Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services

DRAFT Qualitative Risk Assessment
Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm

August 2012

CONTRIBUTORS

Team Leader: Jenny Scott, FDA

Team Members:
Linda Kahl, FDA
Donald Kraemer, FDA
Julie Lovas, FDA
Sharon Edelson Mammel, FDA
Michael Mahovic, FDA
John Misock, FDA

ACKNOWLEDGEMENTS

The following individuals and groups are acknowledged for their contributions to this project:

CFSAN food safety and processing experts, (in addition to the team members), for their input and advice on activity/food combinations likely to be conducted by farm mixed-type facilities:

Samir Assar
Cecilia (Maria) Crowley
Dennis Gaalswyk
James Gorny
Daria Kleinmeier

Yinqing Ma (FDA), for organizing and managing references

Sherri Dennis (FDA), for advice on the approach to a risk assessment

Lori Papadakis (FDA), for professional formatting and editing of the report

Richard Galloway (Galloway & Associates LLC), for information regarding the production of soybeans

Pamela Miles (Virginia Department of Agriculture and Consumer Services, Food Safety & Security Program), for information regarding on-farm manufacturing, processing, packing, and holding activities of food not grown, raised or consumed on the farm that conducts the manufacturing, processing, packing, and holding activity

EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) has conducted a qualitative risk assessment (RA) related to manufacturing, processing, packing and holding activities for human food when such activities are conducted on farms. The purpose of the RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk. FDA conducted this RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that FDA determines to be low risk involving specific foods FDA determines to be low risk from the requirements of sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or whether to modify such requirements for such facilities.

The RA identified the following as low-risk activity/food combinations:

- Making hard candy, fudge, taffy, toffee;
- Making cocoa products from roasted cocoa beans;
- Making honey;
- Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- Making maple syrup;
- Making soft drinks and carbonated water;
- Making sugar from sugarcane and sugar beets;
- Artificial ripening of intact fruits and vegetables;
- Boiling/evaporation of maple sap to make maple syrup;
- Coating intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
- Chopping peanuts and tree nuts;
- Cooling intact fruits and vegetables using cold air;
- Drying/dehydrating intact fruits and vegetables (without sulfiting), grains and grain products, peanuts and tree nuts, coffee beans, and cocoa beans;
- Extracting oils from grains (e.g., corn, soybeans, oilseeds);
- Fermenting cocoa beans and coffee beans;
- Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal), coffee beans, cocoa beans, and peanuts and tree nuts (e.g., making ground peanuts);
- Labeling (including stickering) intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), intact single-ingredient peanuts or tree nuts (shelled and unshelled), honey, maple sap, maple syrup, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, hard candy, cocoa products from roasted cocoa beans (other than milk chocolate), jams/jellies/preserves, and soft drinks and carbonated beverages;
- Mixing intact fruits and vegetables, grain and grain products, peanuts, tree nuts, honey, maple sap and maple syrup, coffee beans, and cocoa beans;

- Packing or re-packing (including weighing or conveying incidental to packing or re-packing) intact fruits and vegetables, grain and grain products, peanuts, tree nuts, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, honey, maple sap, maple syrup, soft drinks and carbonated water, jams, jellies, and preserves
- Packaging intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grains and grain products; peanuts and tree nuts (including modified atmosphere or vacuum packaging); honey; maple syrup; sugarcane, sugar beets and sugar; coffee beans; cocoa beans; cocoa products, hard candy, fudge, taffy, toffee; jams, jellies and preserves; and soft drinks and carbonated water;
- Salting peanuts and tree nuts;
- Sifting grains and grain products;
- Shelling/ hulling intact fruits and vegetables (e.g., dried peas and beans), peanuts, tree nuts, and cocoa beans (i.e., winnowing);
- Sorting, culling and grading intact fruits and vegetables, grain and grain products, peanuts, tree nuts, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, honey, maple sap, maple syrup, soft drinks and carbonated water, jams, jellies, and preserves;
- Storing intact fruits and vegetables, grain and grain products, peanuts, tree nuts, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, honey, maple sap, maple syrup, soft drinks and carbonated water, jams, jellies, and preserves;
- Treating intact fruits and vegetables, grains and grain products, peanuts, tree nuts, coffee beans and cocoa beans against pests other than during growing, e.g., fumigation; and
- Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

Under the statutory and regulatory framework applicable to farms and to food facilities co-located on farms, a specific activity (such as washing fruits and vegetables) may have a different classification within the classes of manufacturing, processing, packing and holding (with consequences for what regulations apply to the activity) based on whether the food being operated upon is a raw agricultural commodity (RAC) or a processed food and whether a RAC was grown or raised on the farm performing the activity or a farm under the same ownership. An appendix to the RA arranges the results of the RA in groups shaped by these factors.

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I. BACKGROUND AND PURPOSE

A. Statutory and Regulatory Framework of the FDA Food Safety Modernization Act (FSMA)

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111–353) was signed into law. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to create a new section 418 with the same name. Among other things, Section 418 requires facilities to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418 is applicable to food facilities that are required to register under section 415 of the FD&C Act (Registration of Food Facilities). The registration requirement in section 415 of the FD&C Act does not apply to farms. However, it does apply to "farm mixed-type facilities", which are establishments that grow and harvest crops or raise animals and may conduct other activities within the farm definition, but that also conduct activities that require the establishment to be registered.

Section 103(c) of FSMA directs the Secretary of HHS to conduct a science-based risk analysis to cover "(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership." The listed activities are those on-farm activities that trigger the registration requirements of section 415 of the FD&C Act and, thus, would make an establishment subject to the new requirements of section 418 of the FD&C Act and the mandatory inspection frequencies in section 421 of the FD&C Act.

Section 103(c) of FSMA also requires that the Secretary of HHS consider the results of the science-based risk analysis and exempt certain facilities from the requirements in section 418 of the FD&C Act, and the mandatory inspection frequency in section 421 of the FD&C Act, or modify the requirements, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk. The exemptions or modifications would apply only to small businesses and very small businesses (as would be defined in the regulation implementing section 418).

The purpose of this document is to satisfy these requirements of FSMA 103(c) for a science-based risk analysis covering certain manufacturing, processing, packing, and holding activities conducted on farms. Risk managers at FDA will consider the results of the risk analysis presented in this RA in determining, in part, whether to establish any exemptions from, or modifications to, requirements that would otherwise apply to small or very small farm mixed-type facilities. For more information on the regulatory framework and its relationship to this document, see Appendix 1. Regulatory Background

B. Approach to the Qualitative Risk Assessment

We focused on activity/food combinations that we identified as being conducted on farms (and, thus, might be conducted by farm mixed-type facilities), but we did not consider activity/food combinations that would be solely within the farm definition (such as growing fruits and vegetables) and, thus, are not relevant to the requirements of section 103 of FSMA.

We focused on considering the risk of activity/food combinations rather than separately considering the risk of specific food categories because doing so would better enable us to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on food by a farm mixed-type facility warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act. For example, because many foodborne illness outbreaks have been associated with tomatoes (Institute of Food Technologists, 2001a; CDC, 2007; FDA Memorandum, 2011b), we would not consider tomatoes to be a "low-risk food" as a general matter. However, different activities involved in handling tomatoes involve different levels of public health risk and should be considered in their specific context. For example, infiltration of wash-water into intact fruit may have contributed to an outbreak of salmonellosis associated with fresh market tomatoes (Institute of Food Technologists, 2001a); this type of risk associated with washing tomatoes does not apply to activities such as sorting and culling tomatoes.

The decision before FDA was in part to determine the need for preventive controls required by section 418 of the FD&C Act for small and very small farm mixed-type facilities. Therefore, in this RA we assessed whether the types of controls that would be required by section 418 of the FD&C Act are needed to ensure the safety of the food manufactured, processed, packed or held by small or very small farm mixed-type facilities in light of the regulatory framework that would apply to such facilities that would become exempt from, or subject to modified requirements for, the requirements for hazard analysis and risk-based preventive controls that would be established under section 418 of the FD&C Act. Examples of the types of controls that facilities may implement under section 418 include process controls (where a process is used to significantly minimize or prevent a hazard), sanitation controls, and food allergen controls. The regulatory framework that would apply to small or very small farm mixed-type facilities includes the current good manufacturing practice (CGMP) requirements in 21 CFR part 110 for manufacturing, packing, or holding human food and the adulteration provisions of section 402 of the FD&C Act. Any classification of an activity/food combination as "low risk" should not be interpreted to suggest that facilities engaged in these activities do not have an obligation to ensure the safety of the food they manufacture, process, pack, or hold and to comply with requirements of the FD&C Act and its implementing regulations, including CGMP requirements.

C. Food Types That Are Out of Scope of the Qualitative Risk Assessment

The following foods are not within the scope of this RA:

- Cut fruits and vegetables;

- Eggs;
- Game meat; and
- Milk and milk products (e.g., butter, cheese, cream, and ice cream mixes).

All of these food types require one or more preventive controls (e.g., heat treatment, time/temperature control for safety) to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death. (For additional discussion regarding foods that require time/temperature control for safety, see FDA's Food Code (FDA, 2009a).) Additionally, we considered that when a food requires refrigeration to control pathogens (Institute of Food Technologists, 2001b; FDA, 2009d; FDA, 2009b; FDA, 2009e; FDA, 2009c), temperature control is necessary at all steps, and therefore no activity involving such food would be low risk. Thus, activities involving cut produce, milk and a number of milk products, game meat, and eggs could not be considered low-risk activity/food combinations, and we eliminated these foods and on-farm activities that applied solely to them (e.g., churning, curing, eviscerating) from further consideration.

In addition, based on the statutory framework of FSMA described in general in section I.A of this document (and described in more detail in Appendix 1), activities solely related to the production of seafood, juice, dietary supplements, and alcoholic beverages are outside the scope of this RA and activities related to low-acid canned foods are within the scope of the RA only with respect to chemical, physical, and radiological hazards.

D. Specific Questions to be Addressed in the RA

Question 1: What are the foods that would be manufactured, processed, packed or held by a farm mixed-type facility?

Question 2: What are the activities that might be conducted by farm mixed-type facilities on those foods?

Question 3: What are the hazards reasonably likely to occur in those foods?

Question 4: For the purpose of determining whether an activity/food combination is low risk, which hazards should be considered to have a reasonable probability of causing serious adverse health consequences or death?

Question 5: For the purpose of determining whether an activity/food combination is low risk, what foods have inherent controls that significantly minimize or prevent a biological hazard that is reasonably likely to occur in these foods and that is reasonably likely to cause serious adverse health consequences or death?

Question 6: What interventions significantly minimize or prevent a hazard that is reasonably likely to occur in these foods and that is reasonably likely to cause serious adverse health consequences or death?

Question 7: Which of these activities are reasonably likely to introduce, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death and what are these hazards?

Question 8: Which of these activities are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death from consumption of these foods?

Question 9. Which activity/food combinations are low risk?

E. Definitions of Low-Risk Activity and Low-Risk Activity/Food Combination

For the purpose of the analysis required by section 103(c)(1)(C) of FSMA, we are defining "low-risk activity" and "low-risk activity/food combinations" as follows:.

- We are defining "low-risk activity" to mean an activity that:
    1. Is performed on, or during production of, a food that has inherent controls for foodborne pathogens, provided that the food does not require preventive controls to significantly minimize or prevent other types of hazards (e.g., a chemical hazard such as mycotoxins); or
    2. Satisfies both of the following criteria:
        a) Is not reasonably likely to introduce (or increase the potential for) a hazard for which there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans (a SAHCOD hazard); and
        b) Does not significantly minimize or prevent a SAHCOD hazard.
- We are defining "low-risk activity/food combination" to mean a low-risk activity that applies to a specific food.

For the purpose of this analysis, we:

- Refer to the above three parts of the definition of "low-risk activity" as:
    - #1 (inherent controls);
    - #2a (activity not likely to introduce, or increase the potential for, a SAHCOD hazard; and
    - #2b (activity does not significantly minimize or prevent a SAHCOD hazard).
- Use the term "inherent controls" to mean that in making the food the hazard is controlled, and it is highly unlikely that the food will be made in a way that the hazard is not adequately addressed.
- Use the phrase "reasonably likely to cause serious adverse health consequences or death" to mean that there is a reasonable probability that use of, or exposure to, a food containing a hazard will cause serious adverse health consequences or death to humans. It is important to note that our conclusions in this document with respect to whether there is a reasonable probability that use of, or exposure to, a food containing a hazard will cause serious adverse health consequences or death to humans are limited to the purposes of this document. In this document, we are

considering such hazards and foods in general terms, on a forward-looking basis, and not in reference to a particular food contamination incident or foodborne illness outbreak. Determinations of whether there is such a reasonable probability in specific situations may be different from the conclusions made for the limited purposes of this document.

Importantly, under the definition of low-risk activity food combination, to be low risk the activity/food combination must either:

- Satisfy part #1; or
- Satisfy both part #2a and part #2b.

F. Data Limitations

There are many limitations to the data used in this analysis.

- We have limited data on the types of activity/food combinations associated with small and very small farm mixed-type facilities, especially for foreign facilities.
- We lack data on the frequency and levels of contamination of the food and occurrences of serious adverse health consequences or death from hazards associated with manufacturing, processing, packing or holding activities conducted on foods by small and very small farm mixed-type facilities. Thus, we relied in large part on our existing understanding of hazards (such as pathogens associated with food types) and processes in order to characterize risk.
- The CDC data on biological and chemical hazards associated with foodborne illness is not limited to foods that are in the scope of this RA, nor are the data limited to reports of serious adverse health consequences or death.
- CDC illness data have limitations in that most cases of foodborne illness are sporadic and go unreported; many outbreaks go undetected; and the vehicle for a foodborne illness outbreak is often not identified.
- Data on serious adverse health consequences or death from physical, chemical and radiological hazards associated with manufacturing, processing, packing or holding of food are limited, and there are no data of this kind associated specifically with manufacturing, processing, packing or holding activities conducted on foods by small and very small farm mixed-type facilities.
- We lack data to conduct a dose-response assessment for hazard characterization for foods that may be manufactured, processed, packed or held by small and very small farm mixed-type facilities, especially for foreign facilities.
- We lack data on the amount of food consumed per serving and the number of servings consumed annually for the food categories produced by small or very small farm mixed-type facilities within the scope of the RA, which is a limitation in conducting an exposure assessment.

The lack of evidence associating occurrences of serious adverse health consequences or death with biological, chemical, physical and radiological hazards associated with manufacturing, processing, packing or holding activities conducted on foods by small and very small farm mixed-type facilities, along with the other data limitations noted above, are significant limitations of this RA.

II. SCOPE

A. Activity/food Combinations within the Scope of the RA

The scope of the RA is limited to an assessment of the risk of serious adverse health consequences or death from hazards associated with manufacturing, processing, packing or holding activities conducted on foods by small and very small farm mixed-type facilities, including both domestic and foreign facilities, to determine which activity/food combinations conducted by such facilities are low risk.

The activity/food combinations considered within the scope of this RA are those that we identified as likely to be conducted by farm mixed-type facilities by soliciting input from food safety and processing experts and economists within the Center for Food Safety and Applied Nutrition (FDA Memorandum, 2012d; FDA Memorandum, 2002); by requesting information from outside experts (FDA Memorandum, 2011a; FDA Memorandum, 2012b); by conducting an Internet search on state requirements for on-farm marketing (farm-direct sales), farm stands and farmers' markets (Washington State Department of Agriculture, 2010; University of California Small Farm Program, 2005; Best, 2009; Oregon Department of Agriculture, 2009; Connecticut Department of Agriculture, 2009; Connecticut Department of Agriculture, 2008; Connecticut Department of Agriculture, 2011; Leff, 2009; Massachusetts Department of Public Health, 2005; New York Department of Agriculture & Markets Agricultural Districts, 2010); and by considering information from a Food Processing Sector Study on domestic establishments co-located on farms (Muth et al., 2011). We did not have data on activity/food combinations likely to be conducted by foreign farm mixed-type facilities, which may include activity/food combinations not considered here. FDA is seeking comment on other activity/food combinations that should be considered.

If an expert or a reference identified an activity/food combination that is outside the scope of this RA (i.e., for activities conducted on cut produce, eggs, game meat, milk and milk products, seafood, juice, dietary supplements, or alcoholic beverages), we did not include that activity/food combination in the list. We also did not include activity/food combinations (e.g., manufacturing pet food) that are solely related to food for animals or activity/food combinations (e.g., applying pesticides prior to harvest) that are always within the farm definition. (See Table 21 in Appendix 1 for a summary and examples of how activities would be classified as inside or outside the farm definition under the rulemaking required by section 103(c) of FSMA.)

Table 1 lists the resulting activity/food combinations that we identified as likely to be conducted by farm mixed-type facilities. Table 1 includes activities that would not be within the farm definition when done on others' RACs even though they would be within the farm definition when they are done on a farm's own RACs (e.g., washing fruits and vegetables). Table 1 also includes activities that may encompass multiple steps (e.g., making jams, jellies and preserves may involve steps such as peeling and cutting, mashing, boiling, concentrating, and canning) and groups these steps to better identify the end product. Table 1 does not include activity/food combinations that are always within the farm definition (e.g., growing fruits and vegetables).

Table 1: Manufacturing, Processing, Packing and Holding Activity/Food Combinations That May Be Conducted by Farm Mixed-type Facilities on Foods for Human Consumption, Excluding Those Always Within the Farm Definition*

Activity	Food
Acidification/Pickling/Fermenting	Fruits, vegetables, coffee beans, cocoa beans
Artificial Ripening	Fruits, vegetables
Baking	Grain products
Boiling	Fruits, vegetables, peanuts, maple sap
Canning/bottling/jarring (packaging that involves processing, e.g., water bath canning, pressure canning)	Fruits, vegetables
Coating	Fruits, vegetables, peanuts, tree nuts
Concentrating /evaporating	Maple sap
Cooking	Fruits, vegetables
Cooling-Air (includes refrigerating)	Fruits, vegetables
Cooling-Water	Fruits, vegetables
Cutting/Coring/Chopping/Shredding/ Slicing/Peeling/Trimming	Fruits, vegetables, peanuts, tree nuts
Dehydration/ Drying	Fruits, vegetables, grains, grain products, tree nuts, peanuts, cocoa beans, coffee beans
Extraction	Honey, grains
Filtration	Honey, maple sap
Grinding/Milling/Cracking/Crushing	Grains, peanuts, tree nuts, cocoa beans, coffee beans
Labeling (including stickering)	Fruits, vegetables, grains and grain products, peanuts, tree nuts, honey, maple syrup, coffee beans, cocoa beans, cocoa products, sugarcane, sugar beets, sugar, jams, jellies and preserves, soft drinks and carbonated water; hard candy, fudge, taffy, toffee
Making hard candy, fudge, taffy, toffee	Sugar
Making cocoa products from roasted cocoa beans	Cocoa beans
Making jams/jellies/preserves from acid foods	Fruits, vegetables (e.g., rhubarb)
Making jams/jellies/preserves from low-acid foods	Fruits, vegetables
Making soft drinks and carbonated water	Water
Making sugar	Sugarcane, sugar beets
Mixing/Blending	Fruits, vegetables, grains and grain products, tree nuts, peanuts, honey, maple sap and maple syrup, cocoa beans, coffee beans
Packaging other than modified atmosphere or vacuum packaging	Fruits, vegetables, grains and grain products, tree nuts, peanuts, honey, maple syrup, coffee beans, cocoa beans, cocoa products, jams, jellies and preserves, hard candy, fudge, taffy, toffee, soft drinks and carbonated water, sugarcane, sugar beets, sugar
Packaging, Modified Atmosphere or Vacuum	Fruits, vegetables, peanuts, tree nuts
Packing/Re-Packing (including conveying	Fruits, vegetables, grains and grain products,

Activity	Food
and weighing incidental to packing/re-packing)	peanuts, tree nuts, honey, maple syrup, sugarcane, sugar beets, sugar, cocoa beans, coffee beans, jams, jellies and preserves, soft drinks and carbonated water, hard candy, fudge, taffy, toffee, and cocoa products
Roasting	Tree nuts, peanuts, coffee beans, cocoa beans
Salting	Tree nuts, peanuts
Sifting	Grains and grain products
Shelling/hulling/winnowing	Fruits, vegetables, tree nuts, peanuts, cocoa beans
Sorting, Culling & Grading	Fruits, vegetables, grains and grain products, peanuts, tree nuts, honey, maple syrup, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, soft drinks and carbonated water, sugarcane, sugar beets, sugar, jams, jellies, and preserves
Storing (Cold, ambient or controlled atmosphere)	Fruits, vegetables, grains and grain products, peanuts, tree nuts, honey, maple syrup, sugarcane, sugar beets, sugar, cocoa beans, coffee beans, jams, jellies and preserves, soft drinks and carbonated water, hard candy, fudge, taffy, toffee, cocoa products
Sulfiting	Fruits, vegetables
Treating against pests, e.g., fumigation	Fruits, vegetables, grain and grain products, peanuts and tree nuts, cocoa beans, coffee beans
Washing/Rinsing	Fruits, vegetables
Waxing	Fruits, vegetables

*Some activities in the Table are within the farm definition when performed on a farm mixed-type facility's own RACs (see Table 21 in Appendix 1).

FDA believes that Table 1 includes most of the activity/food combinations (except for those always within the farm definition) that are conducted by farm mixed-type facilities on foods that are within the scope of the RA. However, based on the Food Processing Sector Study, we acknowledge that Table 1 may not include all such activity/food combinations. For example, the Food Processing Sector Study classifies 175 small and very small facilities co-located on farms that produce "Food Preparations, Not Elsewhere Classified" (Muth et al., 2011). The SIC code (Standard Industrial Classification code from Dun & Bradstreet) for this category lists more than a dozen foods for which we are unable to determine the specific foods produced by the small and very small facilities co-located on farms. Thus, Table 1 may not include activity/food combinations for these facilities.

In addition, Table 1 does not include certain activity/food combinations identified in the Food Processing Sector Study as being conducted at an establishment co-located on a farm because the raw materials or ingredients, the specific steps involved, or the actual product made on-farm are unknown, e.g., making industrial organic chemicals (one establishment), making flavoring extracts/syrups (3 establishments), making animal and marine fats and oils (two establishments), making frozen specialties not elsewhere classified (e.g., meals and pizzas, five establishments).

The list of activity/food combinations likely to be conducted at farm mixed-type facilities contains the food categories that would be within the scope of the RA (see the second column in Table 1). We grouped these food categories as follows:

- Cocoa beans and cocoa products;
- Coffee beans;
- Grains as described immediately below (e.g., corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, soybeans, oilseeds);
- Grain products (e.g., flour, bran, breads, pasta);
- Hard candy, fudge, taffy, toffee;
- Honey;
- Intact fruits and vegetables (as described immediately below). Note that, for the purpose of this analysis, we separately consider several foods (i.e., coffee beans, cocoa beans, peanuts, sugarcane, sugar beets, and tree nuts) that are within the category of fruits and vegetables to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods;
- Maple sap (for making maple syrup) and maple syrup;
- Peanuts;
- Soft drinks and carbonated water;
- Sugarcane, sugar beets and sugar; and
- Tree nuts (e.g., almonds, walnuts);

For the purpose of this document, a fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. For the purpose of this document, a vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Examples of fruits and vegetables are apples, apricots, avocados, bananas, berries, broccoli, cabbage, cantaloupe, carrots, cauliflower, celery, cherries, citrus, cucumbers, garlic, grapes, green beans, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, mushrooms, onions, papaya, peaches, pears, peas, peppers, pineapple, plums, radish, scallions, snow peas, spinach, sprouts, squash, tomatoes, and watermelon..

For the purposes of this document, grains means the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.

III. HAZARD IDENTIFICATION

The purpose of the Hazard Identification step of a food safety risk assessment is to identify the hazards of concern. The scope of this RA requires consideration of the broad range of biological, chemical (including allergens, drug residues, and unapproved food and color additives), physical, and radiological hazards that are relevant to a farm mixed-type facility under section 418 of the FD&C Act. Whether or not a hazard can cause adverse health effects in an individual depends on the host, the agent and the environment. For our purposes, we are interested in identifying (based on sources such as illness data, the scientific literature, and the Reportable Food Registry), the hazards that are reasonably likely to cause adverse effects. To identify the hazards of concern, we initially considered surveillance information, available from CDC, on biological and chemical hazards associated with foodborne illness, even though this surveillance information covers a broader range of foods than those that are in the scope of this RA and is not limited to reports of serious adverse health consequences (i.e., serious illness) or death. For example, the CDC surveillance information includes reports of foodborne illness:

- From consumption of eggs, milk products, and seafood, which are outside the scope of this RA;
- Associated with pathogens (such as norovirus) that have low rates of causing hospitalization or death (see the discussion of norovirus in the Hazard Characterization section of this RA);
- Associated with biological hazards likely to have been introduced at retail or food service operations rather than through manufacturing, processing, packing or holding food prior to retail or foodservice operations.

The vast majority of hazards identified in the CDC surveillance information that are reasonably likely to cause serious adverse health consequences or death from foods, including foods that are manufactured, processed, packed or held on a farm mixed-type facility, are biological hazards - i.e., foodborne pathogens and their toxins (CDC, 2011c; Muth et al., 2011) (see Table 2). During the period 2003-2007, chemical hazards (such as natural toxins (e.g., mycotoxins) accounted for only approximately two percent of mean annual illnesses (CDC, 2011c), and more than two-thirds of these chemical-related outbreaks were due to seafood toxins (e.g., scombrotoxin/histamine, ciguatoxin) that are outside the scope of this RA (because seafood is outside the scope of this RA).

Table 2. Surveillance Information, Foodborne Illness, 2003-2007 (CDC, 2011c)

Hazard	Mean Annual Outbreaks (No.)	Mean Annual Outbreaks (Percent)	Mean Annual Illnesses (No.)	Mean Annual Illnesses (Percent)	Comments
Biological: Bacterial pathogens	316	41	7623	40	Examples of bacterial foodborne pathogens include *L. monocytogenes*, *E. coli* O157:H7, *Salmonella* spp., and *C. botulinum*.

Biological: Viral pathogens	385	50	9233	51	Examples of viral foodborne pathogens include norovirus and hepatitis A virus.
Biological: Parasites	7	1	273	1	E.g., *Cryptosporidium*
Chemical (excluding allergens)	63	8	361	2	E.g., natural toxins such as mycotoxins.

Viral pathogens account for an estimated 5.5 million foodborne illnesses each year, with norovirus responsible for most foodborne illnesses on an annual basis (58 percent) (Scallan et al., 2011). Among the bacterial pathogens causing foodborne illnesses, the three most common are *Salmonella* spp. (11 percent), *Clostridium perfringens* (10 percent) and *Campylobacter* spp. (9 percent) (Scallan et al., 2011). Other bacterial pathogens causing relatively large numbers of illness include *Bacillus cereus*, *E. coli* O157:H7, non-O157 Shiga-toxin producing *E. coli*, *Shigella* spp., *Staphylococcus aureus*, and *Yersinia enterocolitica* (Scallan et al., 2011).

For the purpose of this RA, we selected several pathogens we consider representative of the food types identified as being manufactured, processed, packed or held by farm mixed-type facilities. We are not considering several of the foodborne pathogens commonly associated with foodborne illness because they are not representative of pathogens associated with the foods that are within the scope of the RA. The foodborne pathogens we are not considering further are *C. perfringens* (because it is largely associated with temperature abuse of prepared foods (FDA, 2012a)); *Campylobacter* spp. and *Yersinia enterocolitica* (because they are largely associated with animal products that are out of scope of this RA (FDA, 2012a)); and *Shigella* (because it is largely transmitted through fecally contaminated water and unsanitary handling by food handlers (FDA, 2012a) and because other biological hazards being considered (e.g., norovirus and hepatitis A virus) can be considered representative of this type of biological hazard).

The CDC surveillance information does not include reports of illness or injury due to consumption of food products contaminated with physical hazards. The CDC surveillance information also does not include reports of illness or injury due to consumption of food products contaminated with the subset of chemical hazards that are allergen hazards. For the purpose of this RA, we consider allergen hazards to be the major food allergens as defined in section 201(qq) of the FD&C Act.[1] To supplement the CDC surveillance information with information about the frequency of consumption of

[1] Section 403(w) of the FD&C Act establishes the circumstances under which food is considered misbranded if it is, or it contains an ingredient that bears or contains, a major food allergen. 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.

food contaminated with physical hazards or allergen hazards, we considered information about primary reports to the RFR regarding human food available from the Reportable Food Registry Annual Reports. Table 3 provides information obtained from September 8, 2009 through September 7, 2010 (Year 1) and Table 4 provides information September 8, 2010 through September 7, 2011 (Year 2) (FDA, 2011a; FDA, 2012b). To provide context relevant to the CDC surveillance information, Table 3 and Table 4 include summary information about all primary reports associated with multiple biological hazards in human food, even though the RFR Annual Reports separately report information regarding specific biological pathogens (e.g., *L. monocytogenes*, *Salmonella*). As with the CDC surveillance information, the information in Table 3 and Table 4 includes information about foods (e.g., eggs, milk products, and seafood) that are outside the scope of this RA. In contrast to the CDC surveillance information, the information in Table 3 and Table 4 is limited to reports of hazards that are reasonably likely to cause serious adverse health consequences or death.

Table 3. Primary RFR Reports for Human Food in Year 1 (FDA, 2011a) (FDA, 2012b)

Hazard	Number of Primary RFR Reports for Human Food	Percent of Primary RFR Reports for Human Food*
Biological (including *E. coli* O157:H7, *L. monocytogenes*, *Salmonella*)	112	56
Undeclared allergens	69	34
Undeclared sulfites	11	5.5
Physical	0	0
Total	**192**	

*Total number of primary RFR reports for human food = 201

Table 4. Primary RFR Reports for Human Food in Year 2 (FDA, 2012b)

Hazard	Number of Primary RFR Reports for Human Food	Percent of Primary RFR Reports for Human Food
Biological (including *E. coli* O157:H7, *L. monocytogenes*, *Salmonella*)	119	58
Undeclared allergens	75	36
Undeclared sulfites	3	1
Physical	2	1
Total	**199**	

*Total number of primary RFR reports for human food = 206

The information from the RFR Annual Reports for Years 1 and 2 regarding reports of allergen hazards in human food is consistent with FDA's analysis of Class I and Class II recalls during the periods 1999 through 2003 (FDA Memorandum, 2004) and 2008 through 2009 (FDA Memorandum, 2012a). A Class I recall situation is one in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1). A Class II recall situation is one in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote (21 CFR 7.3(m)(2)). Undeclared allergens accounted for 34 percent of Class I and Class II recalls analyzed by FDA during the period 1999 through 2003 and for 42.9 percent of Class I and Class II recalls analyzed by FDA during the period 2008 through 2009. Of 174 recalls for allergens in 2008-2009, 120 (69%) involved recall of foods classified as Class I (reasonable probability of serious adverse health consequences or death). Undeclared sulfites accounted for 8.4 percent of Class I and Class II recalls analyzed by FDA during the period 2008 through 2009; 82 percent of the 34 recalls for sulfites were classified as Class I. (The analysis of recalls from 1999-2003 did not break out recalls that were due to undeclared sulfites.)

Physical hazards infrequently are the cause of Class I and Class II recalls, which is consistent with the information from the RFR Annual Reports from Years 1 and 2 regarding reports of physical hazards in human food. Foreign objects, which include physical hazards, accounted for only 3 percent of Class I and Class II recalls analyzed by FDA during the period 1999 through 2003 and 3.2 % of those during 2008-2009 (FDA Memorandum, 2004; FDA Memorandum, 2012a). None of the recalls for physical hazards in 2008-2009 were Class I (FDA Memorandum, 2012a)

The CDC surveillance information and the RFR Annual Reports do not include reports of illness or injury due to consumption of food products contaminated with radiological hazards. The most common way these radionuclides are incorporated into foods is through use of water that contains a radionuclide to manufacture a food. For example, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium have been detected in private wells (Ayotte et al., 2007; Focazio et al., 2001). We are not aware of any reports of illness from the consumption of food contaminated with radiological hazards in the last 10 years.

Table 5 provides information about the association of biological and chemical hazards (including allergen hazards) that are the subject of reports of illness or injury to CDC or FDA's RFR with the food categories that we identified in section II.B of this document as likely to be manufactured, processed, packed or held on a farm mixed-type facility. The biological and chemical hazards identified in Table 5 as associated with specific food categories are representative of the types of biological and chemical hazards that could be associated with the manufacturing, processing, packing, or holding of food by a farm mixed-type facility. Table 5 is not intended to be exhaustive; extensive information on the association of biological and chemical hazards with specific food categories is available in textbooks and other scientific literature that are widely available. We provide information about the severity of each of the hazards identified in Table 5 in the Hazard Characterization section of this document.

Table 5 does not include physical hazards, which could be a contaminant in virtually any food category. Table 5 also does not include radiological hazards because they are too rare in food to be considered associated with any food category other than water.

Table 5. Potential Biological and Chemical Hazards That Are Reasonably Likely to Be Associated with the Food Categories Manufactured, Processed, Packed or Held on a Farm Mixed-Type Facility

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
Fruits and vegetables	Bacterial pathogens (e.g., *C. botulinum*, *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*), Viruses (e.g., norovirus and hepatitis A virus) Parasites (e.g., *Cryptosporidium*)	Sulfites Pesticide residues	Institute of Food Technologists, 2001a; Timbo et al., 2004; FDA, 2010
Honey	N/A*	N/A	Honey has not been associated with illnesses from foodborne pathogens (other than infant botulism from *C. botulinum* spores (FDA, 2012a), which can only be addressed by not feeding honey to infants). Although pathogenic sporeforming bacteria may be present, the water activity of honey is such that they cannot grow and thus the production of toxin from *C. botulinum* is not a concern (International Commission on Microbiological Specifications for Foods, 2005e). We have taken action against imported honey containing residues of the antibiotic chloramphenicol but we are not aware of adverse reactions from such products.
Maple sap and syrup	N/A	N/A	Maple syrup has not been associated with illnesses from foodborne pathogens. Maple sap must be extensively boiled (evaporated) to produce maple syrup. This boiling, combined with the reduced water activity of 0.83-0.86, acts as an inherent control for foodborne pathogens (International Commission on Microbiological Specifications

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
			for Foods, 2005e).
Peanuts and peanut-containing products (such as peanut butter)	Bacterial pathogens (e.g., *Salmonella*)	Food allergen Mycotoxins (e.g., aflatoxin)	(International Commission on Microbiological Specifications for Foods, 2005c; Taylor and Hefle, 2001) Outbreaks of salmonellosis in the United States have been attributed to the consumption of peanut butter or peanut-containing products (CDC, 2011a; CDC, 2009; Cavallaro et al., 2011)
Tree nuts and tree nut-containing products (such as nut butters)	Bacterial pathogens (e.g., *Salmonella* and *E. coli* O157:H7)	Food allergen Mycotoxins (e.g., aflatoxin)	(International Commission on Microbiological Specifications for Foods, 2005c) Outbreaks of salmonellosis have been attributed to almonds (CDC, 2004; Isaacs et al., 2005) and a recent outbreak of foodborne illness caused by *E. coli* O157:H7 was attributed to hazelnuts (CDC, 2011b; Taylor and Hefle, 2001)
Grains	Bacterial pathogens (e.g., *Salmonella* spp., and sporeforming bacteria such as *B. cereus*)	Food allergen, Gluten associated with celiac disease) Mycotoxins (e.g., aflatoxin and deoxynivalenol)	International Commission on Microbiological Specifications for Foods, 2005a; Taylor and Hefle, 2001; FDA, 2011b
Oilseeds (as a subsidiary of grains)	Bacterial pathogens (e.g., *Salmonella* spp.)	Mycotoxins (e.g., aflatoxin)	(Andrews et al., 1979; International Commission on Microbiological Specifications for Foods, 2005c) The process of extracting and refining oil from oilseeds effectively removes bacterial pathogens and aflatoxin from the products consumed by humans and acts as an inherent control (International Commission on Microbiological Specifications for Foods, 2005c).
Grain products (e.g. breads, pastries, pies, cookies, crackers,	Bacterial pathogens (e.g., *Salmonella* spp., and sporeforming bacteria such as *B. cereus*	Food allergen, Gluten (associated with celiac disease), Mycotoxins (e.g., aflatoxin and	International Commission on Microbiological Specifications for Foods, 2005a; Taylor and Hefle, 2001; FDA, 2011b

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
pastas, noodles)		deoxynivalenol)	
Soft drinks and carbonated water	Foodborne pathogens that could be present in water not subject to EPA's National Primary Drinking Water Requirements in 40 CFR 141	N/A	International Commission on Microbiological Specifications for Foods, 2005d
Sugarcane, sugar beets and sugar	Bacterial pathogens (e.g., *Salmonella*)	N/A	As with many RACs, sugarcane and sugar beets may be susceptible to contamination with enteric pathogens. However, no significant foodborne pathogens are associated with the sugar made from sugarcane and sugar beets (International Commission on Microbiological Specifications for Foods, 2005e).
Cocoa beans and cocoa products (e.g., chocolate, cocoa powder and cocoa butter)	Bacterial pathogens (e.g. *Salmonella*)	Allergens	(International Commission on Microbiological Specifications for Foods, 2005b). Cocoa beans are susceptible to contamination with *Salmonella* and several outbreaks of salmonellosis have been attributed to cocoa powder and chocolate (International Commission on Microbiological Specifications for Foods, 2005b; Scott et al., 2009). Milk chocolate contains the allergen milk.
Coffee beans	Bacterial pathogens (e.g., *Salmonella*)	Mycotoxins (e.g. Ochratoxin A)	International Commission on Microbiological Specifications for Foods, 2005c; Bayman and Baker, 2006
Jams, jellies and preserves	Bacterial pathogens (e.g., *C. botulinum*, *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*), Viruses (e.g., norovirus and hepatitis A virus) Parasites (e.g., *Cryptosporidium*)	Pesticides	The hazards are those associated with the raw materials (fruits and vegetables). However, shelf-stable jams, jellies and preserves made from acid foods have inherent controls against biological hazards due to a combination of the boiling required to produce them, the low pH, and the reduced water activity (International

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
			Commission on Microbiological Specifications for Foods, 2011). This is not the case when made with low-acid fruits or vegetables, as spores of *C. botulinum* can survive and must be controlled.
Hard candy, fudge, taffy, toffee	Bacterial pathogens (e.g., *Salmonella*)	Allergens	Salmonellosis has been associated with contaminated candy, but not the ones specified here (International Commission on Microbiological Specifications for Foods, 2005b). The boiling required to make these products provides inherent control against biological hazards. Fudge, taffy and toffee usually contain the allergen milk (from butter). In addition, fudge often contains peanuts or tree nuts.

N/A = Not Applicable

We did not identify drug residues or decomposition products as potential chemical hazards reasonably likely to occur in any of the foods within the scope of this RA. Drug residues and decomposition products would have a greater probability of being in foods of animal origin.

Sulfites, which are a chemical hazard when not declared on a food label, are a food ingredient added as a substance that is generally recognized as safe (GRAS) under specified conditions of use (21 CFR 182.3798; Sodium sulfite); that regulation excludes the use of sodium sulfite in certain foods. The uses of sulfites that are GRAS are not subject to the premarket review and approval requirements that apply to food additives.

We did not identify any specific unapproved food or color additives reasonably likely to be a chemical hazard in any of the foods within the scope of this RA. A hypothetical discussion of the potential association of all possible food and color additives associated with each of the food categories that are within the scope of this RA is beyond the scope of this RA.

IV. HAZARD CHARACTERIZATION

The Hazard Characterization step describes the nature, severity, and duration of adverse effects that may result from ingestion of the hazard applicable to a food category. These will depend on the host, the agent and the environment, and there is generally a range of adverse effects (i.e., there is a high degree of variability) that occurs in a population ingesting a contaminated food.

A. Biological Hazards

In the Hazard Identification section of this RA, we identified six bacterial foodborne pathogens (i.e., *B. cereus*, *C. botulinum*, *E. coli* O157, *L. monocytogenes*, *Salmonella*, and *S. aureus*), two viral foodborne pathogens (i.e., norovirus and hepatitis A virus), and one parasite (i.e., *Cryptosporidium*) as representative of the biological (microbial) hazards of concern for food categories that are likely to be manufactured, processed, packed or held on a farm mixed-type facility and within the scope of this RA. Adverse effects associated with biological hazards occur as a result of consumption of a contaminated food during a single eating occasion. A common measure of the frequency of a hazard is the number of reported illnesses. Two common measures of the severity of illness are the rates of hospitalization and death. Table 6 presents information about the number of illnesses and the number and rate of hospitalizations and deaths associated with these foodborne pathogens. Whereas information about the number of hospitalizations and deaths demonstrates the frequency of serious foodborne illness associated with these foodborne pathogens, the rates of hospitalization and death present a more accurate reflection of the severity of the foodborne illnesses. For example, although Table 6 demonstrates a large number of illnesses, hospitalizations, and deaths from norovirus, Table 6 also demonstrates that norovirus has the lowest hospitalization rate and has one of the lowest death rates. Thus, the relatively large numbers of hospitalizations and death associated with norovirus reflect the frequency, rather than the severity, of the illness.

Table 6. Numbers of Illness and Numbers and Rates of Hospitalization and Death for Representative Foodborne Pathogens Identified in the Hazard Identification (Scallan et al., 2011)

Pathogen	Mean Number of Annual Episodes of Foodborne Illness*	Mean Number of Annual Hospitalizations	Hospitalization Rate (%)**	Mean Number of Annual Deaths**	Death Rate (%)**
B. cereus	63,400	20	0.4	0	0
C. botulinum	55	42	82.6	9	17.3
Cryptosporidium	57,616	210	25	4	0.3
E. coli O157	63,153	2,138	46.2	20	0.5
Hepatitis A Virus	1,566	99	31.5	7	2.4
L. monocytogenes	1,591	1,455	94	255	15.9
Norovirus	5,461,731	14,663	0.03	149	<0.1

Pathogen	Mean Number of Annual Episodes of Foodborne Illness*	Mean Number of Annual Hospitalizations	Hospitalization Rate (%)**	Mean Number of Annual Deaths**	Death Rate (%)**
Salmonella (non-typhoidal)	1,027,561	19,336	27.2	378	0.5
S. aureus	241,148	1,064	6.4	6	<0.1

* Based on laboratory surveillance adjusted for underreporting and underdiagnosis. For additional information, see the 2011 report by Scallan et al., 2011.
** Based on unadjusted laboratory-confirmed illnesses. For additional information about this calculation, see the 2011 report by Scallan et al., 2011.

In the paragraphs that follow, we briefly characterize the nature, severity and duration of the adverse effects associated with the representative biological (microbial) hazards of concern for the food categories that are likely to be manufactured, processed, packed or held on a farm mixed-type facility and within the scope of this RA.

Bacillus cereus is a sporeforming aerobic bacterium that causes two types of illness, a diarrheal illness due to an enterotoxin produced in the intestine when large numbers of toxigenic *B. cereus* are ingested and an emetic (vomiting) illness due to an emetic toxin produced in food (FDA, 2012a). Symptoms of the diarrheal type of foodborne illness include watery diarrhea, abdominal cramps, and pain within 6-15 hours after consumption of contaminated food and mimic those of *C. perfringens* foodborne illness. Nausea may accompany diarrhea, but vomiting rarely accompanies the diarrheal type of illness. Symptoms of the diarrheal type of foodborne illness generally persist for no more than 24 hours. Symptoms of the emetic type of foodborne illness include nausea and vomiting within 0.5 to 6 h after consumption of contaminated foods and mimic those caused by *S. aureus* foodborne intoxication. Occasionally, abdominal cramps and/or diarrhea may also occur. Symptoms of the emetic type of food poisoning generally persist for no more than 24 hours. Both types of illness are associated with relatively large numbers of *B. cereus* in a food (greater than a million organisms per gram of food). On rare occasions, *B. cereus* has caused severe systemic infections, septic meningitis, and death (FDA, 2012a; Granum, 2007).

Clostridium botulinum is a sporeforming anaerobic bacterium that causes botulism, a rare but serious paralytic illness caused by a nerve toxin that is produced by the bacterium (CDC, 2010). Symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness, which, if untreated, may progress to paralysis of the respiratory muscles, arms, legs, and trunk. Death due to respiratory failure can occur. A patient with severe botulism may require a breathing machine as well as intensive medical and nursing care for several months, and some patients die from infections or other problems related to remaining paralyzed for weeks or months. Patients who survive an episode of botulism intoxication may have fatigue and shortness of breath for years and long-term therapy may be needed to aid recovery.

Cryptosporidium is a protozoan parasite that causes an intestinal disease (cryptosporidiosis) that is self-limiting in most healthy individuals (i.e., symptoms resolve without medical intervention) (FDA, 2012a; Ortega, 2007). The principal symptom of cryptosporidiosis in most people is profuse watery diarrhea (FDA, 2012a; Ortega, 2007). Symptoms generally persist for 2-4 days, although in some outbreaks at day care centers diarrhea has lasted 1 to 4 weeks. Individuals who have a deficient immune system, especially AIDS patients, develop severe, watery, cholera-like diarrhea that can persist for years, contributing to death (FDA, 2012a; Ortega, 2007). Invasion of the pulmonary system may also be fatal (FDA, 2012a). Hospitalization rates are high for those ill enough to see a doctor and be tested (Scallan et al., 2011); 24 percent of hospitalizations for cryptosporidiosis involve immunocompromised patients and the average length of hospitalization is 6.5 days (Collier et al., 2012).

Escherichia coli O157:H7 is a bacterium that causes an intestinal illness (FDA, 2012a). The infectious dose is low (fewer than 100 cells) (Meng et al., 2007). Symptoms include severe cramping (abdominal pain) and diarrhea, which often becomes bloody (hemorrhagic colitis) after 1 to 2 days (Meng et al., 2007). Occasionally vomiting occurs. The illness is usually self-limiting and lasts for an average of 8 days. Some hemorrhagic colitis victims, particularly the very young (up to 15 percent in children under 10), develop hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia (Meng et al., 2007). The disease can lead to permanent loss of kidney function and death (the case fatality rate is approximately 1 percent) (FDA, 2012a; Meng et al., 2007).

Infection with hepatitis A virus (HAV) may or may not result in clinical disease (FDA, 2012a), or it can take 15-50 days for symptoms to manifest themselves (Fiore, 2004). Symptoms of HAV infection include fever, malaise, nausea, vomiting, diarrhea, anorexia, and abdominal discomfort, followed in several days by jaundice (FDA, 2012a; Fiore, 2004). Many persons (particularly children) infected with HAV do not experience clinical disease or, if they do experience clinical disease, do not experience jaundice (FDA, 2012a; Fiore, 2004). When disease does occur, symptoms are usually mild and recovery is complete in 1-2 weeks. Occasionally, the symptoms are severe and convalescence can take several months. Patients who experience severe symptoms suffer from feeling chronically tired during convalescence, and their inability to work can cause financial loss. The illness can be fatal (estimated to be as high as 2.4 percent based on laboratory-confirmed cases of those who are sick enough to see a doctor and be tested) (Scallan et al., 2011). Deaths usually occur in the elderly and in persons with underlying chronic liver disease (Fiore, 2004). The infectious dose is unknown but has been assumed to be 10-100 virus particles. Persons who are exposed to HAV generally develop immunity to the virus, and vaccination against the virus has increased. Consequently, in the United States the percentage of adults with immunity increases with age (i.e., 10 percent of adults aged 18-19 years show signs of immunity whereas 65 percent of adults over 50 years show signs of immunity) (FDA, 2012a).

Listeria monocytogenes is a bacterium that can cause a mild non-invasive intestinal illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis). Most healthy persons who are infected *with L.*

monocytogenes either show no symptoms or experience the mild illness listerial gastroenteritis (FDA, 2012a). Symptoms of listerial gastroenteritis include diarrhea, fever and fatigue (Painter and Slutsker, 2007). Persons at higher risk for severe, invasive listeriosis include the elderly, individuals who have a deficient immune system, pregnant women, and fetuses and neonates who are infected after the mother is exposed to *L. monocytogenes* during pregnancy (Painter and Slutsker, 2007; FDA, 2012a. Symptoms and manifestations of invasive listeriosis include septicemia, meningitis, encephalitis, or intrauterine or cervical infections in pregnant women, which may result in spontaneous abortion or stillbirth (FDA, 2012a; Painter and Slutsker, 2007). Serious, invasive listeriosis is usually preceded by influenza-like symptoms (including persistent fever) or gastrointestinal symptoms such as nausea, vomiting, and diarrhea (Food and Agriculture Organization and World Health Organization, 2004b; Goulet et al., 2012). The infective dose of *L. monocytogenes* is unknown but is believed to vary with the strain and susceptibility of the victim (FDA, 2012a). In 2003, FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture, in consultation with CDC, released a quantitative assessment (the FDA/FSIS Lm RA) of relative risk associated with consumption of 23 categories of ready-to-eat (RTE) foods that had a history of contamination with *L. monocytogenes*, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis (FDA and USDA, 2003b). The FDA/FSIS Lm RA shows that the risk of illness from *L. monocytogenes* increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of *L. monocytogenes* than from those that do not (FDA and USDA, 2003a). A key finding of the 2004 FAO/WHO risk assessment on L. monocytogenes in RTE foods in 2004 was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (Food and Agriculture Organization and World Health Organization, 2004b). Refrigerated foods present a greater risk from *L. monocytogenes* because some refrigerated foods that support growth may be held for an extended period of time, thus increasing the risk if *L. monocytogenes* is present in a food. Growth of *L. monocytogenes* does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with *L. monocytogenes* is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from *L. monocytogenes* in that food increases.

Infection with norovirus causes an intestinal illness (FDA, 2012a). Symptoms usually include acute-onset vomiting, watery non-bloody diarrhea with abdominal cramps, and nausea. Low-grade fever also occasionally occurs, and diarrhea is more common than vomiting in children. Dehydration is the most common complication, especially among the young and elderly, and may require medical attention. Symptoms usually persist 24 to 72 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae (i.e., chronic conditions resulting from the illness) (CDC, 2012).

Salmonella is a bacterium that causes the illness salmonellosis (FDA, 2012a). Symptoms of salmonellosis include diarrhea, fever, abdominal cramps, headache, nausea, and vomiting (FDA, 2012a). Acute symptoms may persist for 1 to 2 days or may be prolonged, depending on host factors, ingested dose, and characteristics of the specific bacterial strain (FDA, 2012a). Most healthy people recover, but the infection can spread to the bloodstream, and then to other areas of the body, leading to severe and fatal illness,

which is more likely to occur in children, the elderly, and persons with weakened immune systems (FDA, 2012a). The infective dose can be as few as 15-20 cells, depending on age and health of the victim and strain differences among the members of the genus (FDA, 2012a). *S*. Typhi and *S*. Paratyphi A, B, and C produce typhoid and typhoid-like fever in humans, infecting various organs and leading to lesions. The fatality rate for most forms of salmonellosis is less than 1 percent, although it is usually higher for typhoid fever (FDA, 2012a). However, a number of strains can cause severe disease, e.g., the fatality rate of *S*. Dublin is 15 percent when septicemic in the elderly, and the fatality rate of *S*. Enteritidis is approximately a 3.6 percent in hospital/nursing home outbreaks, with the elderly being particularly affected (FDA, 2012a). Reactive arthritis may occur in about 2 percent of culture-confirmed cases (FDA, 2012a). Septic arthritis, subsequent to or coincident with septicemia, also occurs and can be difficult to treat (FDA, 2012a).

S. aureus is a bacterium that produces an enterotoxin causing an illness called staphylococcal food poisoning (FDA, 2012a). Symptoms include nausea, vomiting, retching, abdominal cramping, and prostration. In more severe cases, headache, muscle cramping, and transient changes in blood pressure and pulse rate may occur. Symptoms generally persist for two days; however, in severe cases symptoms may persist for three days or longer. Death from staphylococcal food poisoning is very rare, although such cases have occurred among the elderly, infants, and severely debilitated persons.

For additional information on pathogens, including a discussion of the diseases they cause, see FDA's Bad Bug Book (FDA, 2012a). In addition, a number of textbooks on foodborne pathogens have been published.

B. Chemical Hazards – Non-Allergic-type Reactions

The Hazard Identification section of this RA identified mycotoxins (e.g., aflatoxins, ochratoxin A, deoxynivalenol) as representative of the chemical hazards associated with food categories (e.g., grains, peanuts, tree nuts) that are likely to be manufactured, processed, packed or held on a farm mixed-type facility and within the scope of this RA. The adverse reactions due to mycotoxin hazards depend upon the type of mycotoxin and the amount to which a person is exposed, and may be acute or chronic. The effects of mycotoxins on humans are still not well understood, and much information on adverse effects is based on animal models. In the past, a number of outbreaks of human illness (including some with severe illnesses and death) associated with high levels of mycotoxins have been documented. Currently, in developed countries such as the United States and those of the European Union, significant investments in production, storage and drying facilities, coupled with the country's regulatory system, now result in low concentrations of mycotoxins in foods (Williams et al., 2004). Acute adverse effects of mycotoxins currently are more common in developing countries (Pestka and Smolinski, 2005; Williams et al., 2004). Adverse effects associated with chemical hazards such as mycotoxins tend to be the result of chronic exposure rather than manifesting as an acute illness (Williams et al., 2004).

Large doses of aflatoxin can result in acute illness and death, usually through liver cirrhosis; reports of serious illness and death usually originate in the zone of risk for

mycotoxin production (at latitudes between 40 degrees North and South of the equator) and occur infrequently (Williams et al., 2004). Adults usually have a high tolerance for aflatoxin, and some ingested aflatoxin is detoxified (Williams et al., 2004). Long-term, cumulative exposure to aflatoxin can result in liver cancer (Shephard, 2008; Williams et al., 2004). Ochratoxins, which have been identified in barley, wheat, rye, corn, rice and coffee, are classified as human carcinogens and have been associated with kidney effects in animals but have not been associated with acute illnesses (Bayman and Baker, 2006). In contrast, deoxynivalenol, associated with wheat, corn and barley, has been associated with acute gastroenteritis similar to staphylococcal food poisoning (vomiting, abdominal pain, diarrhea, headache, dizziness and fever), although not in the United States (Pestka and Smolinski, 2005). Although mycotoxins have been associated with a number of diseases, FAO has noted that in most instances conclusive evidence for the role of mycotoxins is lacking (Bhat and Miller, 1991).

C. Chemical Hazards – Allergic-type Reactions

The Hazard Identification section of this RA identified tree nuts, peanuts, and grains as allergen hazards of concern with respect to food categories that are likely to be manufactured, processed, packed or held on a farm mixed-type facility and within the scope of this RA. Food allergies affect two to three percent of adults and four to six percent of children (Sampson, 2004; Sampson, 2005; Sicherer and Sampson, 2010). Allergic reactions (immediate hypersensitivity reactions) can range from mild to severe and symptoms can involve the gastrointestinal tract (e.g., nausea, vomiting, diarrhea), skin (e.g., hives, eczema), or respiratory tract (e.g., asthma) (Taylor and Hefle, 2001). The most severe reaction is anaphylactic shock, which usually involves multiple systems, including the gastrointestinal tract, skin, respiratory tract and the cardiovascular system (Taylor and Hefle, 2001). Severe hypotension and death from cardiovascular and/or respiratory collapse can occur within minutes of ingestion of the allergen-containing food (Taylor and Hefle, 2001). The severity of a food allergic reaction varies depending on factors such as the amount of allergen ingested, the type of allergen, and the presence of other underlying medical conditions, but as high as one-third of sensitive individuals can experience severe reactions at the minimal eliciting dose of an allergen. Allergic reactions from food result in an estimated 125,000 emergency room visits in the United States each year (Ross et al., 2008), and as many as 100-150 deaths in the United States each year (Simon and Mulla, 2008; Yocum et al., 1999). For children under 18 years of age, CDC estimates that there are approximately 9,500 food allergy-related hospitalizations per year (Branum and Lukacs, 2009).

Allergic reactions due to peanuts (and peanut-containing products) and tree nuts (and tree nut-containing products) often cause severe, life-threatening allergic reactions in allergic individuals (Sicherer et al., 1998). Only a few people with food allergies are at risk for severe, life-threatening allergic reactions, but numerous deaths involving asthma and/or anaphylactic shock have been reported (Taylor and Hefle, 2001). Cereal grains such as wheat are not a frequent cause of allergic reactions in adults, but cereal allergy is frequent in children, and wheat is the most frequent cause of allergy among the cereal grains (European Food Safety Authority, 2004). Cereals elicit the typical immediate symptoms of allergic diseases such as atopic dermatitis (eczema), hives, swelling and anaphylaxis (European Food Safety Authority, 2004).

Celiac disease is a delayed hypersensitivity reaction that involves an abnormal immunological response by genetically predisposed individuals to gluten in certain grains (e.g., wheat, rye, barley) (Taylor and Hefle, 2001). An inflammatory response damages the small intestine and impairs the absorption of nutrients (72 FR 2795 at 2796) (Taylor and Hefle, 2001). The symptoms associated with celiac disease can be gastrointestinal (e.g., abdominal bloating, cramping and pain, chronic diarrhea, vomiting) or can involve other parts of the body (e.g., fatigue, bone or joint pain, skin rash, mouth ulcers) (72 FR 2795 at 2796). A large portion of the subpopulation with celiac disease may not have any symptoms (72 FR 2795 at 2796). The disease is also associated with a number of significant health problems, including iron-deficiency anemia, vitamin deficiencies, growth retardation, and infertility, and persons with celiac disease may be at increased risk of developing other serious medical conditions including cancers (72 FR 2795 at 2797). A more complete review of the health effects of celiac disease can be found in FDA's Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease (FDA, 2011b).

The Scope section of this RA identified sulfiting (i.e., adding sulfur dioxide, potassium metabisulfite, sodium metabisulfite, potassium bisulfite, sodium bisulfite or sodium sulfite to fruits and vegetables) as a manufacturing or processing activity that may be conducted by a farm mixed-type facility and Table 5 in the Hazard Identification section of this RA identified sulfites as a hazard that can be associated with fruits and vegetables (e.g., dried fruits). The adverse response to sulfites is not a true allergy, but the response is similar to that of some allergic reactions (i.e., asthma, hives, swelling within a short time after ingestion), so we discuss sulfites as a chemical hazard leading to allergic-type reactions (Timbo et al., 2004; Yang and Purchase, 1985). Although sulfite-induced asthma affects only a small percentage of asthmatics (1-1.5 percent), the reaction to sulfites may be quite severe, including death (Taylor and Hefle, 2001). Ingestion of 10 mg or more on a single occasion could potentially cause a serious adverse reaction in a susceptible person (Timbo et al., 2004).

Table 5 in the Hazard Identification section of this RA identified pesticide residues as a chemical hazard that can be associated with fruits and vegetables. Whether a 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 pesticide is ingested by a living animal before slaughter, how the product is metabolized in that animal. Pesticide residues that are present in food in the absence of or in excess of a tolerance established by the EPA are deemed by the FD&C Act to be unsafe (60 FR 65096 at 65119, Federal Register of December 18, 1995). Reports from FDA's pesticide monitoring program consistently demonstrate that levels of pesticide residues in the U.S. food supply are overwhelmingly in compliance with EPA's permitted pesticide uses and tolerances (FDA, 2010).

D. Physical Hazards

The scope of this RA requires consideration of physical hazards that are relevant to a farm mixed-type facility under section 418 of the FD&C Act. Table 5 in the Hazard Identification section of this document does not include physical hazards because they could be a contaminant in virtually any food category. Injuries associated with physical

hazards have been reviewed (Hyman et al., 1993; Olsen, 1998). They include laceration of the throat or mouth tissues, breaking or chipping teeth, and gastrointestinal perforations. Most ingested foreign objects (80-90 percent) pass through the gastrointestinal tract spontaneously, but some require removal by endoscopy or, less frequently, surgery (Olsen, 1998). An estimated 1-5 percent of foreign objects ingested by people result in minor to serious injury (Hyman et al., 1993; Olsen, 1998). In the first year of the RFR, there were 12 submissions involving foreign objects in foods, none of which were deemed reasonably likely to pose serious adverse health consequences or death, and in the second year there were 18 submissions, of which 2 were deemed reportable (i.e., two presented the risk of serious adverse health consequences or death - one with metal and one with glass) (FDA Memorandum, 2012c).

E. Radiological Hazards

The scope of this RA requires consideration of radiological hazards that are relevant to a farm mixed-type facility under section 418 of the FD&C Act. Table 5 in the Hazard Identification section of this document does not include radiological hazards because they are too rare in food to be considered associated with any food category other than water. The health effect from radiological hazards depends upon the type of radionuclide and the amount to which a person is exposed. Consuming food contaminated with radioactive material will increase the amount of radioactivity a person is exposed to and could increase the health risks (e.g., increased risk of cancer) associated with exposure to radiation (World Health Organization, 2011). For instance, exposure to certain levels of radioactive iodine is associated with increased risk of thyroid cancer (World Health Organization, 2011). However, contaminated food would have to be consumed over prolonged periods to represent a risk to human health (World Health Organization, 2011).

V. EXPOSURE ASSESSMENT

A. Approach

Exposure assessment for foodborne hazards includes an evaluation of the actual or anticipated human exposure to the hazards from consumption of contaminated foods. Factors that have a direct effect on consumer exposure to hazards include:

- Frequency and levels of contamination of the food; and
- Frequency of consumption of the food and the amount of food consumed.

For the purposes of this qualitative RA, we used CDC surveillance information on the frequency of occurrence of illness (see Table 2 and Table 6) as an overall indicator of exposure to biological hazards. We took this approach because the CDC surveillance information provides data on illnesses from the nine representative biological hazards relevant to this RA. An alternative approach would be to attempt to characterize (e.g., as high, medium, or low) the frequency and levels of contamination of each of the food categories addressed by the RA with each of these nine biological hazards, as well as to characterize (e.g., as high, medium, or low) the frequency of consumption of the food, and the amount of food consumed, for food manufactured, processed, packed, or held by farm mixed-type facilities. There are limitations to our approach of using CDC surveillance information on illness as an overall indicator of exposure to biological hazards - e.g., the illness data are not limited to the food categories addressed by this RA. However, these limitations do not outweigh the expediency of using this information in light of the difficulty in obtaining meaningful information on frequency and levels of contamination of the food categories with the representative biological hazards, as well as data on the frequency of consumption of the food, and the amount of food consumed, for food manufactured, processed, packed, or held by farm mixed-type facilities.

For the purposes of this qualitative RA, we used the frequency of occurrence, as reflected in reports to the RFR (see Table 3 and Table 4) and recall data (FDA Memorandum, 2004; FDA Memorandum, 2012a), as an overall indicator of exposure to allergen hazards, sulfite hazards, and physical hazards. We took this approach because most of the available data and information address the presence, but not the level, of allergen hazards, sulfite hazards, and physical hazards. For example, RFR reports and recall reports generally would provide some information about the level of sulfites in foods, because the level is needed to determine whether a food meets the definition of a reportable food and to classify a recall. However, RFR reports and recall reports generally do not provide information about the level of allergen hazards (because sensitive individuals may experience allergic reactions at doses as low as a few micrograms) or to physical hazards (because a single foreign object may cause injury). As with our approach to exposure to biological hazards, the approach of using frequency of occurrence as an overall indicator to exposure to allergen hazards, sulfite hazards, and physical hazards has limitations - e.g., the RFR reports and recall data are not limited to the food categories addressed by this RA. In addition, we did not attempt to include the frequency of consumption of foods contaminated with allergen hazards, sulfite hazards, or physical hazards, and the amount of food consumed, for food manufactured, processed, packed, or held by farm mixed-type facilities in light of the difficulty in

obtaining meaningful data on the frequency of consumption of the food, and the amount of food consumed, for food manufactured, processed, packed, or held by farm mixed-type facilities. However, these limitations do not outweigh the expediency of using this information in light of the difficulty in obtaining meaningful information on frequency and levels of contamination of the food categories with the allergen hazards, sulfite hazards, and physical hazards, as well as data on the frequency of consumption of the food, and the amount of food consumed, for food manufactured, processed, packed, or held by farm mixed-type facilities.

For the purpose of this RA, we considered exposure to mycotoxins and radiological hazards to be low. We discuss our reasons in section V.C of this RA.

For the purpose of this RA, the factors that are relevant to likelihood that hazards would contaminate the food when consumed include:

- Potential for growth of biological hazards in the food;
- Inherent controls for biological hazards (e.g., low water activity preventing growth);
- Interventions (e.g., preventive control measures applied to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death (e.g., cooking); and
- Activities that can introduce hazards into food (e.g., cutting fresh fruits and vegetables).

B. Factors That Impact the Frequency and Levels of Contamination of the Food - Biological Hazards

In some cases, the presence of a foodborne pathogen in food may not present a risk to consumers unless they are exposed to high numbers resulting from growth of the organism in foods (e.g., pathogenic sporeformers such as *B. cereus*) (Granum, 2007). In other cases, the presence of a foodborne pathogen in food may present a significant risk to consumers even when they are exposed to low numbers of the organism (e.g., *Salmonella* in a ready-to-eat food) (D'Aoust and Maurer, 2007). In still other cases, the presence of high numbers of a foodborne pathogen in food may present a risk of only mild illness to the general population while the presence of fewer organisms presents a risk of serious illness and death to susceptible populations (e.g., *L. monocytogenes* in refrigerated ready-to-eat foods) (Food and Agriculture Organization and World Health Organization, 2004a).

Importantly, the risk of illness from foodborne pathogens that cause illness from consumption of only a few cells significantly increases if growth occurs. Thus, if the food containing a foodborne pathogen supports growth of that pathogen, and the food may be subject to conditions that allow growth, the risk for illness increases. The primary factors impacting the risk of illness from most foodborne pathogens in a food, therefore, are intrinsic factors and extrinsic factors that influence growth (Jay, 2000; Montville and Matthews, 2007). Intrinsic factors are chemical and physical factors that are inherent to the food (e.g., pH and water activity (abbreviated a_w). Extrinsic factors are those that refer to the environment surrounding the food (e.g., storage temperature).

Below, we discuss key intrinsic and extrinsic factors that can influence growth of bacterial pathogens. We also describe inherent controls for the representative biological hazards relevant to this RA, interventions to control these representative biological hazards, and activities that can introduce these representative biological hazards into the food categories relevant to this RA.

1. Impact of water activity on growth of foodborne pathogens

The a_w of a food product is a key intrinsic factor affecting the growth of foodborne pathogens. The term "water activity" relates to the amount of unbound water that a microorganism needs to grow. As moisture is removed from a food or bound by solutes such as salt or sugar, a_w decreases. All microorganisms require a certain a_w for growth to occur, and when a_w is reduced below that point, the organism stops growing. For example, *Salmonella* does not grow below an a_w of 0.94 (International Commission on Microbiological Specifications for Foods, 1996b), *S. aureus* does not grow below an a_w of 0.83 (International Commission on Microbiological Specifications for Foods, 1996c), and *C. botulinum* does not grow below an a_w of 0.935 (International Commission on Microbiological Specifications for Foods, 1996a).

Generally, the a_w of most fresh foods is greater than 0.99, which supports the growth of bacterial foodborne pathogens (Jay, 2000). Foods such as honey, chocolate, potato chips, crackers and cereal have very low water activities (e.g., 0.60 and below) (Scott et al., 2001) and do not support growth of bacterial foodborne pathogens. Some foods may be dried to a moisture level at which foodborne pathogens will not grow (e.g., pasta and dried fruits and vegetables, including herbs). However, many foodborne pathogens will survive for extended periods of time under dry conditions, including *Salmonella* spp. (Scott et al., 2009; D'Aoust and Maurer, 2007) and the spores of sporeforming pathogens such as *B. cereus*. Overall, moist foods with a_w of 0.85 and above (e.g., cut fruits and vegetables) usually require refrigeration or other processes as an intervention to control growth of foodborne pathogens, while foods with lower a_w (e.g., flour, jam, honey, dried fruits) do not require refrigeration to control growth of pathogens (although in some cases the food might have limited shelf life without refrigeration as a result of spoilage due primarily to yeasts and molds).

Intervention measures that rely on a_w to prevent the growth of foodborne pathogens require strict control. Lack of such control can result in growth of foodborne pathogens, leading to serious adverse health consequences or death.

2. Impact of pH on growth of foodborne pathogens

The pH of a food product is a key intrinsic factor affecting the growth of foodborne pathogens. Most bacterial pathogens grow best at pH values near neutral (i.e., 6.6-7.5) (Jay, 2000). Low pH inhibits the growth of bacterial foodborne pathogens and in some cases can kill such pathogens. Some foods are naturally acidic (i.e. have a low pH) (e.g., many fruits, including citrus fruits, apples and grapes) and do not support growth of bacterial foodborne pathogens. Other foods (e.g., melons) have pH values that support growth of bacterial foodborne pathogens. Most vegetables (e.g., lettuce, cabbage, beans) have pH values above 5.0 and support growth of bacterial foodborne pathogens when the natural protective barriers are cut. Some foods may be fermented by bacteria to produce

products with a reduced pH (e.g., sauerkraut, pickles, and yogurt). While many strains of foodborne pathogens die off under conditions of low pH, other strains, including strains of *E. coli* O157:H7 and *Salmonella*, can survive under conditions of low pH for a long time, even though their growth might be inhibited (Conner and Kotrola, 1995; Leyer and Johnson, 1992). Therefore, the effectiveness of pH as an intervention measure to kill, or prevent the growth of, bacterial foodborne pathogens is variable. Such intervention measures require strict control throughout manufacturing or processing. Lack of such control can result in the survival and growth of foodborne pathogens, leading to serious adverse health consequences or death.

3. Impact of temperature on growth of foodborne pathogens

Temperature is a key extrinsic parameter affecting growth of foodborne pathogens. As temperature decreases, the growth of microorganisms slows; all microorganisms have a temperature below which growth cannot occur. Some foodborne pathogens do not grow, or grow very slowly, at refrigeration temperatures (e.g., most strains of *Salmonella* (International Commission on Microbiological Specifications for Foods, 1996b) and *S. aureus* (International Commission on Microbiological Specifications for Foods, 1996c)), whereas others (such as *L. monocytogenes*) do grow at refrigeration temperatures (Swaminathan et al., 2007; FDA, 2012a. The risk of illness from *L. monocytogenes* associated with a particular food is dependent on five key factors (Codex Alimentarius Commission, 2007; FDA and USDA, 2003b), including the temperature of refrigerated/chilled food storage; and the duration of refrigerated/chilled storage. Foodborne pathogens cannot grow when a food is frozen (Jay, 2000). Intervention measures that use reduced temperatures to minimize growth of foodborne pathogens require strict, ongoing control (often referred to as "maintaining the cold chain"). Lack of such control can result in the growth of foodborne pathogens, leading to serious adverse health consequences or death.

The growth of foodborne pathogens can also be controlled by increasing temperature above a temperature that permits growth (e.g., holding foods hot). Increasing the temperature high enough will kill foodborne pathogens. Intervention measures that use high temperatures to kill foodborne pathogens require expert knowledge of the heat resistance of the specific pathogen in the specific food product, the delivery of heat to foods to inactivate pathogens, and the parameters that impact the heat process. Improper application of such interventions can result in survival and growth of foodborne pathogens, leading to serious adverse health consequences or death.

4. The impact of other factors on growth of foodborne pathogens

Raw foods from plant and animal origins often have physical barriers that provide very good protection against entry and growth of foodborne pathogens. These physical barriers are biological structures that act as natural coverings for the foods. Examples of such physical barriers include the outer coverings of fruits and vegetables (including the shells of nuts), animal hides, and the cuticle, shell and membranes of eggs. Activities that cut or remove these barriers can result in contamination of tissues and allow growth of pathogens in the contaminated tissues. Survival and growth of foodborne pathogens on produce are significantly enhanced once the protective epidermal barrier has been

broken e.g., by physical damage, such as punctures or bruising, or in the manufacturing or processing of fresh cut produce (Institute of Food Technologists, 2001a). For example, an intact fruit such as a melon or a tomato is unlikely to support growth. Once the fruit is cut, protective barriers of the food are compromised, allowing microorganisms to access parts of the fruit that can support growth. An example is tomatoes used to make salsa. The intact fresh tomato does not support growth of pathogens such as *Salmonella*. However, once the tomato is chopped and mixed with other ingredients to produce salsa, the salsa may support growth of pathogens such as *Salmonella*, unless there is an intervention such as adding one or more antimicrobial compounds to the salsa during manufacture, heating the salsa during manufacture to a sufficient temperature to eliminate the pathogens of concern, or refrigerating the final salsa product in order to control the growth of pathogens. Increasing the temperature of foods during manufacture, e.g., the cooking of vegetables, could also result in the breakdown of these protective coverings and hence could allow the potential contamination of foods with pathogens.

The oxidation-reduction potential of a substance can affect the growth of foodborne pathogens. (The oxidation-reduction potential of a substance (often called the "redox potential") is a measurement of the ease by which a substance loses or gains electrons, and this affects the type of bacteria that can grow (Jay, 2000). The reduction of oxygen in a packaged food product can enhance the ability of anaerobic foodborne pathogens such as *C. botulinum* to grow and produce a potent neurotoxin in foods (Johnson, 2007). Thus, operations such as modified atmosphere packaging, vacuum packaging and canning can present a significant risk to the consumer if the food supports growth of *C. botulinum* (e.g., the pH is above 4.6) and the food is not properly handled, e.g., held under refrigeration temperatures below those at which pathogens can grow.

Preservatives (such as sorbate and benzoate) can minimize growth of foodborne pathogens, and in some cases aid in killing them. If preservatives that are used to control pathogens are not added properly (e.g., at the correct concentration and at the proper pH of the food), pathogens can survive and grow, leading to serious adverse health consequences or death. Thus, intervention measures that use preservatives to control foodborne pathogens require specialized expertise to understand the conditions under which the preservatives are effective in controlling pathogens.

5. Interaction of factors that impact the growth of foodborne pathogens

Factors such as a_w, pH, temperature, and preservatives, can interact to affect growth of foodborne pathogens (Jay, 2000). For example, as temperature decreases, the minimum a_w for growth increases (Koutsoumanis et al., 2004). For example a pathogen that would grow at room temperature if the a_w is 0.95 or above may need an a_w of 0.97 to grow under refrigeration temperatures. These interactions are complex and have been discussed in scientific reviews (The Institute of Food Technologists, 2003) and in regulatory references such as FDA's Food Code (FDA, 2009a). Using combinations of factors to control foodborne pathogens requires specialized expertise. Improper application of interventions involving the interaction of intrinsic and extrinsic factors can result in the growth of foodborne pathogens, leading to serious adverse health consequences or death.

6. Inherent Controls for the Biological Hazards Relevant to This Risk Assessment

Table 7 provides information about inherent controls for the biological hazards relevant to this RA. The products listed in Table 7 as having inherent controls for biological hazards generally have not been associated with illnesses from pathogens.

Table 7. Inherent Controls for Biological Hazards

Food	Inherent Control	Comments
Honey	Lack of association of the food with microbial pathogens and low a_w that would prevent their growth if present	See Table 5 and International Commission on Microbiological Specifications for Foods, 2005e.
Maple syrup	• Lack of association of the food with microbial pathogens and low a_w that would prevent their growth if present • Heat evaporation process	See Table 5 and International Commission on Microbiological Specifications for Foods, 2005e.
Shelf-stable jams, jellies and preserves made from acid foods	Combination of the boiling required to produce the foods, and the low pH and low a_w that would prevent the growth of pathogens if present	International Commission on Microbiological Specifications for Foods, 2011
Oil from oilseeds	Process of extracting and refining oils from seeds	International Commission on Microbiological Specifications for Foods, 2005c
Sugar	Process of making sugar	International Commission on Microbiological Specifications for Foods, 2005e
Carbonated soft drinks and carbonated water	Combination of low pH, high carbon dioxide level and the antimicrobial activity of acids such as phosphoric acid	International Commission on Microbiological Specifications for Foods, 2005d
Hard candy, fudge, taffy and toffee	Boiling ingredients to achieve the needed texture	International Commission on Microbiological Specifications for Foods, 2005b

7. Interventions to Control the Biological Hazards Relevant to This Risk Assessment

As discussed in sections V.B.1 through V.B.5 of this document, there are a number of interventions that may reduce the risk of the biological hazards relevant to this RA. If an intervention is not properly conducted, the applicable hazard is reasonably likely to occur. Moreover, some interventions may require special expertise to ensure they are conducted properly. For example, acidification or "pickling" of vegetables significantly minimizes or prevents the hazard of toxin production by *C. botulinum*. The proper processing of acidified foods such as pickles, relishes and salsas requires an

understanding of the principles of salt and acid diffusion, heat penetration and the microbiology of canned foods, as well as the equipment to accurately measure acidity and temperature. The time for acid to penetrate and reduce the pH of low-acid components is critical in the safe preparation of acidified foods, and this depends on a number of factors that require stringent controls. If the vegetable is not properly acidified, *C. botulinum* spores can germinate and the organism can grow and produce toxin (44 FR 16204 at 16204, Federal Register of March 16, 1979) (Townsend et al., 1954; Ito and Chen, 1978; Notermans, 1993).

Table 8 provides examples of interventions to control the representative biological hazards relevant to this RA. Some of these interventions are CGMPs already required by current part 110, such as disease controls and personal hygiene controls in 21 CFR 110.10 and requirements for the safety and sanitary quality of water in 21 CFR 110.37(a). Other interventions would be preventive controls that facilities may implement under section 418 of the FD&C Act, such as treatment of food to inactivate foodborne pathogens.

Table 8. Examples of Interventions to Control Representative Biological Hazards

Hazard	Examples of Interventions to Control Hazards	Comments
B. cereus	• Inactivating the spores of the organism with heat. • Preventing germination of spores and growth of the organism/toxin production by: o Reducing pH to below 4.9 (e.g., by acidification or through fermenting); o Refrigerating or freezing; o Adding preservatives; o Reducing the a_w.	Granum, 2007 FDA, 2012a When a kill step is applied the food must be protected from recontamination.
C. botulinum	• Inactivating the spores of the organism with heat (e.g., canning under pressure). • Preventing germination of spores and growth of the organism/toxin production by: o Reducing pH to 4.6 or below (e.g., by acidification or through fermenting); o Refrigerating or freezing; o Adding reservatives; o Reducing the a_w.	Johnson, 2007 When a kill step is applied the food must be protected from recontamination.
Cryptosporidium	• Use of water that is safe and of adequate sanitary quality. • Disease controls and personal hygiene controls to prevent contamination by	Based on information in Ortega, 2007 and FDA, 2012a. When a kill step is applied

Hazard	Examples of Interventions to Control Hazards	Comments
	infected food handlers. • Treatment of food, e.g., with heat, to inactivate the organism.	the food must be protected from recontamination.
E. coli O157:H7	• Killing the organism - e.g., through: o Heat treatments (e.g., baking, boiling, cooking, roasting); o Reducing the pH in combination with specific conditions (e.g., type and concentration of acid, time of exposure, and temperature). • Preventing the growth of the organism - e.g., by: o Reducing the pH or a_w; o Refrigerating or freezing; o Adding preservatives. • Sanitation controls. • Personal hygiene controls to prevent contamination by food handlers.	When a kill step is applied the food must be protected from recontamination. The organisms can survive for extended periods of time under some conditions that prevent the growth but do not kill the organism (Conner and Kotrola, 1995).
Hepatitis A virus	• Disease controls and personal hygiene controls to prevent contamination by infected food handlers. • Vaccination of food handlers. • Treatment of food, e.g., with heat, to inactivate the organism.	FDA, 2009a. When a kill step is applied the food must be protected from recontamination.
L. monocytogenes,	• Killing the organism - e.g., through: o Heat treatments (e.g., baking, boiling, cooking, roasting); o Reducing the pH in combination with specific conditions (e.g., type and concentration of acid, time of exposure, and temperature). • Preventing the growth of the organism - e.g., by: o Reducing the pH or a_w; o Refrigerating or freezing; o Adding preservatives. • Sanitation controls. • Personal hygiene controls to prevent contamination by food handlers.	When a kill step is applied the food must be protected from recontamination. The organisms can survive for extended periods of time under some conditions that prevent the growth but do not kill the organism.
Norovirus	Disease controls and personal hygiene controls to prevent contamination by food handlers	
Salmonella spp.	• Killing the organism - e.g., through:	When a kill step is applied

Hazard	Examples of Interventions to Control Hazards	Comments
	o Heat treatments (e.g., baking, boiling, cooking, and roasting); o Reducing the pH in combination with specific conditions (e.g., type and concentration of acid, time of exposure, and temperature). • Preventing the growth of the organism - e.g., by: o Reducing the pH or a_w; o Refrigerating or freezing; o Adding preservatives. • Sanitation controls. • Disease controls and personal hygiene controls to prevent contamination by food handlers.	the food must be protected from recontamination. The organisms can survive for extended periods of time under some conditions that prevent the growth but do not kill the organism (Leyer and Johnson, 1992).
S. aureus	• Killing the organism - e.g., through: o Heat treatments (e.g., baking, boiling, cooking, and roasting); o Reducing the pH in combination with specific conditions (e.g., type and concentration of acid, time of exposure, and temperature). • Preventing the growth of the organism - e.g., by: o Reducing the pH or a_w; o Refrigerating or freezing; o Adding preservatives. • Sanitation controls. • Personal hygiene controls to prevent contamination by food handlers.	When a kill step is applied the food must be protected from recontamination. The organisms can survive for extended periods of time under some conditions that prevent the growth but do not kill the organism (Conner and Kotrola, 1995; Leyer and Johnson, 1992)

8. Activities That Can Introduce, or Increase the Potential for, Biological Hazards Relevant to This Risk Assessment

Conducting some activities on a food may increase the risk from a biological hazard. These are often specific to the food in which the hazard occurs. For example, slicing, peeling or cutting intact fruits and vegetables can transfer microorganisms, including pathogens, from the exterior to the interior of that fruit or vegetable; in many cases this allows growth, thereby increasing the risk of illness (FDA, 2008; Institute of Food Technologists, 2001a). Table 9 provides examples of activities that can introduce, or increase the potential for, biological hazards.

Table 9. Examples of Activities that Can Introduce, or Increase the Potential for, Biological Hazards

Hazard	Examples of Activities That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard	Comments
B. cereus	None identified	
C. botulinum	If a food has a pH and a_w that support growth of *C. botulinum*, packaging that food in a modified atmosphere with reduced oxygen can increase the potential for *C. botulinum* to grow.	Johnson, 2007
Cryptosporidium	Cooling or washing fruits and vegetables with water contaminated with *Cryptosporidium* can lead to contamination of the fruits and vegetables, and water can spread contamination from an individual food item to multiple food items. Use of contaminated water in a food that does not receive a treatment that will remove or inactivate the organism can lead to contamination of the food.	Based on information in Ortega, 2007 and FDA, 2012a.
E. coli O157:H7	Cooling or washing fruits and vegetables with water contaminated with E. coli O157:H7 can lead to contamination of the fruits and vegetables, and water can spread contamination from an individual food item to multiple food items. Cutting fruits and vegetables can transfer the organism from the low-moisture exterior (where it cannot grow) to the high-moisture interior and release juices from tissues, providing conditions that enhance microbial growth.	(FDA, 2008) (Institute of Food Technologists, 2001a)
Hepatitis A virus	Contact with ready-to-eat foods by infected food handlers can result in contamination.	FDA, 2009a.
L. monocytogenes	Cooling or washing fruits and vegetables with water contaminated with L. monocytogenes can lead to contamination of the fruits and vegetables, and water can spread contamination from an individual food item to multiple food items. Cutting fruits and vegetables can transfer the organism from the low-moisture exterior (where it cannot grow) to the high-moisture interior and release juices from tissues, providing conditions that enhance microbial growth.	(FDA, 2008) (Institute of Food Technologists, 2001a)
Norovirus	Contact with ready-to-eat foods by infected food handlers can result in contamination.	

Hazard	Examples of Activities That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard	Comments
Salmonella spp.	Cooling or washing fruits and vegetables with water contaminated with Salmonella can lead to contamination of the fruits and vegetables, and water can spread contamination from an individual food item to multiple food items. Cutting fruits and vegetables can transfer the organism from the low-moisture exterior (where it cannot grow) to the high-moisture interior and release juices from tissues, providing conditions that enhance microbial growth	(FDA, 2008) (Institute of Food Technologists, 2001a).
S. aureus	Contact with ready-to-eat foods by food handlers can result in contamination, which can result in growth and toxin production if the food is held at temperatures that allow growth for sufficient time.	FDA, 2009a.

C. Factors That Impact the Frequency and Levels of Contamination of the Food - Chemical, Physical, and Radiological hazards

The presence and levels of the chemical hazard mycotoxin in foods in the United States is low (Williams et al., 2004). The presence and levels of mycotoxins in foods is dependent in large part on growing and harvesting activities. The type of mold, weather conditions, soil types, insect activity, and commodity type, along with timely harvest and rapid and adequate drying before storage are important in determining the likelihood of contamination (Williams et al., 2004). Insect activity and condensation can result in pockets of moisture that can result in production of mycotoxins (Williams et al., 2004). As noted previously, in developed countries significant investments in production, storage and drying facilities, coupled with the country's regulatory system, have resulted in low concentrations of mycotoxins in foods (Williams et al., 2004). In countries where a wide range of commodities may be contaminated, the country exports the least contaminated foods, while more contaminated foods may be consumed within the country (Williams et al., 2004). Thus, the exposure of the population in the United States to mycotoxins such as aflatoxins is low in both domestic and imported foods (Williams et al., 2004).

The prevalence of undeclared allergen hazards in foods is high (FDA Memorandum, 2004; FDA Memorandum, 2012a; FDA, 2011a; FDA, 2012b). The prevalence of undeclared sulfites in foods is common but not as high as for allergens (FDA Memorandum, 2004; FDA Memorandum, 2012a; FDA, 2012b). Interventions to prevent undeclared food allergen hazards and sulfite hazards include preventing cross-contact between an allergen-containing food and one that does not contain that allergen, and ensuring that the presence of allergens is declared on the package label.

The prevalence of physical hazards in foods is low (FDA, 2011a; FDA, 2012b). The potential presence of physical hazards depends on the activities performed on the food, including activities that can remove foreign objects (e.g., sorting) and those that can introduce them (e.g., cutting, bottling). Adherence to Good Manufacturing Practices minimizes the potential for physical hazards to be present in foods to which consumers are exposed (Jantschke and Elliott, 2006).

The presence of radiological hazards in foods is a rare event and consumer exposure to harmful levels of radionuclide hazards is very low (United Nations Scientific Committee on the Effects of Atomic Radiation, 2008). Use of water that contains a radionuclide to manufacture a food is not reasonably likely when using water from a domestic municipal source subject to regulation by EPA (40 CFR 141.66; see 65 FR 76708, Federal Register of December 7, 2000). When events (such as accidents or natural disasters) occur that could result in radiological contamination of water sources, there is generally much publicity that would alert a farm mixed-type facility to a potential risk in using a potentially contaminated water source, and we expect that government agencies, including FDA, would be likely to take specific actions based on the circumstances to prevent consumer exposure.

Table 10 provides examples of interventions to control the representative chemical hazards relevant to this RA. Some of these interventions are CGMPs already required by current part 110, such as storing raw materials at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the FD&C Act (21 CFR 110.80(a)(5)). Other interventions would be preventive controls that facilities may implement under section 418 of the FD&C Act, such as ensuring that the presence of allergens or sulfites is declared on the package label.

Table 10. Examples of Interventions and Activities that Can Affect Chemical Hazards

Hazard	Examples of Interventions to Control Hazards	Examples of Activities That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard	Comments
Allergen hazards	• Sanitation controls. • Preventing cross-contact between an allergen-containing food and one that does not contain that allergen. • Preventing cross-contact between different allergen-containing foods • Ensuring that the presence of allergens is declared on the package label	• Improper labeling.* • Improper cleaning between allergen-containing foods and foods that do not contain that allergen.	

Hazard	Examples of Interventions to Control Hazards	Examples of Activities That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard	Comments
Mycotoxins	• Control moisture during storage • Pest control	• Improper storage • Lack of pest control	Williams et al., 2004
Sulfites	• Ensuring that the presence of sulfites is declared on the package label	• Improper labeling	Timbo et al., 2004

* Improper labeling of a single-ingredient, allergenic food that can reasonably be expected to be recognizable to a consumer without a label declaration (e.g., whole peanuts or whole specific tree nuts) would not present the same risk as labeling a food that is not a single-ingredient food or that has been manufactured or processed into a form in which the allergenic food cannot reasonably be expected to be recognized by a consumer without a label declaration (e.g., nut flours, chopped tree nuts, wheat flour)

D. Frequency of Consumption and Amount of Food Consumed

The amount of food that is consumed (commonly called "dietary exposure") impacts the risk that consumption of a contaminated food will cause foodborne illness. The risk of foodborne illness can be addressed on a per serving basis (i.e., the amount of food consumed by an individual on a single eating occasion) or on a per annum basis (i.e., the amount of food consumed by a specified population over the course of a year). Several of the food categories considered in this RA are eaten in relatively large quantities on a frequent basis (e.g., fruits, vegetables, grains and grain products), whereas other food categories are eaten in smaller quantities on a less frequent basis (e.g., honey and maple syrup). We have not attempted to determine the amount of food consumed per serving or the number of servings consumed annually for the food categories produced by small or very small farm mixed-type facilities within the scope of the RA. However, we do know, based on the Food Processing Sector Study (Muth et al., 2011), that the proportion of food sold from establishments co-located on farms for small and very small facilities (i.e., those with fewer than 500 employees) is only 1.04 percent of total sales. Thus, on a relative basis, the overall consumption by the U.S. population of all foods produced at farm mixed-type facilities is low and the consumption of such foods containing hazards would be even lower.

VI. RISK CHARACTERIZATION

A. Approach

In this section, we qualitatively characterize the risk from hazards and activity/food combinations based on the available information in the Hazard Identification, Hazard Characterization, and Exposure Assessment sections of this RA. There is uncertainty associated with each of these components of this RA, which leads to uncertainty in the Risk Characterization. The outcome of this risk characterization of hazards is a determination of whether, for the limited purposes of this RA, a hazard presents a reasonable probability of causing serious adverse health consequences or death in the absence of preventive controls that would be required under section 418 of the FD&C Act. In this RA, we are considering such hazards and foods in general terms, on a forward-looking basis, and not in reference to a particular food contamination incident or foodborne illness outbreak. Determinations of whether there is such a reasonable probability in specific situations may be different from the conclusions made for the limited purposes of this document. The characterization of exposure to the hazard, the severity of adverse health consequences resulting from use of, or exposure to, a food containing the hazard, and the conclusions with respect to "reasonable probability of serious adverse health consequences or death" are made in relative terms.

B. Qualitative Risk Characterization of Biological Hazards

Table 14 presents a qualitative risk characterization of representative biological hazards that may be associated with foods manufactured, processed, packed or held on a farm mixed-type facility. Table 14 draws from information presented in Table 2, Table 5, and Table 6 of this RA and from discussions in the Hazard Identification, Hazard Characterization, and Exposure Assessment sections of this RA.

Table 2 and associated text in the Hazard Identification section of this RA summarize surveillance information available from CDC about frequency of outbreaks and illnesses from consumption of food contaminated with biological hazards. Table 5 and associated text in the Hazard Identification section of this RA identify nine biological hazards (i.e., *B. cereus*, *C. botulinum*, *Cryptosporidium*, *E. coli* O157:H7, hepatitis A virus, *L. monocytogenes*, norovirus, *Salmonella*, and *S. aureus*) as representative biological hazards in foods that might be manufactured, processed, packed or held at farm mixed-type facilities. Table 6 and associated text in the Hazard Characterization section of this RA present information about the numbers and rates of hospitalization and death for these nine representative biological hazards. As discussed in Hazard Characterization, adverse effects associated with biological hazards occur as a result of consumption of a contaminated food during a single eating occasion.

To provide a qualitative characterization of risk, we first ordered information from Table 6 related to frequency and severity to group into "high," "medium" and "low" categories. (See Table 11, Table 12, and Table 13.) These rankings are useful for a relative qualitative characterization of risk.

Table 11. Ranking of Numbers of Illness for Representative Foodborne Pathogens Identified in the Hazard Identification (Scallan et al., 2011)

Agent	Frequency of Illness (Mean Number of Annual Episodes)
Norovirus	5,461, 731
Salmonella (non-typhoidal)	1,027,561
S. aureus	241,148
B. cereus	63,400
E. coli O157:H7	63,153
Cryptosporidium	57,616
L. monocytogenes	1,591
Hepatitis A virus	1,566
C. botulinum	55

Table 12. Ranking of Rates of Hospitalization for Representative Foodborne Pathogens Identified in the Hazard Identification (Scallan et al., 2011)

Agent	Hospitalization Rate (Percent)
L. monocytogenes	94
C. botulinum	82.6
E. coli O157:H7	46.2
Hepatitis A virus	31.5
Salmonella (non-typhoidal)	27.2
Cryptosporidium	25
S. aureus	6.4
B. cereus	0.4
Norovirus	0.03

Table 13. Ranking of Rates of Death for Representative Foodborne Pathogens Identified in the Hazard Identification (Scallan et al., 2011)

Agent	Death Rate (Percent)
C. botulinum	17.3
L. monocytogenes	15.9
Hepatitis A virus	2.4
E. coli O157:H7	0.5
Salmonella (non-typhoidal)	0.5
Cryptosporidium	0.3
S. aureus	<0.1
Norovirus	<0.1
B. cereus	0

Table 14 characterizes the mean number of annual episodes of foodborne illness from the information presented in Table 6 and Table 11 of this document as follows:

- Low = No more than 50,000 illnesses;
- Medium = Between 50,000 and 100,000 illnesses; and
- High = 100,000 or more illnesses.

Table 14 characterizes the severity of the biological hazard in terms of rate of hospitalization from the information presented in Table 6 and Table 12 of this document as follows:

- Low = Less than 20%;
- Medium = Between 20% and 50%; and
- High = 50% or more.

Table 14 characterizes the severity of the biological hazard in terms of rate of death from the information presented in Table 6 and Table 13 of this document as follows:

- Low = No more than 1%;
- Medium = Between 1% and 5%; and
- High = More than 5%.

In characterizing the risk of the biological hazards relevant to this RA, we:

- Used CDC surveillance information on the frequency of illness as an overall indicator of exposure to these biological hazards (see discussion in section V.A of this document);
- Considered that all of the representative biological hazards relevant to this RA lead to adverse effects as a result of a single eating occasion;
- Used CDC surveillance information on the rates of hospitalization and death to assess the severity of these representative biological hazards.
    - We considered that a biological hazard presents a reasonable probability of serious adverse health consequences or death for the purposes of this RA if:
        - Severity was assessed as high or medium by either the rate of hospitalization or the rate of death; or
        - One of the measures of severity was assessed as low, but the exposure was medium or high.
    - We did not consider that a biological hazard presents a reasonable probability of serious adverse health consequences or death for the purposes of this RA if both measures of severity were low, even if the exposure was high.

Table 14. Qualitative Risk Characterization of Representative Biological Hazards That Are Reasonably Likely to Be Associated With Foods Manufactured, Processed, Packed or Held on a Farm Mixed-Type Facility*

Hazard	Exposure	Severity (Rate of Hospitalization)	Severity (Rate of Death)	Reasonable Probability of Causing Serious Adverse Health Consequences or Death?**
B. cereus	Medium	Low	Low	No
C. botulinum	Low	High	High	Yes
Cryptosporidium	Medium	Medium	Low	Yes
E. coli O157:H7	Medium	Medium	Low	Yes
Hepatitis A virus	Low	Medium	Medium	Yes
L. monocytogenes	Low	High	High	Yes

Hazard	Exposure	Severity (Rate of Hospitalization)	Severity (Rate of Death)	Reasonable Probability of Causing Serious Adverse Health Consequences or Death?**
Norovirus	High	Low	Low	No
Salmonella spp. (non-typhoidal)	High	Medium	Low	Yes
S. aureus	High	Low	Low	No

* See Table 2, Table 5, and Table 6
**For the purposes of this RA.

Based on Table 14, six of the representative biological hazards relevant to this RA present a reasonable probability of causing serious adverse health consequences or death for the purposes of this RA - i.e., *C. botulinum*, *Cryptosporidium*, *E. coli* O157:H7, hepatitis A virus, *L. monocytogenes*, and *Salmonella* spp. (non-typhoidal).

C. Qualitative Risk Characterization of Chemical, Physical, and Radiological Hazards

Table 15 presents a qualitative risk characterization of chemical, physical, and radiological hazards that may be associated with foods manufactured, processed, packed or held on a farm mixed-type facility.

Table 15 draws from information presented in Table 2, Table 3, Table 4, and Table 5 of this RA and from discussions in the Hazard Identification, Hazard Characterization, and Exposure Assessment sections of this RA.

We lack data on the annual incidence of the chemical, physical, and radiological hazards relevant to this RA. In characterizing the risk of these hazards, we:

- Used reports to the RFR (see Table 3 and Table 4) and recall data (FDA Memorandum, 2004; FDA Memorandum, 2012a) as an overall indicator of exposure to allergen hazards, sulfite hazards, and physical hazards.
- Characterized exposure to mycotoxin hazards as low based on the available information (Williams et al., 2004). We did not assess the effects of long-term exposure to mycotoxin hazards. Data are lacking to assess the frequency with which serious adverse health consequences or death occur due to chronic exposure to mycotoxin hazards in foods nor are there data to indicate that long-term chronic, high exposure to mycotoxin hazards is reasonably likely to occur in the U.S.
- Characterized exposure to radiological hazards as very low because the presence of radiological hazards in foods is a rare event (see discussion in section V.C of this document).
- Characterized severity of the hazard as "High" if adverse reactions resulting from a single eating occasion are serious and are likely to include death.
- Considered that a chemical, physical, or radiological hazard presents a reasonable probability of serious adverse health consequences or death for the purposes of

this RA if exposure was assessed to be relatively high and was likely to result in serious adverse health consequences from a single eating occasion.

Table 15. Qualitative Risk Characterization of Chemical, Physical and Radiological Hazards That Are Reasonably Likely to Be Associated with Foods Manufactured, Processed, Packed or Held on a Farm Mixed-Type Facility

Hazard	Exposure	Single Eating Occasion or Cumulative Exposure?	Severity	Reasonable Probability of Causing Serious Adverse Health Consequences or Death?**	Comments
Allergen hazards	High	Single eating occasion	High	Yes	See Table 3 and Table 4
Sulfites	High	Single eating occasion	High	Yes	See Table 3 and Table 4
Mycotoxins	Low	Cumulative exposure	Low	No	See Table 2 for frequency of chemical hazards relative to frequency of biological hazards
Foreign objects	Low	Single eating occasion	Low	No	See Table 3 and Table 4
Radiological hazards	Very Low	Cumulative exposure	Low	No	No known exposures

** For the purposes of this RA

Based on Table 15:

- Two chemical hazards relevant to this RA present a reasonable probability of causing serious adverse health consequences or death for the purposes of this RA - i.e., allergen hazards and sulfite hazards; and
- None of the physical or radiological hazards relevant to this RA present a reasonable probability of causing serious adverse health consequences or death for the purposes of this RA.

D. Characterizing Interventions with Respect to the Definition of Low-Risk Activity

We characterized the interventions described in Table 8 and Table 10 under part #2b of the definition of low-risk activity (see section I.E of this document). Under part #2b, if a hazard is ordinarily controlled through applicable CGMP controls (e.g., the requirements in current 21 CFR part 110), these CGMP controls should not be considered a preventive control for that food to significantly minimize or prevent a hazard for the purposes of this RA. Our task in this RA is in part to determine whether the additional controls that would be required by section 418 of the FD&C Act are needed to ensure the safety of the product in light of the existing regulatory framework.

The interventions described for two of the six representative biological hazards determined to present a reasonable probability of serious adverse health consequences or death for the purposes of this RA (i.e., *Cryptosporidium* and hepatitis A virus) are largely addressed by the CGMP controls already required by current part 110 (disease controls and personal hygiene controls in 21 CFR 110.10, and requirements for the safety and sanitary quality of water in 21 CFR 110.37(a)). Although both *Cryptosporidium* and hepatitis A virus can also be controlled by additional preventive controls required under section 418 of the FD&C Act, such preventive controls likely would already be applied to significantly minimize or prevent other biological hazards that are more likely to occur (such as *Salmonella* spp.) or have more severe effects (such as *E. coli* O157:H7). Therefore we did not separately consider these hazards in section VI.E of this document (immediately below).

E. Activity/Food Combinations

1. Overview

In sections VI.E.2 of this document, we characterize the risk of activity/food combinations without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/food combinations themselves. In Appendix 2 of this document, we add that regulatory overlay and characterize the risk of activity/food combinations in groups shaped by the applicable regulatory factors and the resulting activity classifications.

2. Characterizing Activity/Food Combinations

Table 16 and Table 17 present a matrix of activity/food combinations. Our use of two tables (i.e., Table 16 and Table 17) rather than a single table reflects practicalities associated with large amounts of information rather than any substantive purpose. We simply present half of the food categories in Table 16 and the remaining half of the food categories in Table 17.

As discussed in section I.E of this document, there are three parts of the definition of low-risk activity/food combination. jbl

Importantly, under the definition of low-risk activity food combination, to be low risk the activity/food combination must either:

- Satisfy part #1 (inherent controls); or
- Satisfy both part #2a (activity not likely to introduce, or increase the potential for, a SAHCOD hazard) and part #2b (activity does not significantly minimize or prevent a SAHCOD hazard).

Within each cell of Table 16 and Table 17, we ask whether an activity/food combination would be low risk (as defined in section I.E of this document). In answering this question, we:

- Answer the question "Yes" if the activity satisfies the definition of low-risk activity/food combination;

- Answer the question "No" if the activity does not satisfy the definition of low-risk activity/food combination; and
- Do not answer the question (i.e., leave a blank cell in the matrix) if the activity generally does not apply to the food.

Within each cell that has a "Yes" answer, we provide the part of the definition of low-risk activity governing the classification of low-risk:

- #1 (inherent controls); or
- #2 (if the activity satisfies both part #2a and part #2b of the definition of low-risk activity).

Within each cell that has a "No" answer, we provide the part of the definition of low-risk activity governing the conclusion that the activity/food combination is NOT low risk:

- #2a (if the activity introduces, or increases the potential for, a SAHCOD hazard); or
- #2b (if the activity significantly minimizes or prevents a SAHCOD hazard)

For those activity/food combinations that are not low risk, Table 18 explains the specific reasons why.

Table 16. Is an Activity/Food Combination Low Risk?

	Cocoa Beans	Coffee Beans	Intact Fruits and Vegetables	Grain	Grain Products
Acidification/Pickling/Fermenting	Yes (#2)	Yes (#2)	No (#2b)	[1]	
Artificial ripening			Yes (#2)		
Baking/Boiling/Cooking/ Concentration/ Evaporation/Roasting	No (#2b)	No (#2b)	No (#2a and 2b)		No (#2a and 2b)
Canning/Bottling/ Jarring (packaging that involves processing, e.g., water bath canning, pressure canning)			No (#2b)		
Coating (coatings other than wax, oil, or resin used for the purposes of storage/transportation)			Yes (#2)		
Cooling - Air			Yes (#2)		
Cooling-Water			No (#2a)		
Cutting/Coring/Chopping/Shredding/ Slicing/Peeling/ Trimming			No (#2a)		

	Cocoa Beans	Coffee Beans	Intact Fruits and Vegetables	Grain	Grain Products
Dehydration/ Drying (for storage/transport or for creating a distinct commodity)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)
Extraction				Yes (#2)	Yes (#2)
Filtration					
Grinding/Milling/Cracking/Crushing	Yes (#2)	Yes (#2)		Yes (#2)	Yes (#2)
Labeling (including stickering)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2) [2]	Yes (#2) [2]
Making hard candy, fudge, taffy, toffee					
Making cocoa products from roasted cocoa beans	Yes (#2)				
Making jams/jellies/preserves from acid foods			Yes (#1)		
Making jams/jellies/preserves from low-acid foods			No (#2b)		
Making soft drinks and carbonated water					
Making sugar					
Mixing/Blending	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)
Packing/Re-Packing (including conveying and weighing incidental to packing/re-packing)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)
Packaging other than modified atmosphere or vacuum packaging	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)
Packaging – Modified atmosphere or vacuum			No (#2a)		
Salting					
Sifting				Yes (#2)	Yes (#2)
Shelling/hulling/winnowing	Yes (#2)		Yes (#2)		
Sorting, Culling & Grading	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)
Storing (Ambient cold, or controlled atmosphere)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)
Sulfiting			No (#2a and 2b)		
Treating against pests other than during growing, e.g. fumigation	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)	Yes (#2)
Washing/rinsing			No (#2a)		
Waxing (wax, oil, or resin used for the purposes of storage/transportation)			Yes (#2)		

[1] Blank cells indicate the activity generally does not apply to the food.

[2] Labeling of foods bearing or containing wheat would not be low risk if the food is not a single-ingredient food or is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration.

Table 17. Is an Activity/Food Combination Low Risk? (Continued)

	Honey	Maple Sap for Syrup and Maple	Peanuts and Tree Nuts	Other [1]
Acidification/Pickling/Fermenting	[2]			
Artificial ripening				
Baking/Boiling/Cooking/ Concentration/ Evaporation/Roasting		Yes (#1)	No (#2b)	
Canning/Bottling/ Jarring (packaging that involves processing, e.g., water bath canning, pressure canning)				
Coating (coatings other than wax, oil, or resin used for the purposes of storage/transportation)			Yes (#2)	
Cooling - Air				
Cooling-Water				
Cutting/Coring/Chopping/Shredding/ Slicing/Peeling/ Trimming			Yes (#2)	
Dehydration/ Drying (for storage/transport or for creating a distinct commodity)			Yes (#2)	
Extraction	Yes (#1)			
Filtration	Yes (#1)	Yes (#1)		
Grinding/Milling/Cracking/Crushing			Yes (#2)	
Labeling (including stickering)	Yes (#2)	Yes (#2)	Yes (#2) [3]	Yes (#2) [4]
Making hard candy, fudge, taffy, toffee				Yes (#1)
Making cocoa products from roasted cocoa beans				Yes (#2)
Making jams/jellies/preserves from acid foods				Yes (#1)
Making jams/jellies/preserves from low-acid foods				No (#2b)
Making soft drinks and carbonated water				Yes (#1)
Making sugar				Yes (#1)
Mixing/Blending	Yes (#1)	Yes (#1)	Yes (#2)	
Packing/Re-Packing (including conveying and weighing incidental to packing/re-packing)	Yes (#1)	Yes (#1)	Yes (#2)	Yes (#2)
Packaging other than modified atmosphere or vacuum packaging	Yes (#1)	Yes (#1)	Yes (#2)	Yes (#2)

	Honey	Maple Sap for Syrup and Maple	Peanuts and Tree Nuts	Other [1]
Packaging – Modified atmosphere or vacuum			Yes (#2)	
Salting			Yes (#2)	
Sifting				
Shelling/hulling/winnowing			Yes (#2)	
Sorting, Culling & Grading	Yes (#1)	Yes (#1)	Yes (#2)	Yes (#2)
Storing (Ambient cold, or controlled atmosphere)	Yes (#1)	Yes (#1)	Yes (#2)	Yes (#1)
Sulfiting				
Treating against pests other than during growing, e.g. fumigation			Yes (#2)	
Washing/rinsing				
Waxing (wax, oil, or resin used for the purposes of storage/transportation)				

[1] "Other" includes cocoa products; hard candy, fudge, taffy, and toffee; jams, jellies, and preserves; soft drinks and carbonated water; and sugarcane, sugar beets and sugar. In addition the primary ingredient may be water.

[2] Blank cells indicate the activity generally does not apply to the food.

[3] Labeling of foods bearing or containing peanuts or tree nuts would not be low risk if the food is not a single-ingredient food or is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration.

[4] Labeling of hard candy, fudge, taffy and toffee bearing or containing allergens, e.g. milk, peanuts, tree nuts, would not be low risk because the food is not a single-ingredient food and is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration. Labeling of cocoa products other than milk chocolate would be low risk, but milk chocolate is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration.

Table 18. Why Certain Activity/Food Combinations Are Not Low Risk

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCOD Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCOD Hazard (#2b)
Acidification/ Pickling/ Fermenting	Intact fruits and vegetables		• Requires careful controls to significantly minimize or prevent a hazard from *C. botulinum.* • Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the fruit or vegetable.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCOD Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCOD Hazard (#2b)
Baking/Boiling/ Cooking/ Evaporation/ Roasting	Intact fruits and vegetables	For some foods increases the potential for a hazard, e.g., growth of pathogenic sporeformers such as *C. botulinum* that survive the heating	Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the fruit or vegetable.
Baking/Boiling/ Cooking/ Evaporation/ Roasting	Grain products	For some foods increases the potential for a hazard, e.g., growth of pathogenic sporeformers such as *C. botulinum* that survive the heating	Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the grains or grain products.
Roasting	Peanuts and tree nuts		Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the peanuts or tree nuts.
Roasting	Raw coffee beans		Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the coffee beans.
Roasting	Raw cocoa beans		Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the cocoa beans.
Canning/Bottling/ Jarring	Intact fruits and vegetables		• Requires careful controls to significantly minimize or prevent a hazard from *C. botulinum.* • Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the fruit or vegetable.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCOD Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCOD Hazard (#2b)
Cooling - water	Intact fruits and vegetables	The activity is reasonably likely to introduce, or create the potential for, a hazard by spreading biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the exterior of the fruit or vegetable.	
Cutting/Coring/ Chopping/ Shredding/ Slicing/Peeling	Intact fruits and vegetables	The activity is reasonably likely to introduce biological hazards (i.e., microbial pathogens) to the interior of the fruit or vegetable where it may be able to grow.	
Labeling	Peanuts, tree nuts, grain products		Labeling of peanuts, tree nuts and wheat when the food is not a single-ingredient food or is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen prevents the hazard of an undeclared allergen.
Labeling	Hard candy, fudge, taffy, toffee and milk chocolate		Labeling of hard candy, fudge, taffy, toffee, and milk chocolate, which may contain allergens such as milk, peanuts or tree nuts in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen, prevents the hazard of an undeclared allergen.
Making jams/jellies/ preserves from low-acid foods	Intact fruits and vegetables		Requires careful controls to significantly minimize or prevent a hazard from *C. botulinum.*

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCOD Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCOD Hazard (#2b)
Packaging – Modified atmosphere or vacuum	Intact fruits and vegetables	The activity is reasonably likely to introduce, or create the potential for, a hazard, by providing an environment in which *C. botulinum* could grow and produce toxin.	
Sulfiting	Intact fruits and vegetables	The activity is reasonably likely to introduce a chemical hazard (i.e., sulfite) which, if not properly labeled, is reasonably likely to cause serious adverse health consequences or death.	Labeling of intact fruits and vegetables treated with sulfites prevents the hazard of an undeclared chemical hazard.
Washing/rinsing	Intact fruits and vegetables	The activity is reasonably likely to introduce, or create the potential for, a hazard by spreading biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the exterior of the fruit or vegetable.	

VII. CONCLUSIONS

A. Answers to the Questions to be Addressed in This Risk Assessment

Question 1: What are the foods that would be manufactured, processed, packed or held by a farm mixed-type facility?

The RA identified the following food categories that are within the scope of the RA and that would be manufactured, processed, packed or held by a farm mixed-type facility:

- Cocoa beans and cocoa products;
- Coffee beans;
- Grains (e.g., corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, soybeans, oilseeds);
- Grain products (e.g., flour, bran, breads, pasta);
- Hard candy, fudge, taffy, toffee;
- Honey;
- Intact fruits and vegetables;
- Maple sap (for making maple syrup) and maple syrup;
- Peanuts;
- Soft drinks and carbonated water;
- Sugarcane, sugar beets and sugar; and
- Tree nuts (e.g., walnuts, almonds, hazelnuts).

Question 2: What are the activities that might be conducted by farm mixed-type facilities on those foods [foods that would be manufactured, processed, packed or held by a farm mixed-type facility]?

Table 1 in section II.B of this document lists the activities that might be conducted by farm mixed-type facilities on those foods.

Question 3: What are the hazards reasonably likely to occur in those foods [that would be manufactured, processed, packed or held by a farm mixed-type facility]?

The RA identified the following hazards as representative of the hazards of concern for food categories that are likely to be manufactured, processed, packed or held on a farm mixed-type facility and within the scope of this RA:

- Nine biological hazards, including six bacterial foodborne pathogens (i.e., *B. cereus*, *C. botulinum*, *E. coli* O157, *L. monocytogenes*, *Salmonella*, and *S. aureus*); two viral foodborne pathogens (i.e., norovirus and hepatitis A virus), and one parasite (i.e., *Cryptosporidium*);
- Mycotoxins and pesticides;
- Allergen hazards and sulfites;
- Physical hazards; and
- Radiological hazards.

Question 4: For the purpose of determining whether an activity/food combination is low risk, which hazards should be considered to have a reasonable probability of causing serious adverse health consequences or death?

For the purpose of determining whether an activity/food combination is low risk, the RA identified the following hazards as having a reasonable probability of causing serious adverse health consequences or death:

- The biological hazards *C. botulinum*, *E. coli* O157, *L. monocytogenes*, *Salmonella*, hepatitis A virus, and *Cryptosporidium*;
- Allergen hazards; and
- Sulfites.

Question 5: For the purpose of determining whether an activity/food combination is low risk, what foods have inherent controls that significantly minimize or prevent a biological hazard that is reasonably likely to occur in these foods and that is reasonably likely to cause serious adverse health consequences or death?

For the purpose of determining whether an activity/food combination is low risk, the RA identified the following foods as having inherent controls that significantly minimize or prevent a biological hazard that is reasonably likely to occur in these foods:

- Hard candy, fudge, taffy, and toffee;
- Honey;
- Maple syrup;
- Shelf-stable jams, jellies and preserves made from acid foods;
- Oil from oilseeds;
- Sugar; and
- Carbonated soft drinks and carbonated water.

Question 6: What interventions significantly minimize or prevent a hazard that is reasonably likely to occur in these foods and that is reasonably likely to cause serious adverse health consequences or death?

The RA identified the following examples of interventions to significantly minimize or prevent a hazard that is reasonably likely to occur in these foods and that for purposes of this RA, is considered reasonably likely to cause serious adverse health consequences or death:

- For the sporeforming bacterial pathogen *C. botulinum*:
  - Inactivating the spores of the organism with heat (e.g., canning under pressure);
  - Preventing germination of spores and growth of the organism/toxin production by:
    - Reducing pH to 4.6 or below (e.g., by acidification or through fermenting);

        - Refrigerating or freezing;
        - Adding preservatives, or
        - Reducing the a_w.
- For the bacteria *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*:
    - Killing the organism - e.g., through:
        - Heat treatments (e.g., baking, boiling, cooking, roasting);
        - Reducing the pH in combination with specific conditions (e.g., type and concentration of acid, time of exposure and temperature);
    - Preventing the growth of the organism - e.g., by:
        - Reducing the pH or a_w;
        - Refrigerating or freezing;
        - Adding preservatives.
    - Applying sanitation controls.
    - Applying disease controls and personal hygiene controls to prevent contamination by food handlers.
- For hepatitis A virus:
    - Preventing contamination by infected food handlers through disease controls and personal hygiene controls;
    - Vaccination of food handlers
    - Treatment of food, e.g., heat, to inactivate the virus.
- For *Cryptosporidium*:
    - Use of water that is safe and of adequate sanitary quality.
    - Preventing contamination by infected food handlers through disease controls and personal hygiene controls.
    - Treatment of food, e.g., with heat, to inactivate the parasite.
- For allergen hazards:
    - Preventing cross-contact between an allergen-containing food and one that does not contain that allergen;
    - Preventing cross-contact between different allergen-containing foods;
    - Ensuring that the presence of allergens is declared on the package label.
- For sulfites: Ensuring that the presence of sulfites is declared on the package label.

Question 7: Which of these activities are reasonably likely to introduce, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death and what are these hazards?

The RA identified the following examples of activities that are reasonably likely to introduce, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death:

- Baking/boiling/cooking/evaporation/roasting of some intact fruits and vegetables and some grain products increases the potential for a hazard, e.g., growth of pathogenic sporeformers such as *C. botulinum* that survive the heating.

- Cooling intact fruits and vegetables with water is reasonably likely to introduce, or create the potential for, a hazard by spreading biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the exterior of the fruit or vegetable.
- Cutting/coring/chopping/shredding/slicing/peeling intact fruits and vegetables is reasonably likely to introduce biological hazards (i.e., microbial pathogens) to the interior of the fruit or vegetable where they may be able to grow. The activity would create a food that requires time/temperature control to prevent the growth of pathogens that survive cooking, e.g., *C. botulinum*.
- Packaging (modified atmosphere or vacuum) of intact fruits and vegetables is reasonably likely to introduce, or create the potential for, a hazard, by providing an environment in which *C. botulinum* could grow and produce toxin;
- Sulfiting intact fruits and vegetables is reasonably likely to introduce a chemical hazard (i.e., sulfite) which, if not properly labeled, is reasonably likely to cause serious adverse health consequences or death.
- Washing/rinsing intact fruits and vegetables is reasonably likely to introduce,, or create the potential for, a hazard by spreading biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the exterior of the fruit or vegetable.

Question 8: Which of these activities are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death from consumption of these foods?

The RA identified the following examples of activities that are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death from consumption of these foods:

- Acidification/pickling/fermenting intact fruits and vegetables;
- Baking/Boiling/Cooking/Evaporation/Roasting intact fruits and vegetables; grain products; peanuts; tree nuts; coffee beans and cocoa beans;
- Canning/bottling/jarring (packaging that involves processing, e.g., water bath canning, pressure canning) intact fruits and vegetables;
- Labeling of food bearing or containing peanuts, tree nuts and wheat if the food is not a single-ingredient food or is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration;
- Labeling of hard candy, fudge, taffy, toffee, and milk chocolate bearing or containing allergens such as milk, peanuts or tree nuts in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen; and
- Labeling intact fruits and vegetables containing sulfites.

Question 9: Which activity/food combinations are low risk, i.e., what on-farm activity/food combinations are not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences or death or serve as preventive controls (interventions) to significantly minimize or prevent a hazard that could cause serious adverse health consequences or death?

In this section of this RA, we answer Question 9 without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/food combinations themselves. In Appendix 2 of this document, we add that regulatory overlay and group the answers to Question 9 based on the applicable regulatory factors and the resulting activity classifications.

Based on the information in Table 16, Table 17, and Table 18, and for the purposes of the analysis required by section 103(c)(1))(C) of FSMA, the RA identified the following low-risk activity/food combinations.

- Making hard candy, fudge, taffy, toffee;
- Making cocoa products from roasted cocoa beans;
- Making honey;
- Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- Making maple syrup;
- Making soft drinks and carbonated water;
- Making sugar from sugarcane and sugar beets;
- Artificial ripening of intact fruits and vegetables;
- Boiling/evaporation of maple sap to make maple syrup;
- Coating intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
- Chopping peanuts and tree nuts;
- Cooling intact fruits and vegetables using cold air;
- Drying/dehydrating intact fruits and vegetables (without sulfiting), grains and grain products, peanuts and tree nuts, coffee beans, and cocoa beans;
- Extracting oils from grains (e.g., corn, soybeans, oilseeds);
- Fermenting cocoa beans and coffee beans;
- Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal), coffee beans, cocoa beans, and peanuts and tree nuts (e.g., making ground peanuts);
- Labeling (including stickering) intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), intact single-ingredient peanuts or tree nuts (shelled and unshelled), honey, maple sap, maple syrup, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, hard candy, cocoa products from roasted cocoa beans (other than milk chocolate), jams/jellies/preserves, and soft drinks and carbonated beverages;
- Mixing intact fruits and vegetables, grain and grain products, peanuts, tree nuts, honey, maple sap and maple syrup, coffee beans, and cocoa beans;
- Packing or re-packing (including weighing or conveying incidental to packing or re-packing) intact fruits and vegetables, grain and grain products, peanuts, tree nuts, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, honey, maple sap, maple syrup, soft drinks and carbonated water, jams, jellies, and preserves;

- Packaging intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grains and grain products; peanuts and tree nuts (including modified atmosphere or vacuum packaging); honey; maple syrup; sugarcane, sugar beets and sugar; coffee beans; cocoa beans; cocoa products, hard candy, fudge, taffy, toffee; jams, jellies and preserves; and soft drinks and carbonated water;
- Salting peanuts and tree nuts;
- Sifting grains and grain products;
- Shelling/ hulling intact fruits and vegetables (e.g., dried peas and beans), peanuts, tree nuts, and cocoa beans (i.e., winnowing);
- Sorting, culling and grading intact fruits and vegetables, grain and grain products, peanuts, tree nuts, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, honey, maple sap, maple syrup, soft drinks and carbonated water, jams, jellies, and preserves;
- Storing intact fruits and vegetables, grain and grain products, peanuts, tree nuts, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, honey, maple sap, maple syrup, soft drinks and carbonated water, jams, jellies, and preserves;
- Treating intact fruits and vegetables, grains and grain products, peanuts, tree nuts, coffee beans and cocoa beans against pests other than during growing, e.g., fumigation; and
- Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

B. Summary

This RA assesses the risk of activities conducted on foods by farm mixed-type facilities to determine low-risk activity/ food combinations. It advances our ability to describe our current state of knowledge about hazards that are reasonably likely to occur for foods and activities on-farm and to assess which activities are low risk. It provides a framework for integrating and evaluating the scientific knowledge related to public health as applied to on-farm activities and can be used in support of regulatory decisions in the implementation of FSMA.

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APPENDIX 1. REGULATORY BACKGROUND

A. Statutory and Regulatory Framework for the Risk Assessment

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111–353) was signed into law. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to create a new section 418 with the same name. Section 418 of the FD&C Act contains requirements applicable to food facilities that are required to register under section 415 of the FD&C Act and mandates agency rulemaking. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. In addition to those areas specified in section 418(a) of the FD&C Act, sections 418(b)-(i) contain more specific requirements applicable to facilities. These include corrective actions (§ 418(e)), verification (§ 418(f)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Section 418(b) of the FD&C Act requires that the hazard analysis identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives. Section 418(n)(1) requires rulemaking to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under section 418 and to define the terms “small business” and “very small business” for the purposes of section 418.

Section 103(c) of FSMA requires rulemaking in two areas: (1) clarification of the activities that are included as part of the definition of the term “facility” under section 415 of the FD&C Act (Registration of Food Facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report) of the FD&C Act for certain facilities as FDA deems appropriate. Section 415 of the FD&C Act directs FDA to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with FDA. The registration requirement in section 415 of the FD&C Act does not apply to farms. Our regulations that implement section 415 and require food facilities to register with FDA are established in part 1 (21 CFR part 1), subpart H (Registration of Food Facilities) (hereinafter the section 415 registration regulations)

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

processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership."

Section 103(c)(1)(D)(i) of FSMA requires that "the Secretary [of HHS] shall consider the results of the science-based risk analysis… and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act ... including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act ..., or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk." Section 103(c)(1)(D)(ii) of FSMA provides, in relevant part, that the exemptions or modifications described in section 103(c)(1)(D)(i) "shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act[.]"

FSMA establishes several exemptions and exceptions to the requirements specified in section 418 of the FD&C Act for hazard analysis and risk-based preventive controls. The exemptions and exceptions most relevant to the analysis required by section 103(c)(1)(C) of FSMA are:

- Section 418(j) of the FD&C Act provides an exemption for facilities that are required to comply and are in compliance with the regulations for seafood Hazard Analysis and Critical Control Point (HACCP), juice HACCP, or thermally processed low-acid foods packed in hermetically sealed containers. The exemption for thermally processed low-acid foods packed in hermetically sealed containers applies only with respect to microbiological hazards (i.e., it does not apply with respect to chemical, physical, and radiological hazards).
- Section 418(k) of the FD&C Act provides an exception for activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety).
- Section 103(g) of FSMA provides an exemption for the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with sections 402(g)(2) and 761 of the FD&C Act (21 U.S.C. 342(g)(2), 379aa-1).
- Section 116(a) of FSMA (21 U.S.C 2206(a)) provides an exemption for alcoholic beverages and limited prepackaged foods other than alcoholic beverages at certain alcohol-related facilities."

To implement sections 103(c)(1)(C)-(D) of FSMA, FDA (we) focused on activity/food combinations that are likely to be conducted on farms (and farm mixed-type facilities), but that are outside the definition of farm in § 1.227 in at least some circumstances. When such activities trigger the registration requirement in section 415 of the FD&C Act, they are subject to requirements under section 418 of the FD&C Act and section 421 of the FD&C Act (Targeting of Inspection Resources).

Consistent with section 418(a) of the FD&C Act, when considering allergen hazards that may be associated with food that is manufactured, processed, packed or held on a farm

mixed-type facility,[2] we considered the major food allergens defined in section 201(qq) of the FD&C Act.[3]

Seafood and juice. Consistent with the statutory exemptions in section 418(j) of the FD&C Act, we did not consider activity/food combinations associated with processing seafood or juice that would be subject to the requirements of part 123 or part 120, respectively.[4] Moreover, if we were to consider them, seafood would be out of scope because it requires time/temperature control for safety (see section I.C of this document) and the activities that we expect farm mixed-type facilities conduct on juice would not satisfy the definition of low-risk activity/food combination because it requires controls to significantly minimize or prevent a SAHCOD hazard (see the definition of low-risk activity/food combination in section I.E of this document).

Thermally processed low-acid foods. The statutory exemption in section 418(j) of the FD&C Act for thermally processed low-acid foods packed in hermetically sealed containers applies only to microbiological hazards. Thus, we did not consider microbiological hazards that could be associated with the activity of canning low-acid foods in our analysis. Moreover, if we were to consider them, activities such as canning LACF foods would not be considered low risk with respect to microbiological hazards because the canning process is a preventive control that significantly minimizes or prevents a SAHCOD hazard. However, we did consider physical, chemical, and radiological hazards that may be associated with canning a low-acid food as well as microbiological hazards associated with canning foods (such as acidified foods) that are not low-acid foods.

Produce. Consistent with the statutory exception in section 418(k) of the FD&C Act, we did not consider activity/food combinations that would be addressed by regulations implementing section 419 of the FD&C Act. For example, we did not consider any growing activities. We did consider activities that may be subject to section 418 if conducted by a farm mixed-type facility (e.g., packing fruit from another farm) even if an analogous activity would be subject to the standards in section 419 of the FD&C Act (e.g., packing the farm mixed-type facility's own fruit). Moreover, activities of a facility

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[2] See the definition of "farm mixed-type facility" in section B of the Appendix of this document.

[3] 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.

[4] For the purpose of this analysis, FDA assumed that all small or very small businesses that are required to comply with the seafood HACCP regulation in part 123 or the juice HACCP regulation in part 120 would be in compliance with the applicable regulation and, thus, that it is not necessary to consider an exemption or modification for small or very small businesses in accordance with section 103(c)(1)(D) of the FD&C Act. Moreover, we see no reason that FDA should consider exempting or modifying the requirements of section 418 for the owner, operator, or agent in charge of a facility that is required to be in compliance with the seafood HACCP regulation in part 123 or the juice HACCP regulation in part 120 and is not in compliance.

that are subject to section 419 of the FD&C Act would not be subject to Section 421 of the FD&C Act, which does not apply to farms.

Dietary supplements. We are not aware of any on-farm manufacturing, processing, packing, or holding of dietary supplements.[5] Therefore, we did not consider any activity/food combinations related to the manufacturing, processing, packing, or holding of dietary supplements.

Alcoholic beverages. Consistent with section 116 of FSMA, we did not consider activity/food combinations that would be solely associated with manufacturing, processing, packing or holding alcoholic beverages.

B. FDA's Clarification of Activities Conducted on Farms

Section 1.227 in the section 415 registration regulations includes definitions that are relevant to the scope of those regulations, including definitions for types of establishments (i.e., "facility" and "farm") and types of activities (i.e., "holding," "manufacturing/processing," "packaging," and "packing"). In relevant part, these definitions play a role in determining whether an establishment is a facility that must register with FDA and implement a provision (in section 415(b)(1) of the FD&C Act) exempting "farms" from the registration requirement in section 415. Table 19 describes key definitions applicable to the current regulatory framework that determines what establishments are required to register with FDA under section 415 of the FD&C Act and, thus, would be subject to the requirements of section 418 of the FD&C Act for hazard analysis and risk-based preventive controls.

Table 19. Key Definitions Applicable to the Current Legal and Regulatory Framework under Sections 415 and 418 of the FD&C Act

Provision of the Section 415 Registration Regulations or the FD&C Act	Definition
§ 1.227(b)(2)	For the purposes of section 415 of the FD&C Act, a facility is, in relevant part, any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States.
§ 1.225	The owner, operator, or agent in charge of either a domestic or foreign facility must register in accordance with the section 415 registration regulations if the facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless the facility qualifies for one of the exemptions in § 1.226.

[5] Moreover, as is the case with seafood and juice, even if such activity/food combinations exist, we see no reason that FDA should consider exempting or modifying the requirements of section 418 for the owner, operator, or agent in charge of a facility that is required to be in compliance with certain requirements for dietary supplements and is not in compliance.

Provision of the Section 415 Registration Regulations or the FD&C Act	Definition
§ 1.226(b)	Farms are not subject to the registration requirement in § 1.225.
§ 1.227(b)(3)	Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.
§ 1.227(b)(5)	Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
§ 1.227(b)(6)	Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.
§ 1.227(b)(8)	Packaging (when used as a verb) means placing food into a container that directly contacts food and that the consumer receives.
§ 1.227(b)(9)	Packing means placing food into a container other than packaging the food.
Section 418(o)(2) of the FD&C Act	A facility that is subject to the requirements of section 418 of the FD&C Act is a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act.

As directed by section 103(c)(1)(B) of FSMA, FDA is initiating rulemaking to clarify what activities would be considered manufacturing, processing, packing, and holding for purposes of section 415 of the FD&C Act. As part of that rulemaking, FDA developed a definition for a "mixed-type facility" as an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. 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.

As part of the rulemaking required by section 103(c)(1)(C) of FSMA, FDA also is initiating rulemaking to revise definitions, in the section 415 registration regulations, that classify activities on-farm and off-farm. As part of that rulemaking, FDA developed the following organizing principles to explain and clarify the basis for these proposed revisions to the definitions. We describe those organizing principles in Table 20. A full

discussion of how FDA developed these organizing principles is being published in the *Federal Register* and is outside the scope of this document.

Table 20. Summary of Organizing Principles Regarding Classification of Activities On-Farm and Off-Farm

No.	Organizing Principle
1	The basic purpose of farms is to produce RACs and RACs are the essential products of farms.
2	Activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs,* removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of "farm" in §§ 1.227.
3	Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food.
4	Activities farms may perform on others' RACs should appropriately be classified as manufacturing, processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.
5	Manufacturing, processing, packing, or holding food-- whether RACs or processed foods, from any source-- for consumption on the farm should remain within the farm definition.

* For the purposes of this discussion, FDA refers to RACs grown or raised on a farm or another farm under the same ownership as a farm's "own RACs," in contrast to RACs grown on a farm under different ownership, which FDA refers to as "others' RACs."

As part of the rulemaking required by section 103(c)(1)(C) of FSMA, based on these organizing principles certain definitions in the section 415 registration regulations would be revised. Appendix 3 includes a comparison of the existing definitions and the proposed revisions to those definitions. Table 21 provides examples of how activities would be classified under the proposed revisions to the definitions.

Table 21. Classification of Activities Conducted Off-Farm and On-Farm (Including Farm Mixed-Type Facilities)

Classification	Off-Farm	On-Farm (Including Farm Mixed-Type Facilities)
Harvesting	*Notes*: Not applicable. Harvesting is a classification that only applies on farms and farm mixed-type facilities.	*Notes*: Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as food. Harvesting is limited to activities performed on RACs on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that change a RAC into processed food. Activities that are harvesting are within the farm definition.

Classification	Off-Farm	On-Farm (Including Farm Mixed-Type Facilities)
Harvesting	*Examples:* Not applicable.	*Examples*: Activities that fit this definition when performed on a farm's "own RACs" (a term we use to include RACs grown or raised on that farm or another farm under the same ownership) include gathering, washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, and cooling. **These activities, performed on a farm's own RACs, are inside the farm definition.**
Packing	*Notes*: Placing food in a container other than packaging the food (where packaging means placing food into a container that directly contacts the food and that the consumer receives).	*Notes*: Placing food in a container other than packaging the food (using the same definition of packaging), or activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on that farm or another farm under the same ownership for storage or transport. Packing does not include activities that change RAC into a processed food. Activities that are packing are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
Packing	*Examples*: Putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates).	*Examples*: Activities that fit the definition of packing when performed on a farm's own RACs include packaging, mixing, coating with wax/oil/resin for the purpose of storage or transport, stickering/labeling, drying for the purpose of storage or transport, and sorting/grading/culling. **These activities, performed on a farm's own RACs, are inside the farm definition.** Activities that fit the definition of packing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, include putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates) -- the same activities that fit the definition of packing off farm. **These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.**

Classification	Off-Farm	On-Farm (Including Farm Mixed-Type Facilities)
Holding	*Notes*: Storage of food.	*Notes*: Storage of food, or activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on that farm or another farm under the same ownership. Holding does not include activities that change a RAC into a processed food. Activities that are holding are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
Holding	*Example:* Storing food, such as in a warehouse.	*Examples*: activities that fit the definition of holding when performed on a farm's own RACs include fumigating during storage, and storing food, such as in a warehouse. **These activities, performed on a farm's own RACs, are inside the farm definition.** An activity that fit the definition of holding when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, is storing food, such as in a warehouse -- the same activity that fits the definition of holding off farm. **This activity, performed on food other than a farm's own RACs, is outside the farm definition unless done on food for consumption on the farm.**
Manufacturing/ Processing	*Notes*: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food. Includes packaging (putting food in a container that directly contacts food and that consumer receives).	*Notes*: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food; except for things that fall into the categories of harvesting, packing, or holding (see rows above). Activities that are manufacturing/processing are outside the farm definition unless done on food for consumption on the farm.

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

APPENDIX 2. RISK CHARACTERIZATION OF ACTIVITY/FOOD COMBINATIONS ARRANGED FOR REGULATORY PURPOSES

In section VI.E.2 of this document, we characterize the risk of activity/food combinations without the regulatory overlay of the definition of "farm" and the associated definitions of manufacturing, processing, packing, and holding. Doing so focused the risk characterization analysis on the risk of the activity/food combinations themselves. In Appendix 2 of this document, we add the regulatory overlay of the definition of "farm" and arrange our results in groups shaped by the applicable regulatory factors and the resulting activity classifications.

A. Regulatory Groups

The groups for regulatory purposes are:

- Type 1: Packing and holding activities that might be conducted on a farm on food not grown, raised, or consumed on that farm or another farm under the same ownership;
- Type 2: Manufacturing and processing activities that might be conducted on a farm on the farm's own RACs for distribution into commerce; and
- Type 3: Manufacturing and processing activities that might be conducted on a farm on food other than the farm's own RACs for distribution into commerce.

B. Regulatory Group Type 1

Table 22 presents a matrix of Type 1 packing and holding activities that might be conducted on a farm on specific food categories not grown, raised, or consumed on that farm or another farm under the same ownership. Under these circumstances, packing and holding activities are outside the farm definition and, thus, trigger the section 415 registration requirement and the new requirements under section 418 of the FD&C Act for hazard analysis and risk-based preventive controls. These packing and holding activities outside the farm definition include:

- Packing or holding others' RACs for distribution into commerce (not for consumption on the farm or another farm under the same ownership);
- Packing or holding others' processed foods for distribution into commerce; and
- Packing or holding processed foods made on the farm for distribution into commerce.

The risk characterization of these packing and holding activity/food combinations tracks the risk characterization of the activity/food combinations presented in section VI.E.2 of this document.

Table 22. Is a Type 1 Packing or Holding Activity/Food Combination Low Risk?

	Cocoa Beans and Coffee Beans (Raw or Roasted)	Grain and Grain Products	Honey (Raw and Pasteurized) and Maple Sap / Maple Syrup	Intact Fruits and Vegetables	Peanuts and Tree Nuts	Sugarcane, Sugar Beets and Sugar	Other Foods [1]
Packing/Re-Packing (including conveying and weighing incidental to packing/re-packing)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sorting, Culling & Grading (incidental to packing or storing)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Storing (Ambient cold, or controlled atmosphere)	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[1] "Other Foods" include cocoa products; hard candy, fudge, taffy, and toffee; jams, jellies and preserves; and soft drinks and carbonated water.

C. Regulatory Group Type 2

Table 23 presents a matrix of manufacturing and processing activities that might be conducted on a farm on the farm's own RACs for distribution into commerce. The risk characterization of these manufacturing and processing activity/food combinations tracks the risk characterization of the activity/food combinations presented in section VI.E.2 of this document. However, the list of activities in Table 23 is shorter than the list of activities in Table 16 and Table 17 because, as described in Appendix 1, some of the activities listed in Table 16 and Table 17 would not be manufacturing or processing activities when conducted on a farm on the farm's own RACs for distribution into commerce.

Table 23. Is a Type 2 Manufacturing or Processing Activity/Food Combination Low Risk?

	Raw Coffee Beans and Raw Cocoa Beans	Intact Fruits and Vegetables	Grains	Raw Honey	Maple Sap	Raw Peanuts and Raw Tree Nuts	Other RACs[1]
Acidification/Pickling/ Fermenting[2]		No	[3]				
Artificial ripening		Yes					

	Raw Coffee Beans and Raw Cocoa Beans	Intact Fruits and Vegetables	Grains	Raw Honey	Maple Sap	Raw Peanuts and Raw Tree Nuts	Other RACs[1]
Baking/Boiling/Cooking/ Evaporation/Roasting	No	No			Yes	No	
Canning/Bottling/ Jarring (packaging that involves processing, e.g., water bath canning, pressure canning)		No					
Coating (coatings other than wax, oil, or resin used for the purposes of storage/ transportation)		Yes				Yes	
Cutting/Coring/Chopping / Shredding/Slicing/Peeling		No				Yes	
Dehydration/ Drying (that creates a distinct commodity)		Yes					
Extraction[4]			Yes				
Grinding/Milling/Cracking/ Crushing			Yes			Yes	
Making jams/jellies/ preserves from acid foods		Yes					
Making jams/jellies/ preserves from low-acid foods		No					
Making sugar							Yes
Salting						Yes	
Sulfiting		No					

[1] "Other RACs" includes sugarcane and sugar beets. In addition the primary ingredient may be water.
[2] "Fermenting" in this table does not include fermenting a farm's own raw cocoa or coffee beans because this activity/food combination is generally part of harvesting and therefore within the farm definition.
[3] Blank cells indicate the activity generally does not apply to the food.
[4] "Extraction" in this table does not include extracting a farm's own raw honey because this activity/food combination is generally part of harvesting and therefore within the farm definition.

D. Regulatory Group Type 3

Table 24and Table 25 show manufacturing and processing activities that might be conducted on a farm on food other than the farm's own RACs for distribution into commerce. These include:

- Manufacturing and processing activities on others' RACs for distribution into commerce; and

- Manufacturing and processing activities on processed foods from any source for distribution into commerce.

The risk characterization of these manufacturing and processing activity/food combinations tracks the risk characterization of the activity/food combinations presented in section VI.E.2 of this document. Our use of two tables (i.e., Table 24and Table 25) rather than a single table reflects practicalities associated with large amounts of information rather than any substantive purpose. We simply present half of the food categories in Table 24 and the remaining half of the food categories in Table 25.

Table 24. Is a Type 3 Manufacturing or Processing Activity/Food Combination Low Risk?

	Cocoa Beans	Coffee Beans	Intact Fruits and Vegetables	Grain	Grain Products
Acidification/Pickling/Fermenting	Yes	Yes	No	[1]	
Artificial ripening			Yes		
Baking/Boiling/Cooking/ Concentration/ Evaporation/Roasting	No	No	No		No
Canning/Bottling/ Jarring (packaging that involves processing, e.g., water bath canning, pressure canning)			No		
Coating (coatings other than wax, oil, or resin used for the purposes of storage/transportation)			Yes		
Cooling - Air			Yes		
Cooling-Water			No		
Cutting/Coring/Chopping/Shredding/ Slicing/Peeling/ Trimming			No		
Dehydration/ Drying (for storage/transport or for creating a distinct commodity)	Yes	Yes	Yes	Yes	Yes
Extraction				Yes	Yes
Filtration					
Grinding/Milling/Cracking/Crushing	Yes	Yes		Yes	Yes
Labeling (including stickering)	Yes	Yes	Yes	Yes [2]	Yes [2]
Making hard candy, fudge, taffy, toffee					
Making cocoa products from roasted cocoa beans	Yes				
Making jams/jellies/preserves from acid foods			Yes		
Making jams/jellies/preserves from low-acid foods			No		
Making soft drinks and carbonated water					
Making sugar					
Mixing/Blending	Yes	Yes	Yes	Yes	Yes
Packaging other than modified atmosphere or vacuum packaging	Yes	Yes	Yes	Yes	Yes

	Cocoa Beans	Coffee Beans	Intact Fruits and Vegetables	Grain	Grain Products
Packaging – Modified atmosphere or vacuum			No		
Salting					
Sifting				Yes	Yes
Shelling/hulling/winnowing	Yes		Yes		
Sorting, Culling & Grading (other than when incidental to packing or storage)	Yes	Yes	Yes	Yes	Yes
Sulfiting			No		
Treating against pests other than during growing, e.g. fumigation	Yes	Yes	Yes	Yes	Yes
Washing/rinsing			No		
Waxing (wax, oil, or resin used for the purposes of storage/transportation)			Yes		

[1] Blank cells indicate the activity generally does not apply to the food

[2] Labeling of foods bearing or containing wheat would not be low risk if the food is not a single-ingredient food or is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration.

Table 25. Is a Type 3 Manufacturing or Processing Activity/Food Combination Low Risk?

	Honey	Maple Sap for Syrup and Maple	Peanuts and Tree Nuts	Other [1]
Acidification/Pickling/Fermenting				[2]
Artificial ripening				
Baking/Boiling/Cooking/ Concentration/ Evaporation/Roasting		Yes	No	
Canning/Bottling/ Jarring (packaging that involves processing, e.g., water bath canning, pressure canning)				
Coating (coatings other than wax, oil, or resin used for the purposes of storage/transportation)			Yes	
Cooling - Air				
Cooling-Water				
Cutting/Coring/Chopping/Shredding/ Slicing/Peeling/ Trimming			Yes	
Dehydration/ Drying (for storage/transport or for creating a distinct commodity)			Yes	
Extraction	Yes			
Filtration	Yes	Yes		
Grinding/Milling/Cracking/Crushing			Yes	
Labeling (including stickering)	Yes	Yes	Yes [3]	Yes [4]
Making hard candy, fudge, taffy, toffee				Yes
Making cocoa products from roasted cocoa beans				Yes
Making jams/jellies/preserves from acid foods				Yes
Making jams/jellies/preserves from low-acid foods				No
Making soft drinks and carbonated water				Yes

	Honey	Maple Sap for Syrup and Maple	Peanuts and Tree Nuts	Other [1]
Making sugar				Yes
Mixing/Blending	Yes	Yes	Yes	
Packaging other than modified atmosphere or vacuum packaging	Yes	Yes	Yes	Yes
Packaging – Modified atmosphere or vacuum			Yes	
Salting			Yes	
Sifting				
Shelling/hulling/winnowing			Yes	
Sorting, Culling & Grading (other than when incidental to packing or storage)	Yes	Yes	Yes	Yes
Sulfiting				
Treating against pests other than during growing, e.g. fumigation			Yes	
Washing/rinsing				
Waxing (wax, oil, or resin used for the purposes of storage/transportation)				

[1] "Other" includes cocoa products; hard candy, fudge, taffy, and toffee; jams, jellies, and preserves; soft drinks and carbonated water; and sugarcane, sugar beets and sugar

[2].Blank cells indicate the activity generally does not apply to the food.

[3] Labeling of foods bearing or containing peanuts, tree nuts and wheat would not be low risk if the food is not a single-ingredient food or is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration.

[4] Labeling of hard candy, fudge, taffy and toffee bearing or containing allergens, e.g. milk, peanuts, tree nuts, would not be low risk because the food is not a single-ingredient food and is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration. Labeling of cocoa products other than milk chocolate would be low risk, but milk chocolate is in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration.

E. Answer to Question 9 in the Risk Assessment

Question 9: Which activity/food combinations are low risk, i.e., what on-farm activity/food combinations are not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences or death or serve as preventive controls (interventions) to significantly minimize or prevent a hazard that could cause serious adverse health consequences or death?

In section VII.A of this RA, we answer Question 9 without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/food combinations themselves. Here, we add that regulatory overlay and group the answers to Question 9 based on the applicable regulatory factors and the resulting activity classifications.

Based on the information in Table 16, Table 17and Table 22, and for the purposes of the analysis required by section 103(c)(1) of FSMA, the RA identified the following low-risk Type 1 packing and holding activity/food combinations when conducted on a farm on food not grown, raised, or consumed on that farm or another farm under the same ownership. The same activities performed on a farm's own RACs or on food consumed

on the farm or another farm under the same ownership would be within the farm definition and therefore outside the scope of the analysis required by section 103(c)(1) of FSMA.

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

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

Based on the information in Table 16, Table 17, Table 18, and Table 23, and for the purposes of the analysis required by section 103(c)(1) of FSMA, the RA identified the following low-risk manufacturing or processing activity/food combinations when conducted on a farm on the farm's own RACs for distribution into commerce. Some activities that would be manufacturing or processing when performed on foods other than a farm's own RACs are not manufacturing or processing when performed on a farm's own RACs (because when performed on the farm's own RACs, those activities are instead classified as packing, holding, or harvesting and are within the farm definition, making them outside the scope of the analysis required by section 103(c)(1) of FSMA). As a result, this list of low-risk manufacturing and processing activity/food combinations for a farm's own RACs is shorter than the list for low risk manufacturing and processing for foods other than a farm's own RACs.

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

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

Based on the information in Table 16, Table 17, Table 18, Table 24, and Table 25, and for the purposes of the analysis required by section 103(c)(1))(C) of FSMA, the RA identified the following low-risk manufacturing and processing activity/food combinations when conducted on a farm on food other than the farm's own RACs for distribution into commerce.

- Making hard candy, fudge, taffy, toffee;
- Making cocoa products from roasted cocoa beans;
- Making honey;
- Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- Making maple syrup;
- Making soft drinks and carbonated water;
- Making sugar from sugarcane and sugar beets;
- Artificial ripening of intact fruits and vegetables;
- Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
- Chopping peanuts and tree nuts;
- Cooling intact fruits and vegetables using cold air;
- Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), grains and grain products, peanuts and tree nuts, coffee beans, and cocoa beans;
- Extracting oils from grains (e.g., corn, soybeans, oilseeds);
- Fermenting cocoa beans and coffee beans;
- Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal), coffee beans, cocoa beans, and peanuts and tree nuts (e.g., making ground peanuts);
- Labeling (including stickering) intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), intact single-ingredient peanuts or tree nuts (shelled and unshelled), honey, maple sap, maple syrup, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, hard candy, cocoa products from roasted cocoa beans (other than milk chocolate), jams/jellies/preserves, and soft drinks and carbonated beverages;
- Mixing intact fruits and vegetables, grain and grain products, peanuts, tree nuts, honey, maple sap and maple syrup, coffee beans, and cocoa beans;
- Packaging intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grains and grain products; peanuts and tree nuts (including modified atmosphere or vacuum packaging); honey; maple syrup; sugarcane, sugar beets and sugar; coffee beans; cocoa beans; cocoa products, hard candy, fudge, taffy, toffee; jams, jellies and preserves; and soft drinks and carbonated water;

- Salting peanuts and tree nuts;
- Sifting grains and grain products;
- Shelling/ hulling intact fruits and vegetables (e.g., dried peas and beans), peanuts, tree nuts, and cocoa beans (i.e., winnowing);
- Sorting, culling and grading (other than when incidental to packing or storage) intact fruits and vegetables, grain and grain products, peanuts, tree nuts, sugarcane, sugar beets, sugar, coffee beans, cocoa beans, cocoa products, hard candy, fudge, taffy, toffee, honey, maple sap, maple syrup, soft drinks and carbonated water, jams, jellies, and preserves;
- Treating intact fruits and vegetables, grains and grain products, peanuts, tree nuts, coffee beans and cocoa beans against pests other than during growing, e.g., fumigation; and
- Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

APPENDIX 3. ABBREVIATIONS, ACRONYMS, AND GLOSSARY

Abbreviation/Acronym	Definition
CDC	Centers for Disease Control and Prevention
CGMP	Current Good Manufacturing Practice
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FSMA	FDA Food Safety Modernization Act
HACCP	Hazard Analysis and Critical Control Point
HHS	Department of Health and Human Services
RA	Risk Assessment
RFR	Reportable Food Registry
SAHCOD hazard	A hazard for which there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans

Term	Definition for the Purpose of this Risk Assessment
Inherent control	In making the food the hazard is controlled, and it is highly unlikely that the food will be made in a way that the hazard is not adequately addressed.
Reasonably likely to cause serious adverse health consequences or death	There is a reasonable probability that use of, or exposure to, a food containing a hazard will cause serious adverse health consequences or death to humans.

Term	Current Regulatory/Legal Definition	Proposed Revision to Regulatory Definition
Farm	A facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term “farm” includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. (21 CFR 1.227(b)(3))	A facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes: (1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Term	Current Regulatory/Legal Definition	Proposed Revision to Regulatory Definition
Holding	Storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. (21 CFR 1.227(b)(5))	Storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act.
Major Food Allergen	Section 201(qq) of the FD&C Act 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.	Not applicable
Manufacturing/ processing	Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. (21 CFR 1.227(b)(6))	Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Term	Current Regulatory/Legal Definition	Proposed Revision to Regulatory Definition
Mixed-Type Facility	Not applicable	An establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.
Packaging	Placing food into a container that directly contacts food and that the consumer receives (when used as a verb) (21 CFR 1.227(b)(8))	No proposed revision
Packing	Placing food into a container other than packaging the food. (21 CFR 1.227(b)(9))	Placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act.