

**Appendix 4 to Draft Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm**

## **Appendix 4. Evaluation of Food Manufactured, Processed, Packed, or Held On-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 this RA to satisfy requirements of FSMA to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that FDA determines to be low risk involving specific foods FDA determines to be low risk from the requirements of sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or whether to modify such requirements for such facilities.

In this Appendix 4 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, caused by a terrorist attack on the human food supply. FDA is proposing to implement the requirements of section 418 of the FD&C Act with respect to hazards that may be intentionally introduced by acts of terrorism, § 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. This Appendix 4 provides the science-based risk analysis required by Section 103(c) of the FDA Food Safety Modernization Act (FSMA) with respect to hazards that may be intentionally introduced, caused by a terrorist attack on the human food supply. FDA determined that the appropriate approach for the analysis would be to conduct an evaluation of the foods manufactured, processed, packed, or held on-farm consistent with past vulnerability assessments done by FDA (Ref. Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types, 2013). FDA will consider the results of this 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 FD&C Act, or whether to modify such requirements for such facilities. In particular, FDA will consider the results of this analysis in its rulemaking implementing Section 418 of the FD&C Act with respect to hazards that may be intentionally introduced by acts of terrorism: the proposed rule titled "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" (hereinafter, the "Intentional Adulteration proposed rule").

### *2. Scope*

The food products considered for the purposes of this Appendix 4 to the RA are the same as those considered in the RA, except that certain changes have been made to reflect the scope of the Intentional Adulteration proposed rule and the criteria used in this Appendix to identify a "low-risk production process" (see section 3 below).

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 Appendix, which evaluates whether a food is produced through a “low-risk production process” (see section 3 below):

- Cut fruits and vegetables
- Eggs and egg products
- Game meat and meat products
- Milk and milk products

As in the RA, alcoholic beverages, seafood, juice, and dietary supplements are excluded from the scope of this Appendix based on the statutory framework of FSMA. 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 statutory framework of FSMA. Also, animal food is excluded from the scope of this Appendix because FDA is proposing to exempt the manufacturing, processing, packing, and holding of animal food from the Intentional Adulteration proposed regulation.

### *3. Characterizing the risk of producing food products with respect to intentional contamination*

FDA has analyzed vulnerability assessments conducted using the CARVER+Shock methodology and identified four key activity types (see the Intentional Adulteration proposed rule). 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. 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.

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.

Unlike in the RA, for which we separated manufacturing, processing, packing, and holding activities, in this Appendix 4 we focus on the overall production practices for various types of

finished foods. This is a result of the different criteria for “low risk” we use to evaluate the risk of hazards that may be intentionally introduced as compared to the criteria for “low risk” used for other hazards in the RA. For intentional adulteration caused by terrorism, we use the concept of a “low risk production practice” rather than a “low risk activity/food combination.” We use this approach because certain 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 Appendix 4 focuses on finished foods and their production practices as a whole.

Within Table 26 below, we ask whether a product’s production process would be low risk for intentional adulteration from terrorism. 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 vulnerable key activity type(s) involved in the production process that prevents it from being considered low-risk.

**Table 26. Is a product’s production process low-risk for purposes of intentional hazards?**

<b>Product</b>	<b>Is the process used to produce this product (including manufacturing, processing, packing, and holding as applicable) low risk for purposes of intentional hazards from acts of terrorism? If not, why not?</b>
Cocoa Beans* (Raw & Roasted)	No - mixing and similar activities
Cocoa Products & Chocolate	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
Coffee Beans* (Raw & Roasted)	No - mixing and similar activities
Coffee Beans* (Ground)	No - mixing and similar activities
Condiments, Sauces, Spreads, Salsas	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
Dairy Products (e.g., 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)	Yes
Egg Products (non-USDA regulated) (e.g., pickled eggs)	No - liquid storage and handling, secondary ingredient handling, mixing and similar activities

Flavoring Extracts & Syrups	No - bulk liquid receiving and loading**, liquid storage and handling, ingredient handling and storage, mixing and similar activities
Fruits & Vegetables Category 1 (Fresh, Intact): <ul style="list-style-type: none"> <li>• Pods (e.g., green beans),</li> <li>• Seeds for Direct Consumption (e.g., lentils, sunflower seeds, pumpkin seeds), and</li> <li>• Hesperidia (fleshy, segmented berries, e.g., oranges, lemons)</li> </ul>	No - mixing and similar activities
Fruits & Vegetables Category 2 (Fresh, Intact): Fruits & Vegetables Other than Pods, Seeds, and Hesperidia	Yes
Fruits & Vegetables (Acidified/Pickled/Fermented)	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
Fruits & Vegetables (Canned/Bottled/Jarred)	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
Fruits & Vegetables (Coated, including Coated with Waxes, Oils, and Resins)	No - secondary ingredient handling, mixing and similar activities
Fruits & Vegetables (Dried)	No - mixing and similar activities
Fruits & Vegetables (“Fresh-cut,” i.e., Cut, Cored, Chopped, Shredded, Sliced, Peeled, Trimmed)	No - secondary ingredient handling**, mixing and similar activities
Fruits & Vegetables (Ground/Cracked/Crushed) (e.g., ground herbs)	No - secondary ingredient handling**, mixing and similar activities
Fruits & Vegetables (Sulfited)	No - 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
Grain	No - mixing and similar activities
Grain Products (e.g., flour, bran, breads, pasta)	No - secondary ingredient handling**, mixing and similar activities
Hard Candy, Fudge, Taffy, & Toffee	No - bulk liquid receiving and loading**, secondary ingredient handling, mixing and similar activities

Honey	No - bulk liquid receiving and loading**, liquid storage and handling, mixing and similar activities
Ice	No - liquid storage and handling, mixing and similar activities
Jams, Jellies, & Preserves	No - secondary ingredient handling, mixing and similar activities
Maple Sap, Maple Syrup, & Maple Products	No - liquid storage and handling, secondary ingredient handling**, mixing and similar activities
Oils	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
Peanuts & Tree Nuts* (Raw, In-Shell)	Yes
Peanuts & Tree Nuts* (Raw, Shelled)	No - mixing and similar activities
Peanuts & Tree Nuts* (Roasted, In-Shell)	No - mixing and similar activities
Peanuts & Tree Nuts* (Roasted, Shelled)	No - bulk liquid receiving and loading**, mixing and similar activities
Peanuts & Tree Nuts* (Bleached/Lightened)	No - secondary ingredient handling, mixing and similar activities
Peanuts & Tree Nuts* (Coated)	No - secondary ingredient handling, mixing and similar activities
Peanuts & Tree Nuts* (Cut/Chopped)	No - mixing and similar activities
Peanuts & Tree Nuts* (Ground)	No - mixing and similar activities
Peanuts & Tree Nuts* (Salted)	No - secondary ingredient handling, mixing and similar activities
Potato Chips & Snacks	No - bulk liquid receiving and loading**, secondary ingredient handling, mixing and similar activities
Soft Drinks & Carbonated Water	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities
Sugar	No - bulk liquid receiving and loading**, secondary ingredient handling**, mixing and similar activities
Sugarcane & Sugar Beets* (Fresh, Intact)	Yes
Soups and Soup Mixes	No - bulk liquid receiving and loading**, liquid storage and handling**, secondary ingredient handling, mixing and similar activities
Teas (Dried and Liquid)	No - bulk liquid receiving and loading**, liquid storage and handling**, secondary ingredient handling,

	mixing and similar activities
Vinegars	No - bulk liquid receiving and loading**, liquid storage and handling, secondary ingredient handling, mixing and similar activities

\* For the purpose of the RA, we separately considered several foods (i.e. coffee beans, cocoa beans, peanuts, sugarcane, sugar beets, and tree nuts) that are within the category of fruits and vegetables to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods. This appendix continues to consider these foods separately even though they are within the category of fruits and vegetables.

\*\* In some cases.

#### 4. Conclusion

The conclusion of this Appendix 4 to the RA is that the production processes for the following products are low-risk with respect to the risk of intentional adulteration caused by acts of terrorism on the human food supply:

- Eggs (In-Shell)
- Fruits & Vegetables Other than Pods, Seeds for Direct Consumption, and Hesperidia (Fresh, Intact)
- Game Meats (Whole or Cut, Not Ground or Shredded, Without Secondary Ingredients)
- Peanuts & Tree Nuts (Raw, In-Shell)
- Sugarcane & Sugar Beets (Fresh, Intact)

#### 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>.