

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

**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: Response to Public Comments**

May 2016

I. Introduction

FDA made available for public comment Appendix 4 to the Draft Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm. We received several comments on the draft risk assessment and we are addressing the comments in this document. We have finalized the final evaluation in a separate document entitled “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,” which is Appendix 3 to the Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm. FDA used the results of the final evaluation to determine 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 from the final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration (IA Rule).

II. Summary of Key Changes

Since the publication of the draft Evaluation of Risk for IA, FDA revised the definition of “farm” in the Final Rule for “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” (Preventive Controls Final Rule)¹. Due to the changes in this definition we have deleted many product categories from the final evaluation of risk for IA. Finished foods that are produced using only activities that fall within the farm definition (for example, RACs such as fruits and vegetables, grains, (unpasteurized) and

¹ Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Final Rule) <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

(unpasteurized) milk) are out of scope for the purposes of the final evaluation, because (1) the final evaluation focuses on the production processes used to produce a finished food and (2) the final evaluation applies to activities outside the farm definition performed by facilities co-located on farms. In the table below, we specify which products were deleted because they are out of scope.

Table 1. A Summary of Key Changes in the Final Evaluation of Risk for Intentional Adulteration (IA) Compared to the Draft Evaluation

For product categories in which there were no significant changes from the draft evaluation to the final evaluation (e.g., “Game meats (whole or cut, not ground or shredded, without secondary ingredients)”, there is no entry in the chart below. Categories identified in italics appeared in the draft evaluation but have been deleted in the final evaluation.

Product (finished food) as described in the final evaluation and <i>deleted categories (italics)</i>	Explanation of Changes
Baked goods (e.g., breads, cookies, crackers)	In the draft evaluation of risk for IA, these products were in the product category “Grain Products.” In the final RA, we separated this category into three categories, “baked goods,” which includes, e.g., breads, cookies, and crackers; “milled grain products”; and “other grain products that are processed foods.” Therefore, we are making conforming changes in the final evaluation of risk for IA. The key activity type determination did not change; baked goods are not low-risk for the purposes of the final evaluation.
Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, toffee)	In the draft evaluation of risk for IA, this product category was called "Hard Candy, Fudge, Taffy & Toffee." In the final RA, the description of this category was expanded to include more examples of varieties of candy and therefore we are making conforming changes in the final evaluation of risk for IA. The key activity type determinations did not change; candy is not low-risk for the purposes of the final evaluation.

Product (finished food) as described in the final evaluation and deleted categories (<i>italics</i>)	Explanation of Changes
<i>Cocoa beans (Raw & Roasted)</i>	In the final evaluation of risk for IA, we deleted raw cocoa beans because they are out of scope, and combined roasted cocoa beans into the “Cocoa products” category.
Cocoa products (e.g., roasted and/or ground cocoa beans, chocolate, cocoa powder and cocoa butter)	In the draft evaluation of risk for IA, there was a category for “Cocoa Beans (Raw & Roasted).” In the final evaluation of risk for IA, we deleted raw cocoa beans because they are out of scope and moved roasted cocoa beans into this product category, which was called “Cocoa products & Chocolate” in the draft evaluation of risk for IA. In the final evaluation of risk for IA, this category was also expanded to include ground cocoa beans as another example of a cocoa product. The key activity type determinations did not change; cocoa products are not low-risk for the purposes of the final evaluation.
<i>Coffee beans (Raw & Roasted)</i>	In the final evaluation of risk for IA, we deleted raw coffee beans because they are out of scope, and combined roasted coffee beans into the “Coffee products” category.
Coffee products (e.g., roasted coffee beans, ground and/or flavored roasted coffee beans)	In the draft evaluation of risk for IA, there were two separate categories for “Cocoa Beans (Raw & Roasted)” and “Cocoa Beans (Ground).” In the final evaluation of risk for IA, we deleted raw coffee beans because they are out of scope and combined the remaining products into a single category which includes processed food products made using coffee beans, including, e.g., ground and/or flavored roasted coffee beans. We added secondary ingredient handling as a key activity type because secondary ingredients, such as flavoring, are sometimes added to make roasted coffee beans. The addition of a key activity type did not change the low-risk determination; coffee products are not low-risk for the purposes of the final evaluation.
<i>Condiments, Sauces, Spreads, Salsas</i>	We deleted this product category due to re-categorization of foods in the final RA. These foods are now included in the product categories “Other fruit and vegetable products that are processed foods,” “Dairy products (e.g., milk, cheese yogurt, ice cream, butter),” and “Jams, jellies, preserves.”

Product (finished food) as described in the final evaluation and <i>deleted categories (italics)</i>	Explanation of Changes
Dairy products (e.g., pasteurized milk, cheese, yogurt, ice cream, butter)	We specify “pasteurized milk” as an example of this category in the final evaluation of risk for IA. Unpasteurized milk is out of scope. The key activity type determinations did not change; Dairy products are not low-risk for the purposes of the final evaluation.
Eggs (In-shell, other than RACs, e.g., pasteurized)	In the draft evaluation of risk for IA, there was a category for “Eggs (In-shell).” We deleted the “Eggs (In-shell)” product category because it is out of scope; however, we added a product category “Eggs (In-shell, other than RACs, e.g., pasteurized) to capture in-shell eggs that are manufactured/processed. We did not identify any of the key activity types; therefore, Eggs (In-shell, other than RACs, e.g., pasteurized) are low risk for the purposes of the final evaluation.
Egg products (non-USDA regulated) (e.g., pickled eggs)	We renamed this food category to “Egg (not in shell but otherwise intact, e.g., pickled eggs)” to be more clear. The key activity type determination did not change. Eggs (not in shell but otherwise intact, e.g., pickled eggs)) are not low-risk for the purposes of the final evaluation.
<i>Flavoring Extracts and Syrups</i>	We deleted this product category due to re-categorization of foods in the final RA. These foods are now grouped under in the product categories “Other fruit and vegetable products that are processed foods” and “Syrups made from saps, e.g., agave, birch, maple, palm.” The key activity types did not change; “Other fruits and vegetable products that are processed foods” are not low-risk for the purposes of the final evaluation.
<i>Fruits & Vegetables Category 1 (Fresh, Intact):</i> <ul style="list-style-type: none"> • <i>Pods (e.g., green beans),</i> • <i>Seeds for Direct Consumption (e.g., lentils, sunflower seeds, pumpkin seeds), and</i> • <i>Hesperidia (fleshy, segmented berries, e.g., oranges, lemons</i> 	We deleted this product category because it is out of scope.

Product (finished food) as described in the final evaluation and deleted categories (<i>italics</i>)	Explanation of Changes
<i>Fruits & Vegetables Category 2 (Fresh, Intact): Fruits & Vegetables Other than Pods, Seeds, and Hesperidia</i>	We deleted this product category because it is out of scope.
<i>Fruits & Vegetables (Dried)</i>	We deleted this product category because it is out of scope.
<i>Fruits & Vegetables (Sulfited)</i>	We deleted this product category due to re-categorization of foods in the final RA. These foods are now grouped under in the product category “Other fruit and vegetable products that are processed foods.” The key activity types did not change; “Other fruits and vegetable products that are processed foods” are not low-risk for the purposes of the final evaluation.
<i>Grain</i>	We deleted this product category because it is out of scope.
Gums, latexes, and resins that are processed foods	This category was added in the final RA, and we added this category in the final evaluation of risk for IA as a conforming change. We identified all four of the key activity types in the production process for these foods: bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, and mixing and similar activities. Gums, latexes, and resins that are processed foods are not low-risk for the purposes of the final evaluation.
Honey (pasteurized)	We specify “pasteurized” in this product category in the final evaluation of risk for IA. Unpasteurized honey is out of scope. The key activity type determination did not change; honey (pasteurized) is not a low-risk food for the purposes of the final evaluation.
Milled grain products (e.g., flour, bran, corn meal)	In the draft evaluation of risk for IA, these products were in the product category “Grain Products.” In the final RA, we separated this category into three categories, “baked goods;” “milled grain products,” which includes, e.g., flour, bran, corn meal; and “other grain products that are processed foods.” Therefore we are making conforming changes in the final evaluation of risk for IA. The key activity types did not change; milled grain products are not low-risk for the purposes of the final evaluation.

Product (finished food) as described in the final evaluation and <i>deleted categories (italics)</i>	Explanation of Changes
Molasses and treacle	This category was added in the final RA, and we added this category in the final evaluation of risk for IA as a conforming change. We identified three of the key activity types in the production process for these foods: bulk liquid receiving and loading, liquid storage and handling, and mixing and similar activities. Molasses and treacle are not low-risk for the purposes of the final evaluation.
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)	In the draft evaluation of risk for IA these products were in the product categories “Condiments, Sauces, Spreads, Salsas,” “Fruits & Vegetables (Acidified/Pickled/Fermented),” “Fruits & Vegetables (Canned/Bottled/Jarred),” “Fruits & Vegetables (Coated, including Coated with Waxes, Oils, and Resins),” “Fruits & Vegetables (‘Fresh-cut,’ i.e., Cut, Cored, Chopped, Shredded, Sliced, Peeled, Trimmed),” “Fruits & Vegetables (Ground/Cracked/Crushed) (e.g., ground herbs),” “Fruits & Vegetables (sulfited),” “Jams, Jellies, & Preserves,” “Soups and Soup Mixes,” and “Potato chips & Snacks.” In the final RA, fruit and vegetable products that are processed foods were organized into two categories: “Dried fruit and vegetable products that are processed foods” and “other fruit and vegetable products that are processed foods,” which includes, e.g., dried apple slices; pitted, dried plums; caramel apples; flours made from legumes; snack chips. “Dried fruit and vegetable products that are processed foods” are out of scope for the final evaluation. Therefore we are making conforming changes in the final evaluation of risk for IA. The combining of food product categories did not affect the outcome and the key activity type determinations did not change; other fruit and vegetable products that are processed foods are not low-risk for the purposes of the final evaluation.

Product (finished food) as described in the final evaluation and <i>deleted categories (italics)</i>	Explanation of Changes
Other grain products that are processed foods (e.g., malt, oat flakes, popcorn, soy nuts, dried pasta)	In the draft evaluation of risk for IA, these products were in the product category “Grain Products.” In the final RA, we separated this category into three categories, “baked goods,” “milled grain products,” and “other grain products that are processed foods,” which includes, e.g., malt, oat flakes, popcorn, soy nuts, dried pasta. Therefore we are making conforming changes in the final evaluation of risk for IA. The key activity types did not change; other grain products that are processed foods are not low-risk for the purposes of the final evaluation.
Other herb and spice products that are processed foods (e.g., chopped fresh herbs, chopped or ground dried herbs, and herbal extracts)	In the draft evaluation of risk for IA these products were in the product categories “Fruits & Vegetables (Ground/Cracked/Crushed) (e.g., ground herbs),” “Fruits & Vegetables (‘Fresh-cut,’ i.e., Cut, Cored, Chopped, Shredded, Sliced, Peeled, Trimmed),” and “Teas (Dried and Liquid).” In the final RA, herbs and products made from them were separated into new categories “Fresh herbs,” “dried herbs and other spices that are processed foods, and “other herb and spice products that are processed foods” (which includes, e.g., chopped fresh herbs, chopped or ground dried herbs, and herbal extracts). Therefore we are making conforming changes in the final evaluation of risk for IA. “Fresh herbs” and “dried herbs and other spices that are processed foods” are out of scope for the final evaluation. The key activity type determinations did not change; other herb and spice products that are processed foods are not low-risk for the purposes of the final evaluation.
<i>Peanuts and tree nuts (Raw, In-shell)</i>	We deleted this product category because it is out of scope.
<i>Peanuts and tree nuts (Raw, Shelled)</i>	We deleted this product category because it is out of scope.

Product (finished food) as described in the final evaluation and <i>deleted categories (italics)</i>	Explanation of Changes
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)	In the draft evaluation of risk for IA, these products were in multiple “Peanut & Tree Nut” categories, i.e., “Roasted, In-Shell,” “Roasted, Shelled,” “Bleached/Lightened,” “Coated,” “Cut/Chopped,” “Ground,” and “Salted.” In the final RA, all of these categories are combined into the product category “Peanut and tree nut products that are processed foods,” which includes, e.g., roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours. The key activity types did not change, peanut and tree nut products that are processed foods are not low-risk for the purposes of the final evaluation.
<i>Potato Chips & Snacks</i>	This product category was deleted. In the final RA, we addressed snack chips in the product category “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).” Therefore, we are making conforming changes in the final evaluation of risk for IA. The key activity types did not change; “Other fruit and vegetable products that are processed foods” are considered not low-risk for the purposes of the final evaluation.
Syrups (made from saps, e.g., agave, birch, maple, palm)	In the draft evaluation of risk for IA, some of these products were addressed in the product category “Maple Sap, Maple Syrup, & Maple Products.” In the final RA we addressed additional products, described as “Sap (e.g., agave, birch, maple, palm)” and “Syrups” made from those saps. Therefore we are making conforming changes in the final evaluation of risk for IA. The product category for purposes of the final evaluation of risk for IA does not include the saps themselves, which are out of scope. The key activity types did not change; syrups are not low-risk for the purposes of the final evaluation.

Product (finished food) as described in the final evaluation and deleted categories (<i>italics</i>)	Explanation of Changes
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)	These products were not addressed in the draft evaluation of risk for IA. In the final RA we included the categories “seeds for direct consumption” and “seeds for direct consumption that are processed foods.” Therefore we are making conforming changes in the final evaluation of risk for IA. “Seeds for direct consumption” are out of scope for the final evaluation. Because we are evaluating finished foods in the final evaluation, we specify as examples in this product category roasted seeds that are oil-roasted, salted, and flavored. We identified three of the key activity types in the production process for these foods: liquid storage and handling, secondary ingredient handling, and mixing and similar activities. Seeds for direct consumption that are processed foods are not low risk for the purposes of the final evaluation.
<i>Soups and Soup mixes</i>	This product category was deleted. In the final evaluation of risk for IA, soups and soup mixes are included under the product categories “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),” and “Other herb and spice products that are processed foods.” The key activity types did not change; “Other fruit and vegetable products that are processed foods” are considered not low risk for the purposes of the final evaluation.
<i>Sugarcane & Sugar Beets* (Fresh, Intact)</i>	We deleted this product category because it is out of scope.
<i>Teas (Dried & Liquid)</i>	This product category was deleted. In the final evaluation of risk for IA, teas are included under the product category “Other herb and spice products that are processed foods.”

Product (finished food) as described in the final evaluation and <i>deleted categories (italics)</i>	Explanation of Changes
Trail mix and granola	These products were not addressed in the draft evaluation of risk for IA. In the final RA we included the category “trail mix and granola.” Therefore we are making conforming changes in the final evaluation of risk for IA. We identified three of the key activity types in the production process for these foods: bulk liquid receiving and loading, secondary ingredient handling, and mixing and similar activities. Trail mix and granola are not low-risk for the purposes of the final evaluation.

III. Public Comments and FDA/CFSAN’s Responses

Several comments agree with the low risk determinations for on-farm manufacturing, processing, packing, or holding as detailed in the draft evaluation of risk for intentional adulteration. Specifically, one comment agrees that finished raw in-shell peanut processes that occur on-farm are low risk for intentional adulteration and thus agree that they be included in the relevant exemption in the Intentional Adulteration Final Rule.

Comment 1) One comment asks why fruits like oranges and lemons are not classified as low risk foods and seeks clarification as to which raw agricultural commodities (RACs) are considered low risk versus not low risk. One comment disagrees with our conclusion that Fruits & Vegetables Category 1 (i.e., pods, seeds for direct consumption, and hesperidia) are not low-risk. The comment argues that the production processes for these foods do not align with the “Mixing and similar activities” key activity type because these foods are not mixed to the point that a uniform product is created and that any mixing is actually commingling and not an attempt to produce a homogenized product.

Response 1) In the draft assessment, we evaluated two categories for fresh, intact fruits and vegetables based on our preliminary determination that the production process for some fruits and vegetables (those we designated “Category 1”) involved the “Mixing and similar activities” key activity type. Category 1 included pods (e.g., green beans), seeds for direct consumption (e.g., lentils, sunflower seeds, pumpkin seeds), and hesperidia (fleshy, segmented berries, e.g., oranges, lemons); and Category 2 included all other fruits and vegetables. However, upon further analysis and in light of the new definition of “farm” from the PCHF, in the final evaluation we determined that fruits and vegetables that are raw agricultural commodities (RACs), as well as all other product categories that included only foods that are produced using only activities that fall within the farm definition (e.g., RACs such as grains, and unpasteurized milk) are out of scope for the purposes of the final evaluation. This is because (1) the final evaluation focuses on the production processes used to produce a finished food and (2) the final evaluation applies to activities outside the farm definition performed by facilities co-located on farms. As such, we specify which products were deleted because they are out of scope in Table 1 above.

Comment 2) One comment questions why in the draft RA for the PCHF rule “mixing” is categorized as a low risk activity for intact fruits and vegetables, grain and grain products, peanuts, tree nuts, honey, maple sap and maple syrup, coffee beans, and cocoa beans, but in the draft evaluation of risk for IA, the production processes for those same foods, with the exception of intact fruits and vegetables, are not considered low risk because they may involve “mixing and similar activities.” The comment also recommends that FDA create consistent requirements for low risk on-farm processing activities for both the PCHF rule and this rule.

Response 2) The RA for the PCHF rule and the final evaluation of risk for IA assess and evaluate different risks. In the RA for the PCHF rule, we assessed whether the types of controls that would be required under the PCHF rule 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. The RA for PCHF rule focuses on hazards that are reasonably likely to cause adverse effects whereas in the final evaluation of risk for IA, we focus on the risk presented by hazards that may be intentionally introduced to cause wide scale public health harm.

As we explain in the final evaluation of risk for IA, the methodology we used in the final evaluation is to use the key activity types approach described in the report “Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types.”² The presence of one or more of the key activity types at a process step indicates a significant

² Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm347023.htm>

vulnerability. To be determined a low-risk production process for the purposes of the final evaluation, the production process must not involve any of the four key activity types, one of which is “Mixing and similar activities.” This is why “mixing” of certain foods in the RA for the PCHF rule is considered low risk whereas “Mixing and similar activities” for the same foods in the final evaluation is not low risk.

Additionally, in the final evaluation of risk for IA, we have made changes to product categories and have deleted some of the foods referenced by the comment because they are out of scope. See Response 1 and Table 1.

Comment 3) Some comments argue that because we performed a separate risk assessment under the PCHF rule for on-farm activities, there are now two categories of low-risk on-farm activities—one for the PCHF rule and one for the intentional adulteration rule. The comment also argues that these two different categories of low-risk will be challenging for farmers to understand and they suggest that we use different terminology when referring to low-risk for intentional adulteration, such as “low-vulnerability.”

Response 3) We conducted the RA for the PCHF rule, and the final evaluation of risk for IA is an appendix to that RA. The RA for the PCHF rule and the evaluation of risk for IA use different methods to determine low risk. We recognize that the different determinations for on-farm activities may be challenging to understand. Unlike in the RA for the PCHF rule, for which we separated manufacturing, processing, packing, and holding activities, in the final 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 risk assessment for PCHF rule. 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.

In addition, we intend to make available guidance documents to help explain the rules, including which facilities are covered and what those covered facilities are required to do under each of the rules.

Comment 4) One comment seeks more information on how we determined that the production practices for “Raw, In-Shell” Peanuts and Tree Nuts are considered low-risk whereas the production practices for “Raw, Shelled” Peanuts and Tree Nuts are not low-risk.

Response 4) Upon further analysis and in light of the new definition of “farm” from the PCHF, in the final evaluation we determined that all product categories that are finished foods that are produced using only activities that fall within the farm definition (including raw, in-shell peanuts and tree nuts and raw, shelled peanuts and tree nuts), are out of scope for the final evaluation. See Response 1 and Table 1.

Comment 5) One comment asks why fruits like grapes (sulfited) were not classified as low-risk food and seeks clarification as to whether gaseous sulfur dioxide treatment of RACs would be considered sulfiting of food. The comment states that sulfur-dioxide emitting pads are routinely used during transit of grapes to reduce decay incidence by phyto-pathogens. The comment also asks whether use of sulfur-dioxide-emitting pads or other gaseous treatment of RACs would be considered a non-low-risk activity.

Response 5) We did not classify sulfited fruits as low-risk in the draft evaluation of risk for IA because they involve two key activity types: secondary ingredient handling and mixing and similar activities. This conclusion has not changed, but in the final evaluation of risk for IA sulfiting is now captured in the category “Other fruits and vegetables that are processed foods.” The use of sulfur-dioxide emitting pads on grapes is not within the scope of what we described as “sulfiting” in the draft. When used on grapes, sulfiting agents are used as a fungicide on a RAC and are subject to regulation by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.). We consider this activity to be application of a pesticide to a RAC, and we treat this as distinct from other uses of sulfites described as “sulfiting” in the draft evaluation of risk for IA (e.g., addition of sulfiting agents as chemical preservatives). As with other applications of pesticides to RACs, use of sulfur-dioxide-emitting pads on grapes is within the farm definition if it is conducted to ensure the safe and effective storage of grapes. In that circumstance, use of sulfur-dioxide-emitting pads on grapes is within the definition of holding, and holding of RACs is within the farm definition. If all the activities conducted on a food are within the farm definition, the food is out of scope of the final evaluation of risk for IA. Therefore, FDA would not make a determination regarding whether it is low risk.

Comment 6) One comment recommends that FDA should consider broadening this exemption to a farm mixed-type facility that engages in other activities that are not considered low risk.

Response 6) We deny this request. Section 103(c)(1)(D)(i) of FSMA explicitly limits the exemption to facilities that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that are determined to be low risk involving specific

foods that are low risk, as determined by the science-based risk analysis conducted by FDA. Our evaluation of risk for intentional adulteration for mixed-type facilities, using the key activity type method, identified low risk production processes for the types of finished foods we expect are produced at these facilities. We determined that production processes for the following finished foods are low risk: eggs (in-shell, other than RACs, e.g., pasteurized) and game meats (whole or cut, not ground or shredded, without secondary ingredients). These are identified in the exemption in §121.5(g). We also recognize that some farm mixed-type facilities engaging in production processes that are not identified as low risk may not have any significant vulnerabilities; however, each covered facility must conduct a facility-specific vulnerability assessment, and that assessment must consider, at a minimum: (1) the potential public health impact if a contaminant were added (e.g., severity and scale); (2) the degree of physical access to product; (3) the ability of an aggressor to successfully contaminate the product. If after conducting a vulnerability assessment, the facility appropriately concludes that there are no actionable process steps in the facility, the facility would not be required to implement mitigation strategies. The food defense plan at this facility would include the vulnerability assessment, the conclusion that no actionable process steps are present, and an explanation for this conclusion at each step.

Comment 7) One comment states that processing activities that have been identified as low risk, and that are occurring at farm mixed-type facilities, should be exempted from this rule in all sizes of farm mixed-type facilities, including farm mixed-type facilities that are larger than small and very small businesses.

Response 7) We disagree that production processes that have been identified as low risk for the purposes of this appendix, and that occur at farm mixed-type facilities, should be exempt

from the intentional adulteration rule when these activities occur at farm mixed-type facilities that are larger than small or very small businesses. Expanding the exemption beyond small and very small businesses is contrary to the statute as section 103(c)(1)(D)(ii) explicitly limits any exemptions for these types of facilities to small and very small businesses. Furthermore, the rule is intended to protect food against intentional adulteration caused by individuals or organizations whose goal is to maximize public health harm. We have concluded that such an attacker would more likely to target the product of relatively large facilities, especially firms whose brand is nationally or internationally recognizable. An attack on such a target would potentially provide the desired wide scale public health consequences and the significant public attention that would accompany an attack on a recognizable brand. Additionally, such facilities are likely to have larger batch sizes, potentially resulting in greater human morbidity and mortality.

We recognize that larger farm mixed-type facilities (i.e., farm mixed-type facilities that are neither small nor very small businesses) engaging in production processes that are not identified as low risk may not have any significant vulnerabilities; however, each covered facility must conduct a facility specific vulnerability assessment, and that assessment must consider, at a minimum: (1) the potential public health impact if a contaminant were added (e.g., severity and scale); (2) the degree of physical access to product; (3) the ability of an aggressor to successfully contaminate the product. If after conducting a vulnerability assessment, the facility appropriately concludes that there are no actionable process steps in the facility, the facility would not be required to implement mitigation strategies. The food defense plan at this facility would include the vulnerability assessment, the conclusion that no actionable process steps are present, and an explanation for this conclusion at each step.