Appendix 3 to Final Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm

Appendix 3. Evaluation of Food Manufactured, Processed, Packed, or Held (Outside the Farm Definition) in a Facility Co-Located on a Farm for Risk of Intentional Adulteration

1. Overview

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 the RA to satisfy requirements of FSMA in Section 103(c)(1)(C) to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that FDA determines to be low risk involving specific foods FDA determines to be low risk from the requirements of sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or whether to modify such requirements for such facilities. FDA is implementing the requirements of section 418 of the FD&C Act with respect to hazards that may be intentionally introduced, § 418(b)(2) of the FD&C Act, through a rulemaking separate from the two Preventive Controls rulemakings that address other hazards in human and animal foods.

In this Appendix to the RA, FDA conducts an additional analysis for the same purposes, but with a specific focus on the risk presented by hazards that may be intentionally introduced to cause wide scale public health harm, including by acts of terrorism ("Evaluation of Risk for IA"). FDA considered the results of this Evaluation of Risk for IA in determining whether to establish any exemptions from, or modifications to, requirements that would otherwise apply to small or very small farm mixed-type facilities for the Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration ("IA final rule").

FDA determined that the appropriate approach for the analysis is to conduct an evaluation of the foods manufactured, processed, packed, or held (outside the farm definition) in a facility co-located on a farm using the Key Activity Types approach described in the report "Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types." (Ref. Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types, 2013).

FDA made available for comment Appendix 4 to the Draft RA, which included a list of finished food products considered and the determination of whether a product's production process would be low risk for intentional adulteration.

Since issuing Appendix 4 to the Draft RA, we have considered the following information:

- Comments submitted to Docket FDA-2013-N-1563 on Appendix 4 to the Draft RA;
- Comments submitted to Docket FDA-2013-N-1425 on Focused Mitigation Strategies To Protect Food Against Intentional Adulteration

2. Scope

The food products considered for the purposes of this evaluation of risk for IA are the same as those considered in the RA, except that certain changes have been made to reflect the scope of the IA final rule and the criteria used in this evaluation of risk for IA to identify a "low-risk production process" (see section 3 below). Finished foods that are produced using only activities that fall within the farm definition (for example, RACs such as fruits and vegetables, grains, and (unpasteurized) milk) are out of scope for the purposes of this evaluation, because (1) this evaluation focuses on the production processes used to produce a finished food and (2) this evaluation applies to activities outside the farm definition performed by facilities co-located on farms. It is important to note that our conclusions in this document with respect to whether a production process is determined to be low risk in the context of intentional adulteration intended to cause wide scale public health harm are limited to the purposes of this document.

The following food types were out of the scope of the RA based on the definition of "low-risk activity/food combination" used in the RA, but are within the scope of this evaluation of risk for IA, which evaluates whether a food is produced through a "low-risk production process" (see section 3 below):

- Baked goods that require time/temperature control for safety (e.g., cream-filled pastries);
- Eggs (in shell, other than RACs);
- Eggs (not in shell but otherwise intact, e.g., pickled eggs);
- Game meat and game meat products that require time/temperature control for safety;
- Honey infused with fresh herbs;
- Low-acid cut fruits and vegetables;
- Milk (pasteurized) 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)

As in the RA, alcoholic beverages, seafood, juice, and dietary supplements are excluded from the scope of this Appendix based on the coverage of section 418 of the FD&C Act. In addition, low-acid canned foods are within the scope of this Appendix only with respect to hazards not regulated under 21 CFR Part 113 based on the coverage of section 418 of the FD&C Act. Also, animal food is excluded from the scope of this Appendix because FDA is exempting the manufacturing, processing, packing, and holding of animal food from the IA final rule.

3. Characterizing the risk of producing food products with respect to intentional adulteration

FDA has analyzed vulnerability assessments conducted using the CARVER+Shock methodology and identified four key activity types. FDA has determined that the presence of one or more of these key activity types at a process step (e.g., manufacturing, processing, packing, or holding of food) indicates a significant vulnerability under section 418 of the FD&C Act. To be a low-risk production process for the purposes of this evaluation of food manufactured, processed, packed,

or held on-farm for risk of intentional adulteration, the production process must not involve any of the four key activity types. These key activity types are:

(1) Bulk liquid receiving and loading – a step in which a bulk liquid is received and unloaded from an inbound conveyance or loaded into an outbound conveyance where a contaminant can be intentionally introduced and, if it is, it is likely that the contaminant will be distributed throughout the liquid due to sloshing, movement, or turbulence caused by the receiving and unloading or loading activity;

(2) Liquid storage and handling – a step in which a liquid is contained in bulk storage tanks or in holding, surge, or metering tanks where a contaminant can be intentionally introduced and, if it is, it is likely that the contaminant will be distributed into the food;

(3) Secondary ingredient handling – a staging, preparation, addition, or rework step where a contaminant can be intentionally introduced into a relatively small amount of ingredient or rework and, if it is, it is likely that the contaminant will be distributed into a larger volume of food; and

(4) Mixing and similar activities – a step, such as mixing, blending, homogenizing, or grinding where a contaminant can be intentionally introduced and, if it is, it is likely that the contaminant will be distributed into the food.

We evaluated the production processes for the types of finished foods we expect are produced at farm mixed-type facilities to determine whether or not they are low-risk with respect to hazards that may be intentionally introduced with the intention of causing wide scale public health harm. For the purposes of this analysis, we evaluated whether a production process involved any of the four FDA-identified key activity types, and identified a production process that did not involve any of the four key activity types as a ‘‘low risk production process.’’

Unlike in the RA, for which we separated manufacturing, processing, packing, and holding activities, in this evaluation of risk for IA, we focus on the overall production practices for various types of finished foods and use the concept of a “low risk production practice” rather than a “low risk activity/food combination.” This is a result of the different criteria for “low risk” we use to evaluate the risk of hazards that may be intentionally introduced, further described below, as compared to the criteria for “low risk” used for other hazards in the RA. We evaluated the low risk production practices because some of the activity types that have been identified as vulnerabilities to intentional hazards can only be evaluated in the context of the complete production process for a finished food. For example, vegetables may be chopped for multiple reasons. They may be chopped to produce a fresh-cut vegetable product in which the chopped vegetable is the finished food. They may also be chopped as an ingredient handling step leading to their inclusion as a secondary ingredient in a different finished food, such as a soup or a sauce. Thus, this evaluation of risk for IA for intentional adulteration focuses on finished foods and their production practices as a whole.

Within Table 20 below, we ask whether a product’s production process would be low risk for intentional adulteration intended to cause wide scale public health harm. In making this determination, we:

- Answer the question “Yes” if the production process does not involve a key activity type;

- Answer the question "No" if the production process includes a key activity type and identify the key activity type(s) involved in the production process that prevents it from being considered low-risk.

Table 20. Is a product's production process low risk for intentional adulteration?

Where possible, the product categories used below are consistent with the descriptions of those categories in the Final RA. However, for some food products we had to deviate from those descriptions because here we are evaluating finished foods. In those situations, we have described the changes in the footnotes below this chart.

Product (finished food)	**Is the process used to produce this product (including manufacturing, processing, packing, and holding as applicable) low risk for intentional adulteration? If not, why not?**
Baked goods (e.g., breads, cookies, crackers)	No- liquid storage and handling, secondary ingredient handling, mixing and similar activities
Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, toffee)	No- bulk liquid and receiving,** secondary ingredient handling, mixing and similar activities
Cocoa products (e.g., roasted and/or ground cocoa beans, chocolate, cocoa powder and cocoa butter)	No - bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, mixing and similar activities,
Coffee products (e.g., roasted coffee beans, ground and/or flavored roasted coffee beans)	No - secondary ingredient handling**, mixing and similar activities,
Dairy products (e.g., pasteurized milk, cheese, yogurt, ice cream, butter)	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling**, mixing and similar activities
Eggs (in shell, other than RACs, e.g., pasteurized)	Yes
Eggs (not in shell but otherwise intact, e.g., pickled eggs)	No- liquid storage and handling, secondary ingredient handling, mixing and similar activities
Game meats (whole or cut, not ground or shredded, without secondary ingredients)	Yes
Game meats (ground or shredded, without secondary ingredients)	No - mixing and similar activities
Game meat products bearing/containing secondary ingredients (other than meat)	No - secondary ingredient handling, mixing and similar activities
Gums, latexes, and resins that are processed foods	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities

Product (finished food)	**Is the process used to produce this product (including manufacturing, processing, packing, and holding as applicable) low risk for intentional adulteration? If not, why not?**
Honey (pasteurized)	No - bulk liquid receiving and loading**, liquid storage and handling, mixing and similar activities
Ice	No- liquid storage and handling, mixing and similar activities
Milled grain products (e.g., flour, bran, corn meal)	No - secondary ingredient handling, mixing and similar activities
Molasses and treacle	No- bulk liquid receiving and loading**, liquid storage and handling**, mixing and similar activities
Oil[1]	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
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)[2]	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
Other grain products that are processed foods (e.g., malt, oat flakes, popcorn, soy nuts, dried pasta)	No - secondary ingredient handling, mixing and similar activities
Other herb and spice products that are processed foods (e.g., chopped fresh herbs, chopped or ground dried herbs, and herbal extracts)[3]	No - secondary ingredient handling, mixing and similar activities
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 nut flours)	No - bulk liquid receiving and loading**, secondary ingredient handling, mixing and similar activities
Syrups (made from saps, e.g., agave, birch, maple, palm)	No - liquid storage and handling, secondary ingredient handling**, mixing and similar activities
Seeds for direct consumption that are processed foods (including roasted, oil-roasted, salted, and flavored/seasoned seeds, e.g., pumpkin seeds, sunflower seeds, flax seeds)[4]	No - liquid storage and handling, secondary ingredient handling**, mixing and similar activities
Soft drinks and carbonated water	No - bulk liquid receiving and loading**, liquid storage and handling**, secondary ingredient handling, mixing and similar activities

Product (finished food)	Is the process used to produce this product (including manufacturing, processing, packing, and holding as applicable) low risk for intentional adulteration? If not, why not?
Sugar	No - bulk liquid receiving and loading**, secondary ingredient handling**, mixing and similar activities
Trail mix and granola	No - bulk liquid receiving and loading**, secondary ingredient handling, mixing and similar activities
Vinegar	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities

** In some cases.

[1] Although oils infused with fruits and vegetables with pH>4.6 or with fresh herbs (e.g., fresh garlic in oil) are out of scope for the Final RA, we note that they are within the scope of this evaluation and are included under the category of other fruit and vegetable products that are processed foods. For the purposes of this Evaluation of Risk for IA, this category includes oils infused with fruits and vegetables with pH>4.6 or with fresh herbs (e.g., fresh garlic in oil).

[2] For the purposes of this Evaluation of Risk for IA, 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). 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 dried fruit and vegetable products made with additional manufacturing/processing include dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins. Although low-acid cut fruits and vegetables are out of scope for the Final RA, we note that they are within the scope of this Evaluation of Risk for IA and are included under this category (other fruit and vegetable products that are processed foods).

[3]For the purposes of this Evaluation of Risk for IA, 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, dried herb- or spice-infused oils and/or vinegars, and liquid tea beverages. 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. 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*.

[4] For the purposes of this Evaluation of Risk for IA, examples of **seeds for direct consumption that are processed foods** include roasted, oil-roasted, salted, and flavored seeds, e.g., pumpkin seeds, sunflower seeds, and flax seeds. (By contrast, the raw (unroasted) seeds are examples of seeds for direct consumption.) 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, both of which are out of scope for this evaluation.

4. Conclusion

The conclusion of this Evaluation of Risk for IA is that the production processes for the following finished foods are low-risk with respect to the risk of intentional adulteration intended to cause wide scale public health harm, including by acts of terrorism on the human food supply:

- Eggs (in shell, other than RACs, e.g., pasteurized)
- Game meats (whole or cut, not ground or shredded, without secondary ingredients)

References

FDA. 2013. Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types. Accessed at: http://www.fda.gov/food/guidanceregulation/fsma/ucm347023.htm.