)

F1.4 How often would a qualified facility need to submit the required documentation? (Proposed § 117.201(c)(1) and (2))

The proposed rule would require that the required documentation be submitted to FDA initially within 90 days of the applicable compliance date of the rule. 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. (78 FR 3770)

The proposed rule also would require that the required documentation be resubmitted to FDA at least every 2 years, or whenever there is a material change to the information. 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. (78 FR 3770)

F1.5 What records would a qualified facility be required to maintain? (Proposed 117.201(e))

The proposed rule would require that a qualified facility maintain records relied upon to support the required documentation. The proposed rule would not require that a qualified facility establish any new records, but merely retain those that the facility relied upon to support the required documentation. The proposed rule also would establish that the records that a qualified facility must maintain are subject to the recordkeeping requirements of subpart F of part 117. 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. (78 FR 3771)

F2. Proposed § 117.7 and 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

F2.1 How would the proposed rule apply to a facility that is solely engaged in the storage of packaged food that is not exposed to the environment? (Proposed §§ 117.7)

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(b) if the facility stores any refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance (78 FR 3772, 3808)

F2.2 What does it mean for a packaged food to be “not exposed to the environment” and “unexposed”? (Proposed § 117.7 and 117.206)

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. (78 FR 3712, 3772)

F2.3 What is "TCS food"?

FDA uses the term "TCS food" to mean food that requires time/temperature control for safety, i.e., to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. (78 FR 3712, 3773)

F2.4 Why does the proposed rule distinguish between unexposed refrigerated packaged TCS food and other unexposed packaged food? (Proposed § 117.206)

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." The proposed rule would distinguish 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. (78 FR 3772)

Most foods that are stored refrigerated have not been processed to eliminate pathogenic sporeformers, including *Clostridium botulinum*, *Bacillus cereus* and *C. perfringens*. If refrigerated foods are exposed to high enough temperatures for sufficient time, these sporeformers may begin to grow and produce toxins. Some strains of *C. botulinum* and *B. cereus* can grow at refrigeration temperatures, e.g., some strains of *B. cereus* grow at 39ºF (4ºC) and some strains of *C. botulinum* grow at 38ºF (3.3ºC). (78 FR 3772)

The modified requirements in proposed § 117.206 would apply to unexposed refrigerated packaged TCS food. (78 FR 3772)

F2.5 Would a facility subject to the modified requirements for a facility solely engaged in the storage of unexposed packaged food be required to conduct a hazard analysis and identify and implement preventive controls for unexposed refrigerated packaged TCS food?

No. 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. (78 FR 3773)

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. (78 FR 3773)

Therefore, 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. (78 FR 3773)

F2.6 How could a facility determine whether an unexposed refrigerated packaged food is a TCS food and the appropriate temperature for storage of any TCS food? (Proposed § 117. 206)

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 by the manufacturer, processor, or packer of the food; and (2) through applicable scientific and technical support literature. (78 FR 3773)

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 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. (78 FR 3774)

F2.7 Would frozen food be considered a TCS food covered by proposed § 117.206?

Usually not. 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. (78 FR 3774)