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

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

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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 involving specific foods that 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:

- Boiling gums, latexes, and resins;
- Chopping/coring/cutting/peeling/pitting/shredding/slicing acid fruits and vegetables with pH<4.2 (e.g., cutting lemons, limes), baked goods (e.g., slicing bread), dried fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact dried basil, intact dried mint), game meat jerky, gums/ latexes/ resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts)
- Coating dried fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens), peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens);
- Dehydration/drying (that includes additional manufacturing or is performed on processed foods) of other fruit and vegetable products with pH<4.2 (e.g., cut fruit and vegetables with pH<4.2), and other herb and spice products (e.g., chopped fresh herbs, including tea);
- Extracting (including by pressing, by distilling, by solvent extraction) dried herbs and other spices (e.g., dried mint), fresh herbs (e.g., mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped, fresh mint);
- Freezing acid fruits and vegetables with pH<4.2 and other fruit and vegetable products with pH <4.2 (e.g., cut fruits and vegetables);
- Grinding/milling/cracking/crushing baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried fruit and vegetable products (e.g., raisins, dried legumes), dried herbs and other spices (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products that are processed foods (e.g., dried, pitted dates), other grain products that are processed foods (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts);

- Labeling baked goods that do not contain food allergens (e.g., crackers that do not contain wheat, milk, egg, or nuts), candy that does not contain food allergens (e.g., maple candy and maple cream), cocoa beans (roasted), cocoa products that do not contain food allergens, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products that do not contain food allergens (e.g. corn meal) or that are single ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products that are single ingredient, are in forms in which the consumer can reasonably be expected to recognize the allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours), processed seeds (e.g., roasted pumpkin or roasted sunflower seeds), soft drinks and carbonated water, sugar/syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the allergen(s) without label declaration), vinegar, any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Making baked goods from milled grain products (e.g., breads and cookies);
- Making candy (including boiling, evaporation, mixing) from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream);
- Making cocoa products (including grinding, mixing, conching, tempering) from roasted cocoa beans;
- Making dried pasta from grains;
- Making jams, jellies and preserves (including cutting/mashing, boiling, mixing, canning) from acid fruits and vegetables with a pH $\leq$ 4.6 (e.g., rhubarb, strawberries) ;
- Making molasses and treacle (including extracting, boiling, concentrating, evaporating) from sugar beets, sugarcane;
- Making oat flakes from grains;
- Making popcorn from grains;
- Making snack chips from fruits and vegetables (e.g., plantains, potatoes);
- Making soft drinks and carbonated water (including flavoring, carbonating) from sugar, syrups, water;
- Making syrups and sugars (including extracting, boiling, concentrating, evaporating, crystalizing) from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), sap (e.g., agave, birch, maple, palm), sugar beets, and sugarcane;
- Making trail mix or granola from cocoa products (e.g., chocolate), dried fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and seeds (processed) (provided that peanut and tree nut products, and seeds (processed) have been treated to significantly minimize pathogens);
- Making vinegar (including fermenting) from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt);
- Mixing/blending baked goods (e.g., cookie types), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried fruit and vegetable products (e.g., raisins, dried

currants and dried blueberries), dried herbs and other spices (e.g., dried intact basil and dried intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried sliced peaches); other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar/syrups, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

- Packaging (including modified atmosphere or vacuum packaging) baked goods, candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds, soft drinks and carbonated water, sugar/syrups, trail mix and granola, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Packing/re-packing baked goods, candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., flours made from legumes, pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs and herbal extracts), peanut and tree nut products, processed seeds, soft drinks and carbonated water, sugar/syrups, trail mix and granola, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Pasteurizing honey;
- Roasting/toasting baked goods (e.g., toasting bread for croutons);
- Salting other grain products (e.g., soy nuts), peanut and tree nut products, processed seeds;
- Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), peanut and tree nut products (e.g., peanut flour, almond flour);
- Storing/holding (cold, ambient or controlled atmosphere) baked goods, candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jam/ jellies/ preserves, milled grain products (e.g., flour, bran, corn, meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted dried fruits, sliced dried apples, snack chips), other grain products (e.g., popcorn), other herb and spice products, peanut and tree nut products, processed seeds, soft drinks and carbonated water, sugar/syrups, trail mix and granola, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).

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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 are farms, but that also conduct activities outside the "farm" definition 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." We previously issued for public comment a document entitled "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (Draft RA) (78 FR 3824, January 16, 2013; Docket No. FDA-2012-N-1258). The activities listed in the Draft RA were those on-farm activities that were outside the farm definition as it existed at the time FSMA became law. Therefore at that time all such activities triggered 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. FDA has since revised the farm definition to include some of the listed activities within the farm definition, thereby narrowing the scope of the activity/food combinations that need to be considered in this risk assessment. (See Appendix 1 for the revised definition of "farm," harvesting, holding, packing, and manufacturing/processing.)

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.

Since issuing the Draft RA, we have considered the following information with respect to its impact on the Draft RA:

- Revisions that FDA proposed to definitions that affect the regulatory status of activities that take place on farm in rulemaking entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," (proposed human preventive controls rule; Docket No. FDA-2011-N-0920):
    - Proposed rule, 78 FR 3646, January 16, 2013;
    - Supplemental notice of proposed rulemaking (79 FR 58524, September 29, 2014).
- Comments submitted to Docket FDA-2012-N-1258 on the Draft RA;
- Comments submitted to Docket FDA-2011-N-0920 on the proposed rule relevant to activities conducted on foods on farms; and
- A Food Processing Sector Study on domestic establishments co-located on farms, (Capogrossi et al., 2015), updated from the Food Processing Sector Study available in 2011 (Muth et al., 2011).

We revised the Draft RA as appropriate after considering all of this information. A summary of key changes in this final risk assessment compared to the draft risk assessment is available (FDA, 2015).

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, harvesting and packing fruits and vegetables on farm) 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.

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 FDA's long-standing current good manufacturing practice (CGMP) requirements 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; such facilities must comply with applicable 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:

- Baked goods that require time/temperature control for safety (e.g., cream-filled pastries)
- Eggs;
- Game meat and game meat products that require time/temperature control for safety;
- Honey infused with fresh herbs[1];
- Low-acid[2] cut fruits and vegetables;
- Milk and milk products (e.g., butter, cheese, cream, and ice cream mixes); and
- Oils infused with fruits and vegetables with pH>4.6 or with fresh herbs (e.g., fresh garlic in oil)[3].

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 Model Food Code (FDA, 2013a).) Additionally, we considered that when a food requires refrigeration to control pathogens (Institute of Food Technologists, 2001b; FDA, 2013d; FDA, 2013b; FDA, 2013e; FDA, 2013c), temperature control is necessary at all steps, and therefore no activity involving such food would be low risk. Thus, activities involving baked goods that require time/temperature control for safety, eggs, game meat and game meat products that require time/temperature control for safety, honey infused with fresh herbs, low-acid cut produce, milk and a number of milk products, and oils infused with fruits and vegetables with pH>4.6 or with fresh herbs 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, 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 (including radiological) and physical hazards.

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[1] Fresh herbs have a moisture content that could allow sporeforming pathogens such as *C. botulinum* to grow in an anaerobic environment; honey could create such an environment.

[2] Low-acid foods have a pH greater than 4.6; acid foods are those that have a natural pH of 4.6 or below. This pH has long been used to separate foods that may support growth of *C. botulinum* from those that do not. However, other pathogens are capable of growing at pH values of 4.6 or below, e.g., *E. coli* O157:H7 (Conner and Kotrola, 1995) and *Salmonella* (Chung and Goepfert, 1970; Jung and Beuchat, 2000) have been shown to grow at pH 4.0 in laboratory media under certain conditions. The minimum pH at which growth of pathogens occurs is higher in foods than the 4.0 minimum in laboratory media; the Food Code considers foods with a pH<4.2 to not require time/temperature control for safety (non-TCS food) (Food Code 2013d).

[3] Fruits and vegetables with pH>4.6, including fresh herbs, in oil provide conditions (e.g., a_w and anaerobic conditions) that present a risk of toxin production by *C. botulinum* (Nummer et al., 2011; Solomon et al. 1991).

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 known or reasonably foreseeable hazards[4] associated with the foods manufactured, processed, packed, or held by a farm mixed-type facility?

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 in these foods a hazard that is a known or reasonably foreseeable biological hazard and that is reasonably likely to cause serious adverse health consequences or death?

Question 6: What interventions significantly minimize or prevent in these foods a hazard that is a known or reasonably foreseeable hazard 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:

[4] A known or reasonably foreseeable hazard is a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

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 SAHCODH hazard); and
b) Does not significantly minimize or prevent a SAHCODH 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 SAHCODH hazard; and
  - #2b (activity does not significantly minimize or prevent a SAHCODH 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.

- Although the final RA considers the additional information, submitted to Docket Nos. FDA-2012-N-1258 and FDA- 2011-N-0920, about activities conducted on farms, we continue to have limited data on the types of activity/food combinations specifically 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 and chemical (including 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, including for specific susceptible populations, for hazard characterization for all pathogens in all foods, in particular for foods that may be manufactured, processed, packed, or held by small and very small farm mixed-type facilities, and 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 (including radiological) and physical 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 (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);
- Requesting information from outside experts (FDA Memorandum, 2011a; FDA Memorandum, 2012b);
- 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

- Considering information from a "Food Processing Sector Study" on co-location of farms with food processing facilities ("Food Processing Sector Study"). A 2011 version of this study was available for the purpose of the draft RA (Muth et al., 2011). For the final RA, we considered an updated Food Processing Sector Study (Capogrossi et al., 2015).

We do not have specific 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 requested and received comments on other activity/food combinations that should be considered (Docket No. FDA-2012-N-1258, 78 FR 3824; and Docket FDA-2011-N-0920, 78 FR 3646). We updated the Draft RA to reflect these additional activity/food combinations.

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 alcoholic beverages, baked goods that require time/temperature control for safety, dietary supplements, eggs, game meat and game meat products that require time/temperature control for safety, honey infused with fresh herbs, juice, low-acid cut fruits and vegetables, milk and milk products, oils infused with fruits and vegetables with pH>4.6 or with fresh herbs, or seafood), 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, drying/dehydrating grapes to produce raisins) that are always within the farm definition.

Table 1 lists the resulting activity/food combinations that we identified as likely to be conducted by farm mixed-type facilities. Table 1:

- Does not include activity/food combinations that are always within the farm definition (e.g., growing fruits and vegetables, drying/dehydrating raw agricultural commodities (RACs) without additional manufacturing/processing, such as drying grapes to make raisins).
- Includes activities that encompass multiple steps (e.g., making jams, jellies and preserves may involve steps such as cutting, mashing, boiling, mixing, and canning) and groups these steps to better identify the end product. As such, activities that are encompassed within the making of a particular product are not listed as separate activities within the table. (For example, because making syrup includes boiling sap, boiling sap is not listed as a separate activity.)
- Breaks the broad categories of foods into smaller groups. These smaller groups are denoted by footnotes in the table (on first mention), and are described within their broader food categories at the end of the table.

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 and vegetables

Activity	Food
Boiling	Fruits and vegetables; gums, latexes, and resins; peanuts
Canning/bottling/jarring (packaging that includes additional manufacturing/processing)	Fruits and vegetables
Chopping/Coring/Cutting/Peeling/ Pitting/Shredding/Slicing	Baked goods (e.g., to make bread crumbs); dried fruit and vegetable products that are processed foods; dried herbs and other spices that are processed foods[a]; fresh herbs; fruits and vegetables; game meat jerky; gums, latexes, and resins; other grain products that are processed foods (e.g., making cereal crumbs); peanuts and tree nuts; peanut and tree nut products that are processed foods
Coating (other than coating fruits and vegetables with wax/oil/resin)	Dried fruit and vegetable products that are processed foods; fruits and vegetables (e.g., adding caramel to apples, coating strawberries and raisins with chocolate); other fruit and vegetable products that are processed foods[a] (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate, coating apples on a stick with caramel); other grain products that are processed foods (e.g., popcorn); peanuts and tree nuts; and peanut and tree nut products that are processed foods[a] (e.g., adding seasoning[1])
Cooking	Fruits and vegetables
Dehydration/ Drying (that includes additional manufacturing/processing or is performed on processed foods)	Other fruit and vegetable products that are processed foods (e.g., cut acid fruits and vegetables); other herb and spice products that are processed foods[a]
Extracting (including by pressing, by distilling, by solvent extraction)	Dried herbs and other spices that are processed foods; fresh herbs; fruits and vegetables (e.g., olives, avocados); grains[b]; other herb and spice products that are processed foods
Freezing	Fruits and vegetables; other fruit and vegetable products that are processed foods

Activity	Food
Grinding/Milling/Cracking/Crushing	Baked goods (e.g., crackers); cocoa beans (roasted); coffee beans (roasted); dried fruit and vegetable products that are processed foods; dried herbs and other spices that are processed foods; grains; other fruit and vegetable products that are processed foods (e.g., dried, pitted dates); other grain products that are processed foods; other herb and spice products that are processed foods; peanuts and tree nuts; peanut and tree nut products that are processed foods
Labeling	Baked goods[b]; candy[c]; cocoa beans (roasted); cocoa products; coffee beans (roasted); game meat jerky; gums, latexes, and resins that are processed foods; honey (pasteurized); jams, jellies, and preserves; milled grain products[b]; molasses and treacle; oils; other fruit and vegetable products that are processed foods[a]; other grain products that are processed foods[b]; other herb and spice products that are processed foods; peanut and tree nut products that are processed foods; seeds for direct consumption that are processed foods[a]; soft drinks and carbonated water; sugar; syrups; trail mix and granola[c]; vinegar; any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).
Making baked goods (including mixing, baking)	Milled grain products
Making candy (including boiling, evaporation, mixing)	Peanuts and tree nuts (e.g., nut brittles); sugar; syrups; saps (e.g., maple candy)
Making cocoa products (including grinding, mixing, conching, tempering)	Cocoa beans (roasted)
Making dried pasta	Grains
Making jams/jellies/preserves from acid fruits and vegetables (including cutting/mashing, boiling, mixing, canning)	Fruits and vegetables (e.g., rhubarb, strawberries)
Making jams/jellies/preserves from low-acid fruits and vegetables (including cutting/mashing, boiling, mixing, canning)	Fruits and vegetables
Making molasses and treacle (including extracting, boiling, concentrating, evaporating)	Sugar beets, sugarcane

Activity	Food
Making oat flakes	Grains
Making popcorn	Grains
Making snack chips	Fruits and vegetables
Making soft drinks and carbonated water (including flavoring, carbonating)	Sugar; syrups; water
Making syrups and sugars (including extracting, boiling, concentrating, evaporating)	Fruits and vegetables (e.g., dates); grains (e.g., rice, sorghum); other grain products that are processed foods (e.g., malted grains such as barley); sap (e.g., agave, birch, maple, palm); sugar beets; sugarcane
Making trail mix or granola	Cocoa products (e.g., chocolate); dried fruit and vegetable products that are processed foods[a]; other fruit and vegetable products that are processed foods; other grain products that are processed foods; peanuts and tree nuts; peanut and tree nut products that are processed foods; seeds for direct consumption; seeds for direct consumption that are processed foods
Making vinegar (including fermenting)	Fruits and vegetables; other fruit and vegetable products that are processed foods (e.g., apple cider, fruit wines); other grain products that are processed foods (e.g., malt)
Malting	Grains
Mixing/Blending	Baked goods; candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee); cocoa beans (roasted); coffee beans (roasted); dried fruit and vegetable products that are processed foods (e.g., different types of raisins); dried herbs and other spices that are processed foods; honey (pasteurized); milled grain products; other fruit and vegetable products that are processed foods; other grain products that are processed foods; other herb and spice products that are processed foods; peanut and tree nut products that are processed foods; sugar; syrups; vinegar; any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)

Activity	Food
Packaging (including modified atmosphere or vacuum packaging)[5]	Baked goods; candy; cocoa beans (roasted) and cocoa products; coffee beans (roasted); game meat jerky; gums, latexes, and resins that are processed foods; honey (pasteurized); jams, jellies and preserves; milled grain products; molasses and treacle; oils; other fruit and vegetable products that are processed foods; other grain products that are processed foods; other herb and spice products that are processed foods; peanut and tree nut products that are processed foods; seeds for direct consumption that are processed foods; soft drinks and carbonated water; sugar; syrups; trail mix and granola; vinegar; any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).
Packing/Re-Packing, including activities incidental to packing/re-packing (e.g., activities performed for the safe or effective packing of that food)	Baked goods; candy; cocoa beans (roasted) and cocoa products; coffee beans (roasted); game meat jerky; gums, latexes, and resins that are processed foods; honey (pasteurized); jams, jellies and preserves; milled grain products; molasses and treacle; oils; other fruit and vegetable products that are processed foods; other grain products that are processed foods; other herb and spice products that are processed foods; peanut and tree nut products that are processed foods; seeds for direct consumption that are processed foods; soft drinks and carbonated water; sugar; syrups; trail mix and granola; vinegar; any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).
Pasteurizing	Honey

[5] Modified atmosphere and vacuum packaging can create an environment conducive to growth of *C. botulinum* in TCS foods; however, such foods are out of scope of this risk assessment.

Activity	Food
Roasting/toasting	Baked goods (e.g., toasting bread for croutons); cocoa beans; coffee beans; grains (e.g., soybeans) peanuts and tree nuts; seeds for direct consumption;
Salting	Peanut and tree nut products that are processed foods; seeds for direct consumption that are processed foods
Sifting	Milled grain products; other fruit and vegetable products that are processed foods (e.g., chickpea flour); peanut and tree nut products that are processed foods (e.g., peanut flour, almond flour)
Storing/Holding (Cold, ambient or controlled atmosphere), including activities incidental to holding (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food)	Baked goods; candy; cocoa beans (roasted) and cocoa products; coffee beans (roasted); game meat jerky; gums, latexes, and resins that are processed foods; honey (pasteurized); jams, jellies and preserves; milled grain products; molasses and treacle; oils; other fruit and vegetable products that are processed foods; other grain products that are processed foods; other herb and spice products that are processed foods; peanut and tree nut products that are processed foods; seeds for direct consumption that are processed foods; soft drinks and carbonated water; sugar; syrups; trail mix and granola; vinegar; any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).
Sulfiting	Fruits and vegetables

[a] *Fruits and Vegetables and their Products*

Examples of **dried fruit and vegetable products that are processed foods** include raisins, unpitted dried plums, and dried legumes. This category includes only dried fruit and vegetable products that have been made without additional manufacturing/processing other than: (1) drying that creates a distinct commodity, (2) packaging, and/or (3) labeling. The drying, packaging, and labeling of these products is within the farm definition and these activity/food combinations are *out of scope of the risk assessment*.

Examples of **other fruit and vegetable products that are processed foods** include those that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include caramel apples, flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. This category does not include dried fruit and vegetable products that have been made without additional manufacturing/processing other than: (1) drying/dehydrating that creates a distinct commodity, (2) packaging, and/or (3) labeling (e.g., raisins). Examples of dried fruit and vegetable products made with additional manufacturing/processing include dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins.

Examples of **peanut and tree nut products that are processed foods** include roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

Examples of **seeds for direct consumption that are processed foods** include roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds. (By contrast, the raw (unroasted) seeds are examples of seeds for direct consumption.) For purposes of this risk assessment, we treat seeds for direct consumption as within the fruit and vegetable category when used for direct consumption, and within the grains category when used as a grain.

Examples of **dried herbs and other spices that are processed foods** include intact dried basil, intact dried bay leaves, and intact dried mint. This category includes only dried herbs and other spices that have been made without additional manufacturing/processing other than: (1) drying/dehydrating that creates a distinct commodity, (2) packaging, and/or (3) labeling. The drying, packaging, and labeling of these products is within the farm definition and these activity/food combinations are *out of scope of the risk assessment*.

Examples of **other herb and spice products that are processed foods** include chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (e.g., essential oils, extracts containing >20% ethanol, extracts containing >35% glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category excludes those dried herbs and other spices made without additional manufacturing/processing other than: (1) drying/dehydrating that creates a distinct commodity, (2) packaging, and/or (3) labeling.

[b] *Grain and Grain Products*

Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Examples of **milled grain products** include flour, bran, and corn meal.

Examples of **baked goods** include breads, brownies, cakes, cookies, and crackers.

Examples of **other grain products that are processed foods** include dried cereal, dried pasta, malt, oat flakes, popcorn, and soy nuts.

[c] *Other Processed Foods*

Other processed foods include candy; honey (pasteurized); jams, jellies, and preserves; oils (e.g., olive, avocado); soft drinks and carbonated water; trail mix and granola; vinegar

Examples of **trail mix and granola** include combinations of dried fruit, dried cut fruit, peanuts, tree nuts, seeds for direct consumption, seeds for direct consumption that are processed foods, other grains that are processed foods (e.g., oat flakes), and/or other ingredients such as chocolate.

Examples of **candy** include hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee.

[1] (By "seasoning" we mean addition of herbs, spices, sugar, honey, soy sauce, pepper sauce or other ingredients to enhance flavor.)

FDA believes that Table 1includes 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 study on co-location of farms with food processing facilities, we acknowledge that Table 1may not include all such activity/food combinations. For example, the Food Processing Sector Study classifies 96 small and very small facilities co-located on farms that produce "Food Preparations, Not Elsewhere Classified" (Capogrossi et al., 2015). 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 1may not include activity/food combinations for these facilities.

In addition, Table 1does not include certain activity/food combinations identified in the study on co-location of farms with food processing facilities as being conducted at an establishment co-located on a farm because the raw materials or other ingredients, the specific steps involved, or the actual product made on-farm are unknown, e.g., making flavored syrups, concentrates, fruit juices (1

establishment), refining and blending fats and oils (3 establishments), making frozen specialties not elsewhere classified (e.g., meals and pizzas, 2 establishments) (Capogrossi et al., 2015).

The list of activity/food combinations likely to be conducted at farm mixed-type facilities contains the food categories that are within the scope of the RA (see the second column in Table 1). We grouped these food categories[6] as follows:

- Baked goods (other than those requiring time/temperature control for safety)
- Candy
- Cocoa beans
- Cocoa products (e.g., chocolate, cocoa powder and cocoa butter)
- Coffee beans
- Dried fruit and vegetable products that are processed foods (e.g., raisins, unpitted dried plums)
- Dried herbs and other spices that are processed foods (e.g., intact dried basil, intact dried bay leaves, intact dried mint)
- Fresh herbs[7]
- 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, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) 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
- Game meat jerky
- Grains as described immediately below (e.g., corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, oilseeds [e.g., soybeans]). (Note that, for the purposes of this analysis, some oilseeds may also be considered to be in the category of fruits and vegetables when consumed directly, e.g., sunflower seeds.)
- Gums, latexes, and resins
- Honey
- Jams, jellies, and preserves
- Milled grain products (flour, bran, corn meal)
- Molasses and treacle
- Oils
- Other fruit and vegetable products that are processed foods (other than low-acid cut fruits and vegetables) (e.g., dried apple slices; pitted, dried fruits, flours made from legumes)
- Other grain products that are processed foods (dried cereal, dried pasta, malt, oat flakes, popcorn, and soy nuts)
- Other herb and spice products that are processed foods (e.g., chopped fresh herbs, chopped or ground dried herbs, and herbal extracts)
- Peanuts and tree nuts (e.g., almonds, walnuts)

[6] Note that the food categories include some foods that may be produced within the farm definition, (e.g., fresh herbs, dried fruit and vegetable products that are processed foods, gums/resins/latexes, honey) because of the activities farm mixed-type facilities perform on these foods that may be low-risk activity/food combinations. The food categories also include some non-TCS foods (e.g., game meat jerky) made from foods that are out of scope (e.g., game meat), because of the activities (e.g., cutting and packaging) that farm mixed-type facilities perform on the non-TCS foods.

[7] For the purpose of this risk assessment we include tea (*Camellia sinensis*) as an herb.

- Peanut and tree nut products that are processed foods (e.g., roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nuts flours)
- Sap (for making syrup, e.g., agave, birch, maple, palm) and the syrups made from them
- Seeds for direct consumption
- Seeds for direct consumption that are processed foods (e.g., roasted pumpkin seeds, roasted sunflower seeds, roasted flax seeds)
- Soft drinks and carbonated water
- Sugarcane, sugar beets and sugar
- Trail mix and granola
- Vinegar
- Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)

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 primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (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 and oilseeds for oil extraction (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

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 food allergens, drug residues, unapproved food and color additives, and radiological hazards) and physical 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 outbreaks of 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 hospitalization or death (see the discussion of norovirus in the Hazard Characterization section of this RA);
- Associated with pathogens (such as *Toxoplasma gondii*) that are primarily germane to foods that are outside the scope of this RA;
- Associated with biological hazards likely to have been introduced at retail or foodservice 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 outbreak 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, 2013; Muth et al., 2011) (see Table 2). During the period 2009-2010, chemical hazards (such as natural toxins (e.g., mycotoxins)) accounted for only approximately one percent of mean annual illnesses associated with outbreaks (CDC, 2013), 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, Outbreak-Associated Foodborne Illness, 2009-2010 (CDC, 2013)

Hazard	Total Outbreaks (No.)	Total Outbreaks (Percent)	Total Illnesses (No.)	Total Illnesses (Percent)	Comments
Biological: Bacterial pathogens	480	47	13,127	45	Examples of bacterial foodborne pathogens include *L. monocytogenes*, *E. coli* O157:H7, *Salmonella* spp., and *C. botulinum.*
Biological: Viral pathogens	497	49	9,825	33	Examples of viral foodborne pathogens include norovirus and hepatitis A virus.
Biological: Parasites	2	0	13	0	E.g., *Cryptosporidium*
Chemical (excluding food allergens)	43	4	209	1	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 food allergen hazards. For the purpose of this RA, we consider food allergen hazards to be the major food allergens as defined in section 201(qq) of the FD&C Act.[8] To supplement the CDC surveillance information with information about the frequency of consumption of food contaminated with physical hazards or food allergen hazards, we considered information about primary reports to the RFR regarding human food available from the Reportable Food Registry Annual Reports.

Table 3, Table 4, Table 5, and Table 6 provide information obtained from 4 years, Year 1 (September 8, 2009 through September 7, 2010); Year 2 (September 8, 2010-September 7, 2011), Year 3 (September 8, 2011-September 7, 2012), and Year 4 (September 8, 2012-September 7, 2013), respectively (FDA, 2011a; 2012b; 2013; 2014). To provide context relevant to the CDC surveillance information, these tables 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, Table 4, Table 5, and Table 6 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, Table 4, Table 5, and Table 6 is limited to reports of hazards that are reasonably likely to cause serious adverse health consequences or death.

[8] 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.

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

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 food allergens	69	34
Undeclared sulfites	11	5.5
Physical	0	0
Total	**192**	**95.5**

*Total number of primary RFR reports for human food for year 1= 201. Percent does not total 100 because the table does not include RFR reports such as uneviscerated fish and "other."

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 food allergens	75	36
Undeclared sulfites	3	1
Physical	2	1
Total	**199**	**96**

*Total number of primary RFR reports for human food for year 2= 206. Percent does not total 100 because the table does not include RFR reports such as uneviscerated fish and "other."

Table 5. Primary RFR Reports for Human Food in Year 3 (FDA, 2013)

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*)	110	54
Undeclared food allergens	85	41
Undeclared sulfites	1	0.5
Physical	0	0
Total	**196**	**95.5**

*Total number of primary RFR reports for human food for year 3= 205. Percent does not total 100 because the table does not include RFR reports such as uneviscerated fish and "other."

Table 6. Primary RFR Reports for Human Food in Year 4 (FDA, 2014)

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*)	79	46
Undeclared food allergens	88	51
Undeclared sulfites	2	1.2
Physical	0	0
Total	**169**	**98.2**

*Total number of primary RFR reports for human food for year 4= 172. Percent does not total 100 because the table does not include RFR reports such as uneviscerated fish and "other."

The information from the RFR Annual Reports for Years 1, 2, 3, and 4 regarding reports of food 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 food 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 undeclared food allergens in 2008-2009, 120 (69%) involved food recalls 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, 2, 3, and 4 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).

Table 7 provides information about the association of biological and chemical hazards (including food 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.A of this document as likely to be manufactured, processed, packed, or held on a farm mixed-type facility. With regard to biological hazards in Table 7, viruses were included if the contamination from the virus may occur in production (e.g., the use

of contaminated water during growing and harvesting of fruits and vegetables); viral contamination that may result from handling by infected food handlers during processing (and that would be ordinarily controlled through applicable CGMP controls) is not included. 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.

Table 7 does not include physical hazards, which could be a contaminant in virtually any food category.

Table 7 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 7 in the Hazard Characterization section of this document.

Table 7. 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
Baked goods (e.g. breads, cookies, crackers)	Bacterial pathogens (e.g., *Salmonella* spp., and sporeforming bacteria such as *B. cereus*)	Food allergens, 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
Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, toffee)	Bacterial pathogens (e.g., *Salmonella*)	Food 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 (e.g., from butter). In addition, fudge may contain food allergens such as tree nuts, and brittles contain peanuts or tree nuts.
Cocoa beans	Bacterial pathogens (e.g. *Salmonella*)	Mycotoxins (e.g., aflatoxins)	Cocoa beans are susceptible to contamination with *Salmonella* (International Commission on Microbiological Specifications for Foods, 2005b).

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
Cocoa products (e.g., chocolate, cocoa powder and cocoa butter)	Bacterial pathogens (e.g. *Salmonella*)	Food allergens	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.
Dried fruit and vegetable products that are processed foods (e.g., raisins, unpitted dried plums)	Bacterial pathogens (e.g., *E. coli* O157:H7, *L. monocytogenes*, *Salmonella*, and *C. botulinum*), 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
Dried herbs and other spices that are processed foods (e.g., intact dried basil, intact dried bay leaves, intact dried mint)	Bacterial pathogens (e.g., *Salmonella*, *E.coli* O157:H7 *C. botulinum*, and *B. cereus*)	Mycotoxins Pesticide residues	FAO/WHO 2014
Fresh herbs	Bacterial pathogens (e.g., *Salmonella*, *E.coli* O157:H7, and *C. botulinum*, *B. cereus*), Parasites (e.g., *Cryptosporidium*)	Pesticide residues	FAO/WHO 2008; Pesticide Residues Committee 2010
Fruits and vegetables	Bacterial pathogens (e.g., *E. coli* O157:H7, *L. monocytogenes*, *Salmonella*, and *C. botulinum*), Viruses (e.g., norovirus and hepatitis A virus) Parasites (e.g., *Cryptosporidium*)	Pesticide residues	Institute of Food Technologists, 2001a; Timbo et al., 2004; FDA, 2010

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
Game meat jerky	Bacterial pathogens (e.g., *Salmonella*, *E.coli* O157:H7)	Antibiotic residues	Animal drugs or antibiotics may be administered to live animals for therapeutic reasons. Failure to observe label withdrawal periods before slaughter may result in illegal drug residues in meat (FDA, 1982).
Grains including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds (e.g., cotton seed, soybeans, rapeseed)	Bacterial pathogens (e.g., *Salmonella* spp., and sporeforming bacteria such as *B. cereus*)	Food allergens, 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; (*for oil seeds:* Andrews et al., 1979); International Commission on Microbiological Specifications for Foods, 2005c)
Gums, latexes and resins	Bacterial pathogens (e.g., *Salmonella* spp., and sporeforming bacteria such as *B. cereus*)	N/A	Gums, latexes, and resins are RACs harvested from plants (often by tapping a tree or bush to obtain an exudate) (Coppen, 1995). As such, they are expected to occasionally be contaminated with bacterial pathogens. FAO includes microbiological specifications for *Salmonella* for a number of gums, e.g. gum Arabic, Tragacanth gum, in its "Combined Compendium of Food Additive Specifications." Although some gums, latexes and resins may be boiled on farm, this boiling is not viewed as a preventive control that significantly minimizes or prevents a hazard because controls to prevent recontamination are lacking. The hazards associated with these ingredients are addressed in further manufacturing.

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
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.
Jams, jellies, preserves	Bacterial pathogens (e.g., *E. coli* O157:H7, *L. monocytogenes*, *Salmonella*, and *C. botulinum*).	Pesticides	The hazards are those associated with the raw materials (fruits and vegetables). However, shelf-stable jams, jellies and preserves made from acid fruits and vegetables 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 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.
Milled grains (e.g., flour, bran, corn meal)	Bacterial pathogens (e.g., *Salmonella* spp., and sporeforming bacteria such as *B. cereus*)	Food allergens, 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

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
Molasses and treacle	N/A	N/A	Molasses and treacle are by-products of the refining of sugarcane or sugar beets into sugar. No significant foodborne pathogens are associated with the sugar made from sugarcane and sugar beets (International Commission on Microbiological Specifications for Foods, 2005e).
Oils	N/A	N/A	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).
Other fruit and vegetable products that are processed foods (e.g., dried apple slices; pitted, dried plums; caramel apples; flours made from legumes; snack chips)	Bacterial pathogens (e.g., *Salmonella*, *L. monocytogenes*, and pathogenic sporeformers (e.g., *B. cereus*, *C. botulinum*)	Sulfites Pesticide residues	Survival of pathogenic bacteria on dried fruits is usually poor; long storage periods further minimize risk from bacterial pathogens (International Commission on Microbiological Specifications for Foods, 2011a). Snack chips (such as potato chips) are cooked and have a low water activity such that the production process provides inherent control. Mycotoxins can occur in dried figs. For dried vegetables, blanching and effective packaging and storage to maintain dry conditions controls bacterial pathogens (International Commission on Microbiological Specifications for Foods, 2011a).

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
Other grain products that are processed foods (e.g., malt, oat flakes, popcorn, soy nuts, dried pasta)	Bacterial pathogens (e.g., *Salmonella* spp. and sporeforming bacteria such as *B. cereus*)	Food allergens, Gluten (associated with celiac disease), Mycotoxins (e.g., aflatoxin and deoxynivalenol)	Heat treatment of cereals reduces the microbial load, including bacterial pathogens (International Commission on Microbiological Specifications for Foods, 2005a, 2011b). Preparing popcorn for consumption involves heating kernels in hot oil. Granum and Lund, 1997; International Commission on Microbiological Specifications for Foods, 2005a; Taylor and Hefle, 2001; FDA, 2011b
Other herb and spice products that are processed foods (e.g., chopped fresh herbs, chopped or ground dried herbs, and herbal extracts)	Bacterial pathogens (e.g., *Salmonella*, *E.coli* O157:H7, *C. botulinum*, and *B. cereus*)	Mycotoxins (e.g. aflatoxins), sulfites, Pesticide residues	Timbo et al., 2004; FAO/WHO 2008; FAO/WHO 2014; Pesticide Residues Committee 2010
Peanuts and tree nuts	Bacterial pathogens (e.g., *Salmonella* and *E. coli* O157:H7)	Food allergens, Mycotoxins (e.g., aflatoxin)	International Commission on Microbiological Specifications for Foods, 2005c; Dorner, 2008; Molyneux et al., 2007; Taylor and Hefle, 2001; Whitaker, 2010; WHO/ IARC, 2012; Wu et al., 2013. 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).

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
Peanut and tree nut products that are processed foods (e.g., roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nuts flours)	Bacterial pathogens (e.g., *Salmonella* and *E. coli* O157:H7)	Food allergens, Mycotoxins (e.g., aflatoxin)	Taylor and Hefle, 2001; International Commission on Microbiological Specifications for Foods, 2005c; Dorner, 2008; WHO/IARC, 2012; Wu et al., 2013; Molyneux et al., 2007; Whitaker, 2010 Outbreaks of salmonellosis have been attributed to peanut-containing products and almonds (CDC, 2004; CDC, 2011a; CDC, 2009; Cavallaro et al., 2011; Isaacs et al., 2005)
Sap (for making syrup, e.g., agave, birch, maple, palm) and the syrups made from them	N/A	N/A	Syrup has not been associated with illnesses from foodborne pathogens. Sap must be extensively boiled (evaporated) to produce 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 for Foods, 2005e).
Seeds for direct consumption	Bacterial pathogens (e.g., *Salmonella*)	Pesticide residues	Andrews et al., 1979; FDA, 2010; FDA memorandum, 2015
Seeds for direct consumption that are processed foods (e.g., roasted pumpkin seeds, roasted sunflower seeds, roasted flax seeds)	Bacterial pathogens (e.g., *Salmonella*)	Pesticide residues	Andrews et al., 1979; FDA, 2010; FDA memorandum, 2015
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

Food Category	Associated Biological Hazards	Associated Chemical Hazards	Comments
Sugar beets, sugarcane, 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).
Trail mix and granola	Bacterial pathogens (e.g., *Salmonella* and *E. coli* O157:H7)	Food Allergen Mycotoxins (e.g., aflatoxins) Sulfites Pesticide residues	The hazards are those associated with the individual ingredients. The processes used in making the individual ingredients may address the hazards. Heat treatment of cereals used to produce granola reduces the microbial load (International Commission on Microbiological Specifications for Foods, 2005a)
Vinegar	N/A	Food allergens (e.g., malt vinegar made from malted wheat)	Fermentation (e.g., of alcohol, wine, malt, cider) results in high acetic acid content (8-11%); vinegar is usually not sensitive to spoilage (ICMSF 2005f)
Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)	Bacterial pathogens (e.g., *Salmonella*) and sporeforming bacteria such as *B. cereus*)	Food allergens	The hazards associated with these foods are variable and depend on the starting components. Many of these foods are likely to be associated with hazards that require preventive controls.

*N/A = Not Applicable

We did not identify drug residues or decomposition products as known or reasonably foreseeable potential chemical hazards 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 as a known or reasonably foreseeable 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 8 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 8 demonstrates a large number of illnesses, hospitalizations and deaths from norovirus, it also demonstrates that norovirus has the lowest hospitalization rate and has one of the lowest death rates of the selected pathogens. Thus, the relatively large numbers of hospitalizations and deaths associated with norovirus reflect the frequency, rather than the severity, of the illness.

Table 8. 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

Pathogen	Mean Number of Annual Episodes of Foodborne Illness*	Mean Number of Annual Hospitalizations	Hospitalization Rate (%)**	Mean Number of Annual Deaths**	Death Rate (%)**
L. monocytogenes	1,591	1,455	94	255	15.9
Norovirus	5,461,731	14,663	0.03	149	<0.1
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 under-diagnosis. 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 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 foodborne illness 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 an 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 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 on 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 (Tran-Dinh 2013; Williams et al., 2004). Acute adverse effects of mycotoxins currently are more common in developing countries (Bryden 2007; 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 (Bryden 2007; 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; Wu et al. 2011). 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 (Santini and Ritieni 2013; Shephard, 2008; Williams et al., 2004; WHO/IARC 2012). Ochratoxin A, which has been identified in barley, wheat, rye, corn, rice and coffee, is classified as a human carcinogen and has been associated with kidney effects in animals but has 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).

Establishing exposure limits on mycotoxins involves various factors, including scientific considerations surrounding hazards, food consumption data, knowledge about the level and distribution of mycotoxins in commodities, and analytical methodologies. Over time there have

been an increased number of limits and regulations established for mycotoxins, given the greater availability of data (Van Egmond and Jonker 2004).

The Hazard Identification section of this RA also identified antibiotic residues as a potential chemical hazard associated with game meat jerky. Animal drugs or antibiotics may be administered to live animals (i.e., before slaughter) for therapeutic reasons. Failure to observe label withdrawal periods before slaughter may result in illegal drug residues in meat (FDA, 1982). Antibiotic residues generally are addressed at slaughter. Both raising the animals and slaughtering them are outside the scope of this risk assessment.

C. Chemical Hazards – Allergic-type Reactions

The Hazard Identification section of this RA identified tree nuts, peanuts, and grains as food 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 7 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 7 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 7 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). No submissions involving foreign objects in foods were deemed to pose a risk of serious adverse health consequences or death in years 3 and 4.

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 1 and Table 8) 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 recall data (FDA Memorandum, 2004; FDA Memorandum, 2012a), as an overall indicator of exposure to food 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 food 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 food 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 food 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 food 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

food 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 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 of the organism resulting from its growth 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.

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, 2013a). 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 9 provides information about inherent controls for the biological hazards relevant to this RA. The products listed in Table 9 as having inherent controls for biological hazards generally have not been associated with illnesses from pathogens.

Table 9. Inherent Controls for Biological Hazards

Food	Inherent Control	Comments
Baked goods (e.g., bread and cookies)	The baking process inactivates vegetative pathogens; factors such as low a_w would prevent the growth of sporeforming pathogens in non-TCS baked goods.	International Commission on Microbiological Specifications for Foods, 2005a.
Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee	Boiling ingredients to achieve the needed texture; low a_w would prevent the growth of pathogens if present.	International Commission on Microbiological Specifications for Foods, 2005b.
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.
Honey (pasteurized)	Lack of association of the food with microbial pathogens and low a_w that would prevent their growth if present	See Table 7 and International Commission on Microbiological Specifications for Foods, 2005e.
Jams, jellies and preserves (shelf-stable) made from acid fruits and vegetables	Combination of the boiling required to produce the foods, and the low pH (below 4.6) and low a_w that would prevent the growth of pathogens (including spores of *C. botulinum*) if present	International Commission on Microbiological Specifications for Foods, 2011.

Food	Inherent Control	Comments
Molasses and treacle	The heat steps needed in the process of making molasses and treacle; low a_w would prevent the growth of pathogens if present	See Table 7 and International Commission on Microbiological Specifications for Foods, 2005e.
Oil	Lack of association of oils with microbial pathogens and process of extracting and refining oils from grains (including oilseeds) and from fruits and vegetables such as herbs, olives	International Commission on Microbiological Specifications for Foods, 2005c; Medina et al. 2007; Palumbo and Harris, 2011.
Popcorn	Heat treatment required to pop the kernels; low a_w would prevent the growth of pathogens if present	Virot, 2015.
Snack chips made from fruits and vegetables (e.g., plantains, potatoes)	Heat treatment needed to cook the chips (e.g., frying 350°-380°F) to the desired texture; low a_w would prevent the growth of pathogens if present	Bernard, 1985; Onyejegbu and Olorunda, 1995.
Sugar	The heat steps needed in the process of making sugar; low a_w would prevent the growth of pathogens if present	International Commission on Microbiological Specifications for Foods, 2005e.
Syrups (e.g., agave, birch, maple, palm)	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 7 and International Commission on Microbiological Specifications for Foods, 2005e.
Vinegar	Fermentation resulting in low pH and high acetic acid content	Medina et al. 2007.

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 be present in food. 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 shelf-stable 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 to below 4.6 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 10 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 10. 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 preservatives; 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 infected food handlers. • Treatment of food, e.g., with heat, to inactivate the organism.	Based on information in Ortega, 2007 and FDA, 2012a. When a kill step is applied the food must be protected from recontamination.

Hazard	Examples of Interventions to Control Hazards	Comments
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, 2013a. When a kill step is applied the food must be protected from recontamination.

Hazard	Examples of Interventions to Control Hazards	Comments
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; refrigeration slows, but does not prevent, growth in all foods (Codex Alimentarius Commission, 2007).
Norovirus	Disease controls and personal hygiene controls to prevent contamination by food handlers	
Salmonella spp.	• 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. • Disease controls and 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 (Leyer and Johnson, 1992).

Hazard	Examples of Interventions to Control Hazards	Comments
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. Humans commonly carry the organism and the organisms can survive for extended periods of time under some conditions that prevent the growth but do not kill the organism; toxin is heat stable (International Commission on Microbiological Specifications for Foods, 1996c)

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 11 provides examples of activities that can introduce, or increase the potential for, biological hazards.

Table 11. 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	

Hazard	Examples of Activities That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard	Comments
C. botulinum	If a food has a pH and a_w that support growth of *C. botulinum*, activities such as cooking that create a food that requires time/temperature control can increase the potential for *C. botulinum* (which survives the heating) to grow if the food is held at temperatures that support growth.	Johnson, 2007.
Cryptosporidium	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	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, 2013a; FDA 2013c.
L. monocytogenes	Cutting (or piercing) fruits and vegetables can transfer the organism from the low-moisture exterior (where it cannot grow) to the high-moisture interior and can release juices from tissues, providing conditions that enhance microbial growth. Coating fresh fruits such as apples with a product such as caramel can result in growth of pathogens such as *L. monocytogenes* on the surface of the fruit under the caramel layer when a contaminated product is stored at room temperature for several days (with and without sticks).	FDA, 2008. Institute of Food Technologists; 2001a; Glass, 2015.
Norovirus	Contact with ready-to-eat foods by infected food handlers can result in contamination.	FDA, 2013a; FDA 2013c.
Salmonella spp.	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.

Hazard	Examples of Activities That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard	Comments
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, 2013a.

C. Factors That Impact the Frequency and Levels of Contamination of the Food – Chemical (including Radiological) and Physical hazards

The presence and levels of mycotoxins 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 developing 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; WHO/IARC, 2012).

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

The prevalence of physical hazards in foods is low (FDA, 2011a; FDA, 2012b; FDA, 2013f; FDA, 2014). The potential presence of physical hazards depends on the activities performed on the food, including activities that can remove foreign objects (e.g., sorting, use of screens) 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).

Table 12 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 food allergens or sulfites is declared on the package label.

Table 12. 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
Food allergen hazards	• Sanitation controls. • Preventing cross-contact between an allergen-containing food and one that does not contain that allergen. • Preventing cross-contact between foods containing different allergens • Ensuring that the presence of food allergens is declared on the package label	• Improper labeling.* • Improper cleaning between allergen-containing foods and foods that do not contain that allergen.	Gendel et al. 2013; Stone and Stevenson, 2009.
Mycotoxins	• Control moisture during storage • Pest control	• Improper storage • Lack of pest control	Williams et al., 2004; Dorner 2008; Abbas and Shier 2010; Pitt et al. 2013
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 (e.g., whole or chopped peanuts, single-ingredient nut flours), and foods that are in a form in which a consumer can reasonably be expected to recognize the food as containing allergen(s) without a label declaration (e.g., trail mix containing whole peanuts), does not present the same risk as labeling a food bearing or containing allergen(s) that is not a single-ingredient food and 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., multi-ingredient nut flours)

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 study on co-location of farms with food processing facilities (Caprogrossi, 2015), 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 2.6 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

To provide a qualitative characterization of risk, we first ordered information from Table 8 related to frequency and severity to allow us to group information into "high," "medium" and "low" categories. (See Table 13, Table 14, and Table 15 and the text that follows.) These rankings are useful for a relative qualitative characterization of risk.

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 7 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 8 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 the Hazard Characterization, adverse effects associated with biological hazards occur as a result of consumption of a contaminated food during a single eating occasion.

Table 13. 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 14. 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 15. 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 16 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 16 draws from information presented in Table 2, Table 7, and Table 8 of this RA and from discussions in the Hazard Identification, Hazard Characterization, and Exposure Assessment sections of this RA.

Table 16 characterizes the mean number of annual episodes of foodborne illness from the information presented in Table 8 and Table 13 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 16 characterizes the severity of the biological hazard in terms of rate of hospitalization from the information presented in Table 8 and Table 14of this document as follows:

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

Table 16 characterizes the severity of the biological hazard in terms of rate of death from the information presented in Table 8 and Table 15 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 16. 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

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

* See Table 2, Table 7, and Table 8.

**For the purposes of this RA.

Based on Table 16, 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 (including Radiological) and Physical Hazards

Table 17 presents a qualitative risk characterization of chemical (including radiological) and physical hazards that may be associated with foods manufactured, processed, packed, or held on a farm mixed-type facility. Table 17 draws from information presented in Table 2, Table 3, and Table 7 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 (including radiological) and physical hazards relevant to this RA. In characterizing the risk of these hazards, we:

- Used reports to the RFR (see Table 3 and recall data (FDA Memorandum, 2004; FDA Memorandum, 2012a) as an overall indicator of exposure to food allergen hazards, sulfite hazards, and physical hazards.
- Characterized exposure to mycotoxin hazards as low based on the available information (Williams et al., 2004; WHO/IARC, 2012; Pereira et al. 2014). 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 likely in the U.S.
- Characterized severity of the hazard as "High" if adverse reactions resulting from a single eating occasion are serious and are reasonably likely to include death.
- Considered that a chemical (including radiological) and physical 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 17. Qualitative Risk Characterization of Chemical (including Radiological) and Physical 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
Food allergen hazards	High	Single eating occasion	High	Yes	See Table 3
Sulfites	High	Single eating occasion	High	Yes	See Table 3
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

** For the purposes of this RA

Based on Table 17:

- 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., food allergen hazards and sulfite hazards; and
- None of the physical 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 10 and Table 12 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. Characterizing Activity/Food Combinations

Table 18 presents a matrix of activity/food combinations. Activities and foods are taken from Table 1, and activity/food combinations are evaluated to determine if they are or are not low-risk. Food groups are explained by letter footnotes in the table on first mention; number footnotes are used when there is a qualification to a low-risk designation.

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

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 SAHCODH hazard) and part #2b (activity does not significantly minimize or prevent a SAHCODH hazard).

For each row in Table 18, we ask whether an activity/food combination would be low risk (as defined in section I.E of this document) and provide the rationale for this determination. In answering the question whether an activity/food combination is low risk, we:

- Answer the question "Yes" if the activity satisfies the definition of low-risk activity/food combination; and
- Answer the question "No" if the activity does not satisfy the definition of low-risk activity/food combination.

In addressing the rationale:

For each activity/food combination 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).

For each activity/food combination 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 SAHCODH hazard); or
- #2b (if the activity significantly minimizes or prevents a SAHCODH hazard, i.e., if the activity would be a preventive control)

For those activity/food combinations that are not low risk, Table 19 explains the specific reasons why.

Table 18. Is an Activity/Food Combination Low Risk?

Activity	Food	Low risk (Y/N)	Rationale
Acidification/Pickling/Fermenting	Fruits &Vegetables	No	#2b
Boiling	Fruits &Vegetables	No	#2a and 2b
Boiling	Gums, latexes, and resins	Yes	#2
Boiling	Peanuts	No	#2a and 2b
Canning/Bottling/Jarring (packaging that includes additional manufacturing/ processing)	Fruits &Vegetables	No	#2b
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Baked goods (e.g. bread)	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Dried F&V products (e.g., pitting dried plums)	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Dried herbs & other spices[b] (e.g., intact dried basil, intact dried mint)	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Fresh herbs	No[1]	#2a
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Fruits &Vegetables (low-acid and acid with pH≥4.2)	No	#2a
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Fruits & Vegetables (acid, pH<4.2), (e.g., lemons, limes)	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Game meat jerky	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Gums, latexes, and resins	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Other grain products (e.g., dried cereal)	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Peanuts and tree nuts	Yes	#2
Chopping/Coring/Cutting/Peeling Pitting/Shredding/Slicing	Peanut and tree nut products	Yes	#2
Coating (other than coating fruits and vegetables with wax/oil/resin)	Dried F&V products[a] (e.g., coating raisins with chocolate)	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Coating (other than coating fruits and vegetables with wax/oil/resin)	Fruits &Vegetables, (e.g., coating intact apples with caramel)	No	#2a
Coating (other than coating fruits and vegetables with wax/oil/resin)	Other F&V products[a] (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate), except for other F&V products that are not dried and not intact	Yes	#2
Coating (other than coating fruits and vegetables with wax/oil/resin)	Other F&V products that are non-dried and non-intact (e.g., coating apples that are on a stick with caramel)	No	#2a
Coating (other than coating fruits and vegetables with wax/oil/resin)	Other grain products (e.g., popcorn), such as by adding caramel or by adding seasonings that have been treated to significantly minimize pathogens	Yes	#2
Coating (other than coating fruits and vegetables with wax/oil/resin)	Other grain products (e.g., popcorn), such as by adding seasonings that have not been treated to significantly minimize pathogens	No	#2a
Coating (other than coating fruits and vegetables with wax/oil/resin)	Peanuts and tree nuts (e.g., adding seasonings that have been treated to significantly minimize pathogens)	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Coating (other than coating fruits and vegetables with wax/oil/resin)	Peanuts and tree nuts (e.g., adding seasonings that have not been treated to significantly minimize pathogens)	No	#2a
Coating (other than coating fruits and vegetables with wax/oil/resin)	Peanut and tree nut products[d] (e.g., adding seasonings that have been treated to significantly minimize pathogens)	Yes	#2
Coating (other than coating fruits and vegetables with wax/oil/resin)	Peanut and tree nut products[d] (e.g., adding seasonings that have not been treated to significantly minimize pathogens)	No	#2a
Cooking	Fruits &Vegetables	No	#2a and 2b
Dehydration/Drying (that includes additional manufacturing/processing or is performed on processed foods)	Other F&V products with pH<4.2 (e.g., cut F&V with pH<4.2)	Yes	#2
Dehydration/Drying (that includes additional manufacturing/processing or is performed on processed foods)	Other F&V products with pH≥4.2 (e.g., cut acid F&V with pH≥4.2)	No	#2a
Dehydration/Drying (that includes additional manufacturing/processing or is performed on processed foods)	Other herb & spice products[c] (e.g., chopped fresh herbs, including tea)	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Extracting (including by pressing, by distilling, by solvent extraction)	Dried herbs & other spices (e.g., dried mint)	Yes	#2 (or in some cases, i.e., by distilling and by solvent extraction: #1)
Extracting including (by pressing, by distilling, by solvent extraction)	Fresh herbs (e.g., mint)	Yes	#2 (or in some cases #1)
Extracting (including by pressing, by distilling, by solvent extraction)	Fruits &Vegetables (e.g., olives, avocados)	Yes	#2 (or in some cases #1)
Extracting (including by pressing, by distilling, by solvent extraction)	Grains (e.g., oilseeds)	Yes	#2 (or in some cases #1)
Extracting (including by pressing, by distilling, solvent extraction)	Other herb & spice products (e.g., chopped, fresh mint)	Yes	#2 (or in some cases #1)
Freezing	Fruits &Vegetables (acid, pH<4.2)	Yes	#2
Freezing	Fruits &Vegetables (low-acid and acid pH≥4.2)	No	#2a
Freezing	Other F&V products (acid, pH <4.2) (e.g., cut rhubarb, cut peaches)	Yes	#2
Freezing	Other F&V products (acid, pH≥4.2)	No	#2a
Grinding/Milling/Cracking/Crushing	Baked goods (e.g., crackers)	Yes	#2
Grinding/Milling/Cracking/Crushing	Cocoa beans (roasted)	Yes	#2
Grinding/Milling/Cracking/Crushing	Coffee beans (roasted)	Yes	#2
Grinding/Milling/Cracking/Crushing	Dried fruit and vegetable products (e.g., raisins, dried legumes)	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Grinding/Milling/Cracking/Crushing	Dried herbs & other spices (e.g., intact dried basil)	Yes	#2
Grinding/Milling/Cracking/Crushing	Grains (e.g., oats, rice, rye, wheat)	Yes	#2
Grinding/Milling/Cracking/Crushing	Other F&V products that are processed foods (e.g., dried, pitted dates)	Yes	#2
Grinding/Milling/Cracking/Crushing	Other grain products (e.g., dried cereal)	Yes	#2
Grinding/Milling/Cracking/Crushing	Other herb & spice products (e.g., chopped dried herbs)	Yes	#2
Grinding/Milling/Cracking/Crushing	Peanuts and tree nuts	Yes	#2
Grinding/Milling/Cracking/Crushing	Peanut & tree nut products (e.g., roasted)	Yes	#2
Labeling	Baked goods that contain food allergen(s) (e.g., those that contain wheat, milk, egg, or nuts)	No[2]	#2b
Labeling	Baked goods that do not contain food allergens (e.g., crackers that do not contain wheat, milk, egg, or nuts)	Yes[2]	#2
Labeling	Candy containing food allergen(s) (e.g., fudge, nut brittles, taffy, toffee containing milk, butter, or chopped nuts)	No[2]	#2b
Labeling	Candy that does not contain food allergens (e.g., maple candy and maple cream)	Yes[2]	#2

Activity	Food	Low risk (Y/N)	Rationale
Labeling	Cocoa beans (roasted) and cocoa products that do not contain food allergens	Yes[2]	#2
Labeling	Cocoa products that contain food allergen(s) (e.g., milk chocolate)	No[2]	#2b
Labeling	Coffee beans (roasted)	Yes	#2
Labeling	Game meat jerky	Yes	#2
Labeling	Gums, latexes, and resins that are processed foods	Yes	#2
Labeling	Honey (pasteurized)	Yes	#2
Labeling	Jams, jellies, & preserves	Yes	#2
Labeling	Milled grain products that do not contain food allergens (e.g. corn meal) or that are single ingredient foods (e.g., wheat flour, wheat bran)	Yes[2]	#2
Labeling	Milled grain products that contain food allergen(s) and are not single ingredient foods (e.g., flour made from wheat and other ingredients)	No[2]	#2b
Labeling	Molasses and treacle	Yes	#2
Labeling	Oils	Yes	#2
Labeling	Other F&V products that do not contain food allergens (e.g., snack chips made from potatoes or plantains)	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Labeling	Other F&V products that contain food allergen(s) (e.g., snack chips made from potatoes or plantains to which ingredients containing food allergens have been added)	No[2]	#2b
Labeling	Other grain products[g] that contain food allergen(s) (e.g., dried pasta)	No[2]	#2b
Labeling	Other grain products that do not contain food allergens (e.g., popcorn)	Yes[2]	#2
Labeling	Other herb & spice products (e.g., chopped fresh herbs, chopped or ground dried herbs)	Yes	#2
Labeling	Peanut & tree nut products that are single ingredient, are in forms in which the consumer can reasonably be expected to recognize the allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)	Yes[2]	#2

Activity	Food	Low risk (Y/N)	Rationale
Labeling	Peanut & tree nut products that contain multiple ingredients and that are in forms in which the consumer cannot reasonably be expected to recognize the food allergen(s) without label declaration (e.g., multi-ingredient peanut or tree nut flours)	No[2]	#2b
Labeling	Seeds (processed)[t] (e.g., roasted pumpkin or roasted sunflower seeds)	Yes	#2
Labeling	Soft drinks & carbonated water	Yes	#2
Labeling	Sugar/syrups	Yes	#2
Labeling	Trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which consumer can reasonably be expected to recognize the allergen(s) without label declaration)	Yes[2]	#2
Labeling	Trail mix and granola (containing milk chocolate, or containing peanuts and/or tree nuts in forms in which consumer cannot reasonably be expected to recognize the food allergen(s) without label declaration)	No[2]	#2b

Activity	Food	Low risk (Y/N)	Rationale
Labeling	Vinegar	Yes	#2
Labeling	Any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)	Yes	#2
Labeling	Any other processed food that does not require time/temperature control for safety that contains a food allergen(s) (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)	No[2]	#2b
Making baked goods (including mixing, baking)	Milled grain products	Yes	#1
Making candy (including boiling, evaporation, mixing)	Peanuts and tree nuts (e.g., nut brittles), sugars/syrups (e.g., taffy, toffee), saps (e.g., maple candy, maple cream)	Yes	#1
Making cocoa products (including grinding, mixing, conching, tempering)	Cocoa beans (roasted)	Yes	#2
Making dried pasta	Grains	Yes	#2
Making jams/jellies/preserves (including cutting/mashing, boiling, mixing, canning)	Fruits & Vegetables (acid, pH $\leq$ 4.6) (e.g., rhubarb, strawberries)	Yes	#1

Activity	Food	Low risk (Y/N)	Rationale
Making jams/jellies/preserves (including cutting/mashing, boiling, mixing, canning)	Fruits & Vegetables (low acid, pH > 4.6)	No	#2b
Making molasses and treacle (including extracting, boiling, concentrating, evaporating)	Sugar beets, sugarcane	Yes	#1
Making oat flakes	Grains	Yes	#2
Making popcorn	Grains	Yes	#1
Making snack chips	Fruits & Vegetables (e.g., plantains, potatoes)	Yes	#1
Making soft drinks and carbonated water (including flavoring, carbonating)	Sugar, syrups, water	Yes	#1
Making syrups and sugars (including extracting, boiling, concentrating, evaporating, crystalizing)	Fruits & Vegetables (e.g., dates)	Yes	#1
Making syrups and sugars (including extracting, boiling, concentrating, evaporating, crystalizing)	Grains (e.g., rice, sorghum)	Yes	#1
Making syrups and sugars (including extracting, boiling, concentrating, evaporating, crystalizing)	Other grain products (e.g., malted grains such as barley)	Yes	#1
Making syrups and sugars (including extracting, boiling, concentrating, evaporating, crystalizing)	Sap (e.g., agave, birch, maple, palm)	Yes	#1
Making syrups and sugars (including extracting, boiling, concentrating, evaporating, crystalizing)	Sugar beets, sugarcane	Yes	#1

Activity	Food	Low risk (Y/N)	Rationale
Making trail mix or granola	Cocoa products (e.g., chocolate), dried F&V products (e.g., raisins), other F&V products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut & tree nut products, seeds (processed) (provided that peanut & tree nut products and seeds (processed) have been treated to significantly minimize pathogens)[e]	Yes	#2
Making trail mix or granola	Cocoa products (e.g., chocolate), dried F&V products (e.g., raisins), other F&V products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanuts & tree nuts, peanut & tree nut products, seeds, seeds (processed) (where peanuts, tree nuts, or seeds have not been treated to significantly minimize pathogens)	No	#2a
Making vinegar (including fermenting)	Fruits &Vegetables	Yes	#1
Making vinegar (including fermenting)	Other F&V products (e.g., fruit wines, apple cider)	Yes	#1
Making vinegar (including fermenting)	Other grain products (e.g., malt)	Yes	#1
Malting	Grains	No[3]	#2a

Activity	Food	Low risk (Y/N)	Rationale
Mixing/Blending	Baked goods (e.g., cookie types)	Yes	#2
Mixing/Blending	Candy (e.g., varieties of taffy)	Yes	#2
Mixing/Blending	Cocoa beans (roasted)	Yes	#2
Mixing/Blending	Coffee beans (roasted)	Yes	#2
Mixing/Blending	Dried F&V products (e.g., raisins, dried currants and dried blueberries)	Yes	#2
Mixing/Blending	Dried herbs & other spices (e.g., intact dried basil and intact dried oregano)	Yes	#2
Mixing/Blending	Honey (pasteurized)	Yes	#2
Mixing/Blending	Milled grain products (e.g., flour, bran, corn meal)	Yes	#2
Mixing/Blending	Other F&V products (e.g., dried, sliced apples and dried sliced peaches)	Yes	#2
Mixing/Blending	Other grain products (e.g., different types of dried pasta)	Yes	#2
Mixing/Blending	Other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars)	Yes	#2
Mixing/Blending	Peanut and tree nut products	Yes	#2
Mixing/Blending	Sugar/Syrups	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Mixing/Blending	Vinegar	Yes	#2
Mixing/Blending	Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Baked goods	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Candy	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Cocoa beans (roasted)	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Cocoa products	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Coffee beans (roasted)	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Game meat jerky	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Gums, latexes, and resins that are processed foods	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Honey (pasteurized)	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Jams, jellies, and preserves	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Milled grain products (e.g., flour, bran, corn meal)	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Molasses and treacle	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Oils	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Other F&V products[e] (e.g., pitted dried fruit, sliced dried apples, snack chips)	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Packaging (including modified atmosphere and vacuum packaging)	Other grain products (e.g., popcorn)	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Other herb and spice products	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Peanut and tree nut products	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Seeds (processed)	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Soft drinks and carbonated water	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Sugar/syrups	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Trail mix and granola	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Vinegar	Yes	#2
Packaging (including modified atmosphere and vacuum packaging)	Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)	Yes	#2
Packing/Re-Packing	Baked goods	Yes	#2
Packing/Re-Packing	Candy	Yes	#2
Packing/Re-Packing	Cocoa beans (roasted)	Yes	#2
Packing/Re-Packing	Cocoa products	Yes	#2
Packing/Re-Packing	Coffee beans (roasted)	Yes	#2
Packing/Re-Packing	Game meat jerky	Yes	#2
Packing/Re-Packing	Gums, latexes, and resins that are processed foods	Yes	#2
Packing/Re-Packing	Honey (pasteurized)	Yes	#2
Packing/Re-Packing	Jams, jellies, and preserves	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Packing/Re-Packing	Milled grain products (e.g., flour, bran, corn meal)	Yes	#2
Packing/Re-Packing	Molasses and treacle	Yes	#2
Packing/Re-Packing	Oils	Yes	#2
Packing/Re-Packing	Other F&V products (e.g., pitted dried fruit, sliced dried apples, snack chips)	Yes	#2
Packing/Re-Packing	Other grain products (e.g., popcorn)	Yes	#2
Packing/Re-Packing	Other herb and spice products (i.e., chopped or ground dried herbs and herbal extracts)	Yes	#2
Packing/Re-Packing	Peanut and tree nut products	Yes	#2
Packing/Re-Packing	Seeds (processed)	Yes	#2
Packing/Re-Packing	Soft drinks and carbonated water	Yes	#2
Packing/Re-Packing	Sugar/syrups	Yes	#2
Packing/Re-Packing	Trail mix and granola	Yes	#2
Packing/Re-Packing	Vinegar	Yes	#2
Packing/Re-Packing	Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)	Yes	#2
Pasteurizing	Honey	Yes	#1
Roasting/toasting	Baked goods (e.g., toasting bread for croutons)	Yes	#2
Roasting/toasting	Cocoa beans	No	#2b

Activity	Food	Low risk (Y/N)	Rationale
Roasting/toasting	Coffee beans	No	#2b
Roasting/toasting	Grains (e.g., Soybeans)	No	#2b
Roasting/toasting	Peanuts and tree nuts	No	#2b
Roasting/toasting	Seeds (e.g., sunflower, pumpkin)	No	#2b
Salting	Other grain products (e.g., soy nuts)	Yes	#2
Salting	Peanut and tree nut products	Yes	#2
Salting	Seeds (processed)	Yes	#2
Sifting	Milled grain products (e.g., flour, bran, corn meal)	Yes	#2
Sifting	Other F&V products (e.g., chickpea flour)	Yes	#2
Sifting	Peanut and tree nut products (e.g., peanut flour, almond flour)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Baked goods	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Candy	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Cocoa beans (roasted)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Cocoa products	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Coffee beans (roasted)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Game meat jerky	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Gums, latexes, and resins that are processed foods	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Honey (pasteurized)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Jams, jellies, and preserves	Yes	#2

Activity	Food	Low risk (Y/N)	Rationale
Storing/Holding (Cold, ambient or controlled atmosphere)	Milled grain products (e.g., flour, bran, corn meal)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Molasses and treacle	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Oils	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Other F&V products (e.g., pitted dried fruit, sliced dried apples, snack chips)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Other grain products (e.g., popcorn)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Other herb and spice products	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Peanut and tree nut products	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Seeds (processed)	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Soft drinks and carbonated water	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Sugar/syrups	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Trail mix and granola	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Vinegar	Yes	#2
Storing/Holding (Cold, ambient or controlled atmosphere)	Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)	Yes	#2
Sulfiting	Fruits &Vegetables	No	#2a

[a]Dried F&V products means **dried fruit and vegetable products that are processed foods** and includes raisins, unpitted dried plums, and dried legumes. This category includes only dried fruit and vegetable products that have been

made without additional manufacturing/processing other than: (1) drying that creates a distinct commodity, (2) packaging, and/or (3) labeling. The drying, packaging, and labeling of these products is within the farm definition and these activity/food combinations are out of scope of the risk assessment.

[b]Dried herbs & other spices means **dried herbs and other spices that are processed foods** and this includes intact dried basil, intact dried bay leaves, and intact dried mint. This category includes only dried herbs and other spices that have been made without additional manufacturing/processing other than: (1) drying/dehydrating that creates a distinct commodity, (2) packaging, and/or (3) labeling. The drying, packaging, and labeling of these products is within the farm definition and these activity/food combinations are out of scope of the risk assessment.

[c] Other herb & spice products means **other herb and spice products that are processed foods** and this includes chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (e.g., essential oils, extracts containing >20% ethanol, extracts containing >35% glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category excludes those dried herbs and other spices made without additional manufacturing/processing other than: (1) drying/dehydrating that creates a distinct commodity, (2) packaging, and/or (3) labeling.

[d] Peanut & tree nut products means **peanut and tree nut products that are processed foods** and this includes roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

[e] Other F&V products means **other fruit and vegetable products that are processed foods** and this includes those that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include caramel apples, flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. This category does not include dried fruit and vegetable products that have been made without additional manufacturing/processing other than: (1) drying/dehydrating that creates a distinct commodity, (2) packaging, and/or (3) labeling (e.g., raisins). Examples of dried fruit and vegetable products made with additional manufacturing/processing include dried apple slices; pitted, dried plums, cherries and apricots; and sulfited raisins.

[f] Seeds (processed) means **seeds for direct consumption that are processed foods** and this includes roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds. (By contrast, raw (unroasted) seeds are examples of seeds for direct consumption.) For purposes of this risk assessment, we treat seeds as within the fruit and vegetable category when used for direct consumption, and within the grains category when used as a grain.

[g] Other grain products means **other grain products that are processed foods** and this includes malt, oat flakes, popcorn, soy nuts, and dried pasta.

[1]Drying chopped herbs is low risk and chopping as part of the process of making dried chopped herbs is considered low risk.

[2]Labeling of foods bearing or containing an allergen (i.e., eggs, fish, milk, peanuts, shellfish, soy beans, tree nuts, wheat) is low risk only if the food is a single-ingredient food, the food is in a form in which a consumer can reasonably be expected to recognize the food as containing the allergen(s) without a label declaration, or both. For example, milk chocolate 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 milk without a label declaration, so labeling foods containing milk chocolate is not low risk. Fudge, nut brittles, taffy, and toffee containing food allergens (e.g. milk, peanuts, tree nuts), are not single-ingredient foods and are in a form in which a consumer cannot reasonably be expected to recognize the food as containing the specific allergen without a label declaration, so labeling these foods is not low risk.

[3] Malting when conducted in conjunction with making sugar, syrups, or vinegar is considered low risk, since the heat process used to make sugar and syrups and the low pH of vinegar mitigate the risk from microbial pathogens.

Table 19. Why Certain Activity/Food Combinations Are Not Low Risk

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Acidification/ Pickling/ Fermenting	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.
Boiling	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. (The activity would create a food that requires time/temperature control to prevent the growth of pathogens that survive cooking, e.g., *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.
Boiling	Peanuts	Increases the a_w and thus the potential for a hazard, e.g., growth of pathogenic sporeformers such as *C. botulinum* that survive the heating. (The activity would create a food that requires time/temperature control to prevent the growth of pathogens that survive cooking, e.g., *C. botulinum*.)	Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the peanuts.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Canning/Bottling/ Jarring (packaging that includes additional manufacturing, processing)	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.
Chopping/Coring/ Cutting/ Peeling/ Pitting/Shredding/ Slicing	Fresh herbs	The activity is reasonably likely to increase the potential for biological hazards (i.e., microbial pathogens) by releasing fluids from tissues, thereby providing conditions that enhance microbial growth.	
Chopping/Coring/ Cutting/ Peeling/ Pitting/Shredding/ Slicing	Fruits and vegetables (acid, pH≥4.2)	The activity is reasonably likely to (1) introduce biological hazards (i.e., microbial pathogens) to the interior of the fruit or vegetable where they may be able to grow and (2) to release fluids from tissues, providing conditions for growth of microbial pathogens.	

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Coating (other than coating fruits and vegetables with wax/oil/resin)	Fruits &Vegetables, (e.g., coating intact apples with caramel)	The activity is reasonably likely to introduce, or create the potential for, a hazard by providing an environment in which biological hazards such as *L. monocytogenes* that may be present on the exterior of the fruit or vegetable can multiply[9].	
Coating (other than coating fruits and vegetables with wax/oil/resin)	Other F&V products that are non-dried and non-intact (e.g., coating apples that are on a stick with caramel)	The activity is reasonably likely to introduce, or create the potential for, a hazard by providing an environment in which biological hazards such as *L. monocytogenes* that may be present on the exterior of the fruit or vegetable can multiply[10].	
Coating (other than coating fruits and vegetables with wax/oil/resin)	Other grain products (e.g., popcorn), such as by adding seasonings that have not been treated to significantly minimize pathogens	The activity is reasonably likely to introduce biological hazards (pathogens).	

[9] Studies have shown that *L. monocytogenes* can grow by 1 log in 7 days in caramel apples without sticks, possibly due to fluid from the apple creating increased a_w and pH at the apple-caramel interface (Glass, 2015). Such coatings appear to create a food that requires time/temperature control for safety.

[10] Studies have shown that *L. monocytogenes* can grow by 3 logs within 3 days in caramel apples with sticks held at 25°C, possibly due to fluid from the apple creating increased a_w and pH at the apple-caramel interface (Glass, 2015). Such coatings appear to create a food that requires time/temperature control for safety.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Coating (other than coating fruits and vegetables with wax/oil/resin)	Peanuts and tree nuts (e.g., adding seasonings that have not been treated to significantly minimize pathogens)	The activity is reasonably likely to introduce biological hazards (pathogens).	
Coating (other than coating fruits and vegetables with wax/oil/resin)	Peanut and tree nut products (e.g., adding seasonings that have not been treated to significantly minimize pathogens)	The activity is reasonably likely to introduce biological hazards (pathogens).	
Cooking	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. (The activity would create a food that requires time/temperature control to prevent the growth of pathogens that survive cooking, e.g., *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.
Dehydration/Drying (that includes additional manufacturing/processing or is performed on processed foods)	Other F & V products with pH≥4.2 (e.g., cut acid F&V with pH≥4.2)	Microbial pathogens may grow prior to reduction of the water activity to a level that prevents growth	

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Freezing	Fruits and vegetables (low acid)	The activity is reasonably likely to create the potential for a biological hazard such as *E. coli* O157, *Salmonella*, and *L. monocytogenes* that may be present on the exterior of the fruit or vegetable to grow when such foods are thawed and held at temperatures that support growth. (The activity would create a food that requires time/temperature control to prevent the growth of pathogens that may be present.)	
Freezing	Other F&V products (acid, pH ≥4.2)	The activity is reasonably likely to create the potential for a biological hazard such as *E. coli* O157, *Salmonella*, and *L. monocytogenes* that may be present on the exterior of the fruit or vegetable to grow when such foods are thawed and held at temperatures that support growth. (The activity would create a food that requires time/temperature control to prevent the growth of pathogens that may be present.)	

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Labeling	Baked goods containing food allergen(s)		Labeling of baked goods containing food allergen(s) such as wheat, peanuts, tree nuts, milk, and eggs (when 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) prevents the hazard of an undeclared food allergen.
Labeling	Candy containing food allergen(s) (e.g., fudge, nut brittles, taffy, toffee)		Labeling of candy containing food allergen(s) such as milk, peanuts, or tree nuts (when 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) prevents the hazard of an undeclared food allergen.
Labeling	Cocoa products that contain food allergen(s) (e.g., milk chocolate)		Labeling of cocoa products containing food allergen(s) such as milk (when 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) prevents the hazard of an undeclared food allergen.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Labeling	Milled grain products that contain food allergen(s) and are not single ingredient foods (e.g., flour made from wheat and other ingredients)		Labeling of milled grain products containing food allergen(s) such as wheat (when 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) prevents the hazard of an undeclared food allergen.
Labeling	Other F&V products containing food allergen(s) (e.g., snack chips made from potatoes or plantains to which ingredients containing food allergens have been added)		Labeling of snack chips containing food allergen(s) (such as milk or soy in added seasonings) (when 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) prevents the hazard of an undeclared food allergen.
Labeling	Other grain products that contain food allergen(s) (e.g., dried pasta)		Labeling of other grain products that contain food allergens such as wheat (when 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) prevents the hazard of an undeclared food allergen.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Labeling	Peanut & tree nut products that contain multiple ingredients and that are in forms in which consumer cannot reasonably be expected to recognize the food allergen(s) without label declaration (e.g., multi-ingredient peanut or tree nut flours)		Labeling of peanut & tree nut products that are not single-ingredient foods and are 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 food allergen.
Labeling	Trail mix and granola (containing milk chocolate, or containing peanuts, and/or tree nuts in forms in which consumer cannot reasonably be expected to recognize the food allergen(s) without label declaration)		Labeling of trail mix or granola containing food allergens such as milk (in milk chocolate), or containing 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 food allergen.
Labeling	Any other processed food that does not require time/temperature control for safety that contains food allergen(s) (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)		Labeling of allergen-containing foods (when 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) prevents the hazard of an undeclared food allergen.
Making baked goods (including mixing, baking)	Milled grain products		Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the milled grain products.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Making jams/jellies/ preserves (including cutting/mashing, boiling, mixing, canning)	Fruits and vegetables (low acid, pH > 4.6)		Requires careful controls to significantly minimize or prevent a hazard from *C. botulinum.*
Making trail mix or granola	Cocoa products (e.g., chocolate), dried F&V products (e.g., raisins), Other F&V products (e.g., chopped dried fruits), Peanuts & tree nuts, Peanut & tree nut products, Seeds, Seeds (processed) (where peanuts, tree nuts, or seeds have not been treated to significantly minimize pathogens)	The activity is reasonably likely to introduce biological hazards (pathogens).	
Malting	Grains	Increases the potential for a hazard, e.g., growth of microbial pathogens such as *Salmonella,* during the germination process.	
Roasting/toasting	Cocoa beans		Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the cocoa beans.
Roasting/toasting	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/toasting	Grains (e.g., soy beans)		Activity needs to significantly minimize biological hazards such as *Salmonella* that may be present on the grains.

Activity	Food	Activity Introduces, or Increases the Potential for, a SAHCODH Hazard (#2a)	Activity Significantly Minimizes or Prevents a SAHCODH Hazard (i.e., it would be a preventive control) (#2b)
Roasting/toasting	Peanuts and tree nuts		Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the peanut and tree nuts.
Roasting/toasting	Seeds (e.g., sunflower, pumpkin)		Activity needs to significantly minimize biological hazards such as *E. coli* O157 and *Salmonella* that may be present on the seeds.
Sulfiting	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.	

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[11] and that would be manufactured, processed, packed, or held by a farm mixed-type facility:

- Baked goods (other than those requiring time/temperature control for safety)
- Candy
- Cocoa beans
- Cocoa products (e.g., chocolate, cocoa powder and cocoa butter)
- Coffee beans
- Dried fruit and vegetable products that are processed foods (e.g., raisins, unpitted dried plums, dried legumes)

[11] Note that the food categories include some foods that may be produced within the farm definition, (e.g., fresh herbs, dried fruit and vegetable products that are processed foods, honey) because of the activities farm mixed-type facilities perform on these foods that may be low-risk activity/food combinations.

- Dried herbs and other spices that are processed foods (e.g., intact dried basil, intact dried bay leaves, intact dried mint)
- Fresh herbs
- Fruits and vegetables (as described previously). Note that, for the purpose of this analysis, we separately consider several foods (i.e., coffee beans, cocoa beans, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) 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
- Game meat jerky
- Grains (e.g., corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, oilseeds [e.g., soybeans]). (Note that for the purpose of this analysis some oilseeds may also be considered to be in the category of fruits and vegetables when consumed directly, e.g., sunflower seeds).
- Gums, latexes, and resins
- Honey
- Jams, jellies, and preserves
- Milled grain products (flour, bran, corn meal)
- Molasses and treacle
- Oils
- Other fruit and vegetable products that are processed foods (other than low-acid cut fruits and vegetables) (e.g., dried apple slices; pitted, dried fruits)
- Other grain products that are processed foods (dried cereal, dried pasta, malt, oat flakes, popcorn, and soy nuts)
- Other herb and spice products that are processed foods (e.g., chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (e.g., essential oils extracts containing >20% ethanol, extracts containing >35% glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars)
- Peanuts and tree nuts (e.g., almonds, walnuts)
- Peanut and tree nut products that are processed foods (e.g., roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nuts flours)
- Sap (for making syrup, e.g., agave, birch, maple, palm) and the syrups made from them
- Seeds for direct consumption
- Seeds for direct consumption that are processed foods (e.g., roasted pumpkin seeds, roasted sunflower seeds, roasted flax seeds)
- Soft drinks and carbonated water
- Sugarcane, sugar beets and sugar
- Trail mix and granola
- Vinegar
- Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)

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

Question 3: What are the known or reasonably foreseeable hazards 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;
- Food allergen hazards and sulfites; and
- Physical hazards

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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*;
- Food 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 in these foods a hazard that is a known or reasonably foreseeable biological hazard 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 known or reasonably foreseeable biological hazard in these foods:

- Baked goods (e.g., breads and cookies)
- Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);
- Carbonated soft drinks and carbonated water;
- Honey (pasteurized);
- Jams, jellies, and preserves (shelf stable) made from acid fruits and vegetables;
- Molasses and treacle;
- Oil from grains (e.g., corn, soybeans, oilseeds) and fruits and vegetables (e.g., olives, avocados, herbs);
- Popcorn;
- Snack chips made from fruits and vegetables (e.g., plantains, potatoes)
- Sugar;
- Syrups (e.g., agave, birch, maple, palm); and

- Vinegar.

Question 6: What interventions significantly minimize or prevent in these foods a hazard that is a known or reasonably foreseeable hazard 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 known or reasonably foreseeable hazard 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 food 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 food 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:

- Boiling some fruits and vegetables and peanuts increases the potential for a hazard, e.g., growth of pathogenic sporeformers such as *C. botulinum* that survive the heating. The activity would create a food that requires time/temperature control to prevent the growth of pathogens that survive cooking, e.g., *C. botulinum*.
- Chopping/coring/cutting/peeling/pitting/shredding/slicing fresh herbs and fruits and vegetables (low-acid and acid, pH≥4.2) is reasonably likely to introduce biological hazards (i.e., microbial pathogens) to the interior of the fruit or vegetable, or to release fluids from tissues, providing conditions that enhance microbial growth.
- Coating (other than coating fruits and vegetables with wax/oil/resin) fruits and vegetables (e.g., coating intact apples with caramel) is reasonably likely to introduce, or create the potential for, a hazard by providing an environment in which a biological hazard such as *L. monocytogenes* that may be present on the exterior of the fruit or vegetable can multiply.
- Coating (other than coating fruits and vegetables with wax/oil/resin) non-dried and non-intact fruits and vegetables (e.g., coating apples that are on a stick with caramel) is reasonably likely to introduce, or create the potential for, a hazard by providing an environment in which a biological hazard such as *L. monocytogenes* that may be present on the exterior of the fruit or vegetable can multiply.
- Coating (other than coating fruits and vegetables with wax/oil/resin) other grain products (e.g., popcorn), such as by adding seasonings that have not been treated to significantly minimize pathogens. Other grain products (e.g., adding seasonings that have not been treated to significantly minimize pathogens to popcorn
- Coating (other than coating fruits and vegetables with wax/oil/resin) peanuts and tree nuts (e.g., adding seasonings that have not been treated to significantly minimize pathogens).
- Coating (other than coating fruits and vegetables with wax/oil/resin) peanut and tree nut products (e.g., adding seasonings that have not been treated to significantly minimize pathogens).
- Cooking some fruits and vegetables increases the potential for a hazard, e.g., growth of pathogenic sporeformers such as *C. botulinum* that survive the heating. The activity would create a food that requires time/temperature control to prevent the growth of pathogens that survive cooking, e.g., *C. botulinum*.
- Dehydration/Drying (that includes additional manufacturing/processing or is performed on processed foods) of other fruit and vegetable products with pH≥4.2 (e.g., cut acid fruits and vegetables with pH≥4.2) is reasonably likely to provide conditions where microbial pathogens may grow prior to reduction of the water activity to a level that prevents growth.
- Freezing intact or cut low-acid fruits and vegetables and intact or cut acid fruits and vegetables with pH≥4.2 is reasonably likely to create the potential for a biological hazard (such as *E. coli* O157, *Salmonella* and *L. monocytogenes* that may be present on the exterior of the fruit or vegetable) to grow when such foods are thawed and held at temperatures that support growth. The activity would create a food that requires time/temperature control to prevent the growth of pathogens that may be present.

- Making trail mix or granola from cocoa products (e.g., chocolate), dried F&V products (e.g., raisins), other F&V products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanuts and tree nuts, peanut and tree nut products, seeds, processed seeds (where peanuts, tree nuts, or seeds have not been treated to significantly minimize pathogens) is reasonably likely to introduce biological hazards (pathogens).
- Malting grains increases the potential for growth of microbial pathogens such as *Salmonella* during the germination process.
- Sulfiting intact or cut 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.

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 fruits and vegetables;
- Boiling fruits and vegetables and peanuts;
- Canning/bottling/jarring (packaging that includes additional manufacturing/processing, e.g., water bath canning, pressure canning) fruits and vegetables;
- Cooking fruits and vegetables;
- Labeling food bearing or containing food allergens if 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 food allergen without a label declaration (e.g., baked goods that contain food allergen(s) (e.g., those that contain wheat, milk, egg, or nuts), candy containing food allergen(s) (e.g., fudge, nut brittles, taffy, toffee containing milk, butter, or chopped nuts), cocoa products that contain food allergen(s) (e.g., milk chocolate), milled grain products that contain food allergen(s) and are not single ingredient foods (e.g., flour made from wheat and other ingredients), other fruit and vegetable products that contain food allergen(s) (e.g., snack chips made from potatoes or plantains to which ingredients containing food allergens have been added), other grain products that contain food allergen(s) (e.g., dried pasta), peanut and tree nut products that contain multiple ingredients and that are in forms in which consumer cannot reasonably be expected to recognize the food allergen(s) without label declaration (e.g., multi-ingredient peanut or tree nut flours), trail mix and granola (containing milk chocolate, or containing peanuts, and/or tree nuts in forms in which consumer cannot reasonably be expected to recognize the food allergen(s) without label declaration), and any other processed food that does not require time/temperature control for safety that contains a food allergen(s) (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form));
- Making jams/jellies/preserves from low-acid (pH >4.6) fruits and vegetables;
- Roasting/toasting cocoa beans, coffee beans, grains (e.g., soy beans), peanuts and tree nuts, and seeds (e.g., sunflower, pumpkin).

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?

Based on the information in 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.

- Boiling gums, latexes, and resins;
- Chopping/coring/cutting/peeling/pitting/shredding/slicing acid fruits and vegetables with pH<4.2 (e.g., cutting lemons, limes), baked goods (e.g., slicing bread), dried fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact dried basil, intact dried mint), game meat jerky, gums/ latexes/ resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts)
- Coating dried fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens), peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens);
- Dehydration/drying (that includes additional manufacturing or is performed on processed foods) of other fruit and vegetable products with pH<4.2 (e.g., cut fruit and vegetables with pH<4.2), and other herb and spice products (e.g., chopped fresh herbs, including tea);
- Extracting (including by pressing, by distilling, by solvent extraction) dried herbs and other spices (e.g., dried mint), fresh herbs (e.g., mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped, fresh mint);
- Freezing acid fruits and vegetables with pH<4.2 and other fruit and vegetable products with pH <4.2 (e.g., cut fruits and vegetables);
- Grinding/milling/cracking/crushing baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried fruit and vegetable products (e.g., raisins, dried legumes), dried herbs and other spices (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products that are processed foods (e.g., dried, pitted dates), other grain products that are processed foods (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts);
- Labeling baked goods that do not contain food allergens (e.g., crackers that do not contain wheat, milk, egg, or nuts), candy that does not contain food allergens (e.g., maple candy and maple cream), cocoa beans (roasted), cocoa products that do not contain food allergens, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products that do not contain food allergens (e.g. corn meal) or that are single ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not

contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products that are single ingredient, are in forms in which the consumer can reasonably be expected to recognize the allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours), processed seeds (e.g., roasted pumpkin or roasted sunflower seeds), soft drinks and carbonated water, sugar/syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the allergen(s) without label declaration), vinegar, any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

- Making baked goods from milled grain products (e.g., breads and cookies);
- Making candy (including boiling, evaporation, mixing) from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream);
- Making cocoa products (including grinding, mixing, conching, tempering) from roasted cocoa beans;
- Making dried pasta from grains;
- Making jams, jellies and preserves (including cutting/mashing, boiling, mixing, canning) from acid fruits and vegetables with a pH $\leq$ 4.6 (e.g., rhubarb, strawberries) ;
- Making molasses and treacle (including extracting, boiling, concentrating, evaporating) from sugar beets, sugarcane;
- Making oat flakes from grains;
- Making popcorn from grains;
- Making snack chips from fruits and vegetables (e.g., plantains, potatoes);
- Making soft drinks and carbonated water (including flavoring, carbonating) from sugar, syrups, water;
- Making syrups and sugars (including extracting, boiling, concentrating, evaporating, crystalizing) from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), sap (e.g., agave, birch, maple, palm), sugar beets, and sugarcane;
- Making trail mix or granola from cocoa products (e.g., chocolate), dried fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and seeds (processed) (provided that peanut and tree nut products, and seeds (processed) have been treated to significantly minimize pathogens);
- Making vinegar (including fermenting) from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt);
- Mixing/blending baked goods (e.g., cookie types), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried fruit and vegetable products (e.g., raisins, dried currants and dried blueberries), dried herbs and other spices (e.g., dried intact basil and dried intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried sliced peaches); other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar/syrups, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins,

minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

- Packaging (including modified atmosphere or vacuum packaging) baked goods, candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds, soft drinks and carbonated water, sugar/syrups, trail mix and granola, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Packing/re-packing baked goods, candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., flours made from legumes, pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs and herbal extracts), peanut and tree nut products, processed seeds, soft drinks and carbonated water, sugar/syrups, trail mix and granola, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Pasteurizing honey;
- Roasting/toasting baked goods (e.g., toasting bread for croutons);
- Salting other grain products (e.g., soy nuts), peanut and tree nut products, processed seeds;
- Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), peanut and tree nut products (e.g., peanut flour, almond flour);
- Storing/holding (cold, ambient or controlled atmosphere) baked goods, candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/ resins that are processed foods, honey (pasteurized), jam/ jellies/ preserves, milled grain products (e.g., flour, bran, corn, meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted dried fruits, sliced dried apples, snack chips), other grain products (e.g., popcorn), other herb and spice products, peanut and tree nut products, processed seeds, soft drinks and carbonated water, sugar/syrups, trail mix and granola, vinegar, any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).

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 known or reasonably foreseeable hazards 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. Definitions Relevant to Activities of Farms and Farm Mixed-Type Facilities

The following definition of "farm" is an excerpt from FDA's regulation entitled "Registration of Food Facilities" as published in the Title 21 of the Code of Federal Regulations, part 1, subpart H. It is formatted according to styles associated with the Code of Regulations including numbering styles not otherwise associated with this document.

> **Farm** means:
>
> (1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:
>
> (i) Pack or hold raw agricultural commodities;
>
> (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
>
> (iii) Manufacture/process food, provided that:
>
> (A) All food used in such activities is consumed on that farm or another farm under the same management; or
>
> (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
>
> (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
>
> (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
>
> (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or
>
> (2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraph (1)(ii) and (iii) of this definition.

The following definitions of "harvesting," "holding," "manufacturing/processing," and "packing" also are excerpted from FDA's regulation entitled "Registration of Food Facilities" as published in the Title 21 of the Code of Federal Regulations, part 1, subpart H.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the

place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

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 include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Appendix 2: Chronology of Technical and Scientific Reviews of the Qualitative Risk Assessment

FDA solicited the advice and opinions of scientific experts and the public throughout the conduct of this risk assessment. A summary of the dates, type of review activity, and participants is provided below.

Chronology of Technical and Scientific Reviews of the Qualitative Risk Assessment

Date	Activity	Participants
2011-2012	Risk Assessment Team assembled	FDA
March 2012	Submit draft risk assessment for peer review	Independent, external peer review conducted by
June 2012	Peer review comments received from Versar, Inc. on draft risk assessment	Independent, external peer review conducted by Versar, Inc.
June 2012	Submit draft risk assessment and draft peer review comments to OMB as part of rulemaking for FSMA	OMB
June – July 2012	Draft risk assessment revised	FDA
August 2012	*External Peer Review of the FDA/CFSAN Draft Qualitative Risk Assessment. Peer Review Report*	FDA
November 2012	Draft risk assessment formatted for posting	FDA
January 2013	Notice of Availability of draft risk assessment for public comment (78 FR 3824, January 16, 2013)	Public
March 2013	Notice reopening public comment period (78 FR 15894)	Public
April 2013	1st extension of public comment period (78 FR 24693)	Public
August 2013	2nd extension of comment period (78 FR 48636)	Public
November 2013-June 2015	Revisions made to draft risk assessment to reflect public comments	FDA
June 2015	Submit draft risk assessment to OMB as part of rulemaking for FSMA	OMB
August 2015	Revisions to draft risk assessment	FDA
September 2015	Notice of Availability of revised risk assessment	N/A