I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for verifying that establishments are accurately controlling and labeling the eight most common (“Big 8”) food allergens. These allergens are designated as “major food allergens” by the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004.

KEY POINTS:

- FSIS will begin an ongoing, monthly verification task beginning April 12, 2015, to determine whether establishments accurately control and label the “Big 8” food allergens.
- The “Big 8 Formulation Verification” task in PHIS will include record review, observation of the production process, and responding to specific task-related questions in PHIS.

II. BACKGROUND

A. Starting from 2008, there has been a sustained increase in the number of recalls of FSIS-regulated products that contain undeclared allergens and ingredients of public health concern.

B. The “Big 8” food allergens account for approximately 90 percent of all food allergy reactions. The “Big 8” food allergens are:

1. Wheat;
2. Crustacean shellfish (e.g. crab, lobster, shrimp, etc.);
3. Eggs;
4. Fish;
5. Peanuts;
6. Milk;
7. Tree nuts (e.g. almonds, pecans, walnuts, etc.); and
8. Soybeans.
C. Ingredients of public health concern include the “Big 8” allergens as well as additives that may cause food intolerance, such as sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG).

D. FSIS analyses of previous issuances and recalls connected to undeclared allergens and ingredients of public health concern revealed that many occurred because of changes in ingredient suppliers, products in the wrong package or with misprinted labels, or changes to product or ingredient formulation.

E. An FSIS analysis of recalls also revealed incidents that occurred when a meat or poultry product came in contact with an undeclared allergenic ingredient that was not directly added to the product. An example would be an establishment that is producing product on a food contact surface sprayed with a non-stick coating containing soy lecithin and is not properly declaring the soy lecithin on labeling.

F. When an establishment ships product into commerce with an undeclared allergen, its food safety system has failed. For establishments producing meat and poultry products, the establishment has either failed to address the chemical (allergen) food safety hazard in its hazard analysis, failed to support the decisions made in the hazard analysis, or failed to effectively implement the controls to support the decisions made in the hazard analysis.

G. It is important that establishments have preventive measures or controls to address undeclared food allergens. When “Big 8” food allergens or other ingredients of public health concern are not properly declared, FSIS may request a voluntary recall. (Refer to FSIS Directive 8080.1, Recall of Meat and Poultry Products, for additional information on recall procedures.)

H. This directive applies to IPP in egg products plants and in meat and poultry product establishments that produce product in the following HACCP categories:

1. Raw – non-intact (03B);
2. Raw – intact (03C);
3. Thermally processed commercially sterile (03D);
4. Not heat treated, shelf stable (03E);
5. Heat treated shelf stable (03F);
6. Fully cooked not shelf stable (03G);
7. Heat treated not fully cooked not shelf stable (03H); and

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. At the next weekly establishment meeting after receipt of this directive, IPP are to meet with establishment management to discuss each of the items in the Background (Section II) of this directive. Additionally, IPP are to:

1. Ask whether the establishment has developed and implemented preventive or control measures within the HACCP plan, Sanitation SOPs, or other prerequisite program to address allergens;
2. Discuss whether the establishment produces any products that contain any of the “Big 8” food allergens. Attachment 1 lists examples of ingredients and products that may be derived from these food allergens;

3. Inform establishment management that IPP will be verifying that the establishment’s labels match its product formulations during an ongoing “Big 8 Formulation Verification” task occurring at a monthly frequency. IPP are to schedule additional verification tasks in response to FSIS concerns in accordance with section IV.C. of this directive; and

4. Inform establishment management that FSIS allergen compliance guidelines and labeling compliance guides are available online, which may assist them in assessing their own allergen program.

B. IPP are to conduct the assigned “Big 8 Formulation Verification” task and document findings in PHIS as directed in section V of this directive.

IV. TIMING OF VERIFICATION ACTIVITIES

A. Each meat and poultry establishment eligible for verification activities per section II.H and each egg products plant will be assigned a directed “Big 8 Formulation Verification” PHIS task on a monthly basis starting April 12, 2015.

B. IPP may schedule the “Big 8 Formulation Verification” task more frequently in an establishment if there are indicators of an increased risk of undeclared allergens and ingredients of public health concern. IPP are to discuss the circumstances that are causing concerns with their supervisor and frontline supervisor (FLS) before scheduling additional tasks. IPP are to consider the situations below when determining whether they need to schedule additional tasks:

1. A recall by the establishment related to “Big 8” allergens, ingredients of public health concern, or other undeclared ingredients in the previous year;

2. Consumer complaints linked to the establishment related to allergens, ingredients of public health concern, or other undeclared ingredients in the previous year;

3. A history of sanitation Non-compliance Records (NRs), and HACCP NRs for meat and poultry establishments, related to allergens, ingredients of public health concern, or other undeclared ingredients in the previous year;

4. Labeling NRs for the establishment in the previous year; or

5. Product formulation changes, adjustments to ingredients, supplier changes, or new products added by the establishment.

NOTE: IPP are to contact their supervisor for guidance if at any time they have reason to believe product bearing labels that fail to declare one of the “Big 8” food allergens or other ingredients of public health concern has entered commerce (refer to FSIS Directive 8080.1).

V. “BIG 8 FORMULATION VERIFICATION” TASK

A. IPP are to perform and complete a directed “Big 8 Formulation Verification” task, at a monthly frequency, no later than 25 days after the initial PHIS task notification.

B. IPP are to schedule the task in advance and determine which products will be produced on that date.
C. IPP are to select one product for the verification task. IPP in establishments with multiple shifts are to complete the verification task on each shift.

D. IPP in establishments with multiple shifts are to coordinate with each other to avoid selecting the same product for a verification task.

E. IPP are not to select the same product for consecutive tasks and are to attempt to first select products that have not been selected previously, unless there has been a change in supplier, change in ingredients, change in formulation, or the establishment produces a very limited number of products.

F. If the establishment produces more than one product, IPP are to use the following product flow chart to prioritize a product for the verification process. IPP are to apply the priority list to all products and eligible establishments per section II.H. whether or not they produce products containing a “Big 8” allergen.

Start: All Establishment Products

Priority 1: Have one or more of the products had a change in supplier of ingredients, a change in ingredients, or a change in formulation within the past six months?

Y

- If only one product has a change, use this product for verification;
- If multiple products had a change, use the product produced in the largest volume.

N

Priority 2: Do one or more of the products incorporate a multi-ingredient component produced outside the establishment?

Y

- If only one product incorporates a component, use this product for verification;
- If multiple products incorporate a component, use the product produced in the largest volume.

N

If the prioritization does not result in a single product, IPP are to choose the product produced in the largest volume. IPP are to avoid selecting the same product for consecutive tasks as described in section V.E.
NOTE: Examples of multi-ingredient components include sauces, condiments such as ketchup or mustard, seasoning packets, flavorings, spice mixes, soup bases, or other combinations of two or more ingredients that are mixed together (in this case, outside of the establishment).

G. IPP are to obtain the selected product formulation from the establishment after completing the prioritization process. The product formulation is to be specific to the actual product, not a general formula.

1. Meat and poultry establishments are required to provide IPP accurate information on all procedures involved in product preparation, including product composition, for verification in accordance with 9 CFR 318.6 and 381.180.

2. Egg products plants are required to furnish IPP with accurate information on product preparation and formulation for verification in accordance with 9 CFR 590.411 as well as records associated with production of products in accordance with 9 CFR 590.200.

H. IPP are to perform the verification using a record review and observation component for the production of the product selected using the product prioritization. IPP are to verify that:

1. All ingredients used in the production of the product are present on the product formulation record (through Record Review and Observation);

2. All ingredients in the product formulation are declared in the ingredients statement on the product label by common or usual name in descending order of predominance and that the appropriate label is applied to the product (through Record Review and Observation); and

3. The applied label is consistent with the establishment’s label approval on file (through Record Review).

NOTE: IPP can use the list of common ingredients and foods in Attachment 1 for help in identifying “Big 8” allergens.

I. IPP are to answer specific questions related to this task in PHIS. These questions are located on the “additional info” tab of the task. See Attachment 2 for questions, answer choices, and guidance.

J. IPP are not to assume, without verification, that all ingredients used in a product formulation are appropriately declared on the final meat, poultry, or egg product labels.

1. IPP are to verify that all ingredients listed on the labels of incoming food and food ingredients (e.g., multi-ingredient components such as sauces or seasoning packets) are listed on the labels of the meat, poultry, or egg products in which they are used.

   a. Ingredients classified as spices and flavoring may be declared under the general declaration of “spices” or “flavoring;”

   b. The label does not need to declare substances that FSIS has determined meet the definition of a processing aid or incidental additive. FSIS does not consider allergens (e.g. soy) and ingredients of public health concern as processing aids or incidental additives that are exempt from labeling.

   c. Releasing agents used to prevent sticking of foods to food contact surfaces are not considered processing aids and incidental additives. The label must declare releasing agents containing food allergens (e.g., soy).
2. IPP are to verify that all of the ingredients listed in a “may contain” or “produced in a facility” statement on incoming food and food ingredients are listed on the final product label, except in situations where the establishment contacts the supplier of the component and addresses the statement. Establishments producing meat and poultry products would address the statement in the hazard analysis. Specifically, all the ingredients in a “may contain” or “produced in a facility” statement of a purchased ingredient need not be listed on the final label if the official establishment:

   a. Contacts the supplier and confirms in writing that the statement is a cautionary statement, and no such ingredient is in the product; and

   b. Includes a written statement in its hazard analysis documentation to support why the “may contain” or “produced in a facility” statement is not carried forward to the finished meat or poultry product label.

VI. “BIG 8 FORMULATION VERIFICATION” NONCOMPLIANCE

A. IPP are to record any noncompliance identified on an NR according to FSIS Directive 5000.1. IPP in egg products plants are to follow the instructions in FSIS Directive 5030.1, Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants. IPP are to notify their supervisor if they identify a noncompliance during the verification.

B. If IPP find an undeclared allergen, they are to cite both the relevant hazard analysis and labeling regulations. Examples of potential noncompliances are:

   1. Hazard analysis:

      a. If during the course of the verification, IPP find that a meat or poultry product contains an undeclared allergen, and the establishment has not identified that ingredient as a chemical hazard in its hazard analysis, IPP are to document a noncompliance. IPP are to cite 9 CFR 417.2(a)(1) as the relevant regulation because the establishment failed to address a chemical food safety hazard in its process. IPP are also to verify that the establishment has implemented corrective actions that meet the requirements of 9 CFR 417.3(b) in response to the unforeseen hazard and are to document any noncompliance identified;

      b. If during the course of the verification, IPP find that a meat or poultry product contains an undeclared allergen, and the establishment has identified the allergen as a chemical hazard in its hazard analysis and determined it is not reasonably likely to occur as a result of a pre-requisite program, there is noncompliance with 9 CFR 417.2(a)(1) and 417.5(a)(1) because there is evidence that the prerequisite program may not effectively prevent the chemical hazard from being reasonably likely to occur. IPP are also to verify that the establishment has implemented corrective actions that meet the requirements of 9 CFR 417.3(b) and 417.3(c) and are to document any noncompliance identified;

      c. If during the course of the verification, IPP find that a meat or poultry product contains an undeclared allergen, and the establishment has identified that ingredient as a chemical hazard in its hazard analysis and has determined that it is reasonably likely to occur, IPP are to document noncompliance citing 9 CFR 417.2(c)(4). They are to do so because they observed a deviation from the critical limit that was not detected by the establishment monitoring procedure. IPP are also to verify that the establishment has implemented corrective actions that meet the requirements of 9 CFR 417.3(a) and 417.3(c) and are to document any noncompliance identified; and

NOTE: IPP are to consider what their findings show about the overall effectiveness of the establishment’s food safety system and take these findings into account during the performance of the next Hazard
Analysis Verification (HAV) task. Refer to FSIS Directive 5000.6, Performance of the Hazard Analysis Verification (HAV) Task, for additional information regarding the performance of the HAV. IPP are to discuss their concerns with their supervisor if they believe a directed HAV task is needed.

2. Labeling: If during the course of the verification, IPP find that a meat, poultry, or egg product contains one of the "Big 8" allergens that is not declared on the final label, IPP are to document a food safety labeling noncompliance. The noncompliance is to be documented under the “Big 8” Formulation Verification task using 9 CFR 317.2, 381.118, or 590.411(c)(1) as the relevant labeling regulations.

NOTE: If IPP detect additional labeling concerns, they are to describe and document the findings. For example, if IPP find that product contains an ingredient other than one of the "Big 8" allergens that is of public health concern, and that ingredient is not declared, or if the order of predominance of the ingredients on the label is incorrect, IPP are to schedule a directed General Labeling task and document a General Labeling noncompliance with 9 CFR 317.2, 381.118, or 590.411(c)(1) as the relevant regulation.

VII. FRONTLINE SUPERVISOR (FLS) RESPONSIBILITIES

A. The FLS is to ensure that IPP know how to review labels and product formulations.

B. The FLS may request or recommend a food safety assessment (FSA) or possible enforcement action if the establishment has not effectively ensured that allergens and ingredients of public health concern are properly used and declared, or if the FLS determines that the lack of controls raises concerns about the adequacy of the meat and poultry establishment’s HACCP system.

VIII. DATA ANALYSIS

The Data Analysis and Integration Staff (DAIS) will analyze PHIS data from this verification activity on a quarterly basis. DAIS and the Risk, Innovations, and Management Staff (RIMS), OPPD, project leaders will use these analyses to determine whether additional policy instructions are needed.

IX. QUESTIONS

Refer questions regarding this directive to RIMS through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter Directive 7230.1
Question Field: Enter question with as much detail as possible.
Product Field: Select General Inspection Policy from the drop-down menu.
Category Field: Select Sampling from the drop-down menu.
Policy Arena: Select Domestic (U.S.) Only from the drop-down menu.

When all fields are complete, press Continue and at the next screen press Finish Submitting Question.

NOTE: Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development
Allergenic Ingredients and Foods

Food Allergy Research and Education is a source of information regarding food allergies. One of their resources for consumers lists allergenic ingredients and foods that may contain allergenic ingredients. The list of ingredients and foods below can be used to help IPP identify “Big 8” allergens.

1. Wheat

Consumers allergic to wheat products are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain wheat.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>bread crumbs</td>
<td>Farina</td>
</tr>
<tr>
<td>bulgur</td>
<td>flour*</td>
</tr>
<tr>
<td>cereal extract</td>
<td>hydrolyzed wheat protein</td>
</tr>
<tr>
<td>club wheat</td>
<td>Kamut</td>
</tr>
<tr>
<td>couscous</td>
<td>matzoh/matzo, matzah/matza</td>
</tr>
<tr>
<td>cracker meal</td>
<td>Pasta</td>
</tr>
<tr>
<td>durum</td>
<td>Seitan</td>
</tr>
<tr>
<td>einkorn</td>
<td>semolina</td>
</tr>
<tr>
<td>emmer</td>
<td>Spelt</td>
</tr>
</tbody>
</table>

* all purpose, bread, cake, durum, enriched, graham, high gluten, high protein, instant, pastry, self-rising, soft wheat, steel ground, stone ground, whole wheat flour

Additionally, wheat is sometimes found in the following foods:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>baking powders (particularly imported)</td>
<td>glucose syrup</td>
</tr>
<tr>
<td>bouillon</td>
<td>soy sauce</td>
</tr>
</tbody>
</table>

2. Crustacean Shellfish

Consumers allergic to crustacean shellfish are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products have these ingredients, they contain a “Big 8” allergen

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>barnacle</td>
<td>crawfish</td>
</tr>
<tr>
<td>crab</td>
<td>Krill</td>
</tr>
</tbody>
</table>

Additionally, crustacean shellfish are sometimes found in the following foods:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>bouillabaisse</td>
<td>fish stock</td>
</tr>
<tr>
<td>cuttlefish ink</td>
<td>glucosamine</td>
</tr>
</tbody>
</table>

3. Eggs

Consumers allergic to eggs are advised to avoid foods that may contain these ingredients. If meat or poultry products contain any of these, they likely contain eggs.
albumin/albumen | egg white | lysozyme | ovalbumin
---|---|---|---
dried egg | egg yolk | mayonnaise | powdered eggs
egg solids | eggnog | meringue | surimi

Additionally, eggs are sometimes found in the following foods:

baked goods | lecithin | marzipan | nougat
---|---|---|---
egg substitutes | macaroni | marshmallows | pasta

4. Fish

It is generally recommended that consumers allergic to fish should avoid all fish. The most common kinds of fish that individuals are allergic to are salmon, tuna, and halibut.

Additionally, fish is sometimes found in the following foods:

Asian foods | bouillabaisse | meatloaf | Worcestershire sauce
---|---|---|---
barbeque sauce | imitation fish/shellfish | salad dressing |

5. Peanuts

Consumers allergic to peanuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain peanuts.

artificial nuts | ground nuts | nut meat | peanut flour
---|---|---|---
beer nuts | mixed nuts | nut pieces | peanut protein hydrolysate
goobers | monkey nuts | peanut butter |

Additionally, peanuts are sometimes found in the following foods:

African, Asian, Latin American foods | Chili | marzipan |
---|---|---|
baked goods | egg rolls | mole sauce |
candy | enchilada sauce | nougat |

The FDA exempts highly refined peanut oil from being labeled as an allergen.

6. Milk

Consumers allergic to milk are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain milk.

butter | caseinates | half-and-half | recaldent
---|---|---|---
butter fat | cheese | lactalbumin | rennet casein
butter oil | cottage cheese | lactoferrin | sour cream
butter acid | cream | lactose | sour milk
butter ester | curds | lactulose | tagatose
buttermilk | custard | milk* | whey
<table>
<thead>
<tr>
<th>casein</th>
<th>diacetyl</th>
<th>milk protein hydrosylate</th>
<th>whey protein hydrosylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>casein hydrolysate</td>
<td>ghee</td>
<td>pudding</td>
<td>yogurt</td>
</tr>
</tbody>
</table>

* milk in all forms (including condensed, derivative, dry, evaporated, goat’s milk and milk from other animals, low fat, malted, milkfat, nonfat, powder, protein, skimmed, solids, whole)

Additionally, milk is sometimes found in the following foods:

<table>
<thead>
<tr>
<th>artificial butter flavor</th>
<th>chocolate</th>
<th>margarine</th>
<th>sausages</th>
</tr>
</thead>
<tbody>
<tr>
<td>baked goods</td>
<td>hot dogs</td>
<td>nisin</td>
<td></td>
</tr>
<tr>
<td>bouillon</td>
<td>lactic acid starter culture and other bacterial cultures</td>
<td>nondairy products</td>
<td></td>
</tr>
<tr>
<td>caramel candies</td>
<td>luncheon meat</td>
<td>nougat</td>
<td></td>
</tr>
</tbody>
</table>

7. Tree Nuts

Consumers allergic to tree nuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain a “Big 8” allergen.

<table>
<thead>
<tr>
<th>almond</th>
<th>coconut</th>
<th>Nangai nut</th>
<th>pili nut</th>
</tr>
</thead>
<tbody>
<tr>
<td>artificial nuts</td>
<td>filbert/hazelnut</td>
<td>natural nut extract</td>
<td>pine nut</td>
</tr>
<tr>
<td>beechnut</td>
<td>gianduja</td>
<td>nut butters</td>
<td>pistachio</td>
</tr>
<tr>
<td>Brazil nut</td>
<td>ginkgo nut</td>
<td>nut meal</td>
<td>praline</td>
</tr>
<tr>
<td>butternut</td>
<td>hickory nut</td>
<td>nut paste</td>
<td>shea nut</td>
</tr>
<tr>
<td>cashew</td>
<td>litchi/lichee/lychee nut</td>
<td>nut pieces</td>
<td>walnut</td>
</tr>
<tr>
<td>chestnut</td>
<td>macadamia nut</td>
<td>pecan</td>
<td></td>
</tr>
<tr>
<td>chinquapin</td>
<td>marzipan/almend paste</td>
<td>pesto</td>
<td></td>
</tr>
</tbody>
</table>

Additionally, tree nuts are sometimes found in the following foods:

<table>
<thead>
<tr>
<th>alcoholic extracts</th>
<th>black walnut hull extract</th>
<th>nut distillates</th>
<th>walnut hull extract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian foods</td>
<td>natural nut extract</td>
<td>nut oils</td>
<td></td>
</tr>
</tbody>
</table>

8. Soybeans

Consumers allergic to soybeans are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain soybeans.

<table>
<thead>
<tr>
<th>edamame</th>
<th>soy fiber</th>
<th>soy sprouts</th>
<th>tamari</th>
</tr>
</thead>
<tbody>
<tr>
<td>miso</td>
<td>soy flour</td>
<td>soy yogurt</td>
<td>tempeh</td>
</tr>
<tr>
<td>natto</td>
<td>soy grits</td>
<td>soya</td>
<td>textured vegetable protein</td>
</tr>
<tr>
<td>shoyu</td>
<td>soy ice cream</td>
<td>soybean</td>
<td>tofu</td>
</tr>
<tr>
<td>soy albumin</td>
<td>soy milk</td>
<td>soy protein</td>
<td></td>
</tr>
<tr>
<td>soy cheese</td>
<td>soy nuts</td>
<td>soy sauce</td>
<td></td>
</tr>
</tbody>
</table>

* FDA exempts highly refined soybean oil from being labeled as an allergen. However cold-pressed soybean oil, which is less commonly used, is not exempt from allergen labeling as it likely contains more residual protein.
Additionally, soybeans are sometimes found in the following foods:

<table>
<thead>
<tr>
<th>Asian foods</th>
<th>vegetable broth</th>
<th>vegetable starch</th>
</tr>
</thead>
<tbody>
<tr>
<td>soy lecithin*</td>
<td>vegetable gum</td>
<td>Worcestershire sauce</td>
</tr>
</tbody>
</table>

* With the exception of a few specific products, FDA does not exempt soy lecithin from allergen labeling as it generally contains residual protein. The use of soy lecithin in non-stick sprays and coatings (i.e. releasing agents) has led to recalls of FSIS-regulated product when the soy was not properly declared.
PHIS Questions for the “Big 8 Formulation Verification” Task

Question 1: Which of the following “Big 8” allergens are included in any product formulation at the establishment?
Choices: Soy, milk, fish, shellfish, peanut, tree nuts, wheat, eggs, none
NOTE: IPP in egg products plants should include “eggs” in their response.

Question 2: Has the establishment developed and implemented prevention or control measures within the HACCP plan, Sanitation SOPs, or other program to address allergens?
Choices: Yes-HACCP plan, Yes-Sanitation SOPs, Yes-Other Program, No
NOTE: Check all choices that apply.

Question 3: Does the establishment use a multi-ingredient component that is produced/mixed outside of the establishment?
Choices: Yes, No
NOTE: Examples of multi-ingredient components include sauces, condiments such as ketchup or mustard, seasoning packets, flavorings, spice mixes, soup bases, or other combinations of two or more ingredients that are mixed together (in this case, outside of the establishment).

Question 4: What is the product chosen for the verification activity?
Answer: Please list the product name of the product chosen for verification based on the prioritization.

Question 5: How many ingredients does the product chosen for the verification activity contain?
Choices: Less than 15, 15-30, More than 30

Question 6: Was the product formulation consistent with what was observed being used in production?
Choices: Yes, No

Question 7: Were all “Big 8” allergens present in the product formulation also declared on the product label being applied to the product?
Choices: Yes, No, Not Applicable

Question 8: Was the product label being applied to the product consistent with the label approval on file?
Choices: Yes, No