UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

7000.6
Revision 1

7/26/24

ALLERGEN VERIFICATION SAMPLING PROGRAM

NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL: SEPTEMBER 1, 2024

I. PURPOSE

This FSIS Directive provides instructions to inspection program personnel (IPP) to collect samples for the allergen verification sampling program conducted at establishments that produce ready-to-eat (RTE) products with labeling claims for 14 food allergens and gluten. FSIS is reissuing this directive to delay implementation of this sampling program until September 1, 2024.

II. CANCELLATION

FSIS Directive 7000.6, Allergen Verification Sampling Program, 7/24/24

III. BACKGROUND

A. Since May 7, 2018, FSIS has conducted sampling and testing of RTE product with claims related to soy. FSIS also verifies product formulation and labeling for the "Big 9" food Allergens. FSIS is now implementing a new analysis method that will continue to test for soy and allow the Agency to also test for 13 other allergens and gluten. This new program will include analysis for soy, crustacean shellfish (e.g., crab, lobster, shrimp), eggs, peanuts, milk, nine tree nuts (almond, Brazil nut, cashew, coconut, hazelnut, macadamia, pine nut, pistachio, and walnut), and gluten. FSIS intends to continue to develop the sampling program to include analysis for sesame and expanded sampling to all multi-ingredient products and will update the instructions in this directive when the Agency is ready to implement the additional sampling and testing.

B. A food allergy is a potentially serious response to consuming certain foods or food additives. For those who are sensitive, a reaction can occur within minutes or hours, and symptoms can range from mild to life-threatening. According to the Centers for Disease Control and Prevention, food allergies are a growing food safety and public health concern that affects an estimated 6% of adults and 8% of children in the United States. Food Allergy Research & Education reports that each year in the United States, every 10 seconds, a food allergy sends a patient to the emergency room, resulting in an estimated 3.4 million hospital visits. There is no cure for food allergies.

C. The “Big 9” food allergens account for approximately 90% of all food allergy reactions. The “Big 9” food allergens are: soybeans, wheat, crustacean shellfish (e.g., crab, lobster, shrimp), eggs, fish, peanuts, milk, tree nuts ((e.g., almonds, cashews, walnuts), and sesame. These allergens are designated as “major food allergens” by the Food and Drug Administration’s Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 and Food Allergy Safety, Treatment, Education, and Research Act (FASTER Act) of 2021. Gluten is currently not designated as a “Big 9” allergen and may be found in foods that do not contain wheat. Products that do not contain wheat but do contain rye or barley could also contain gluten.

D. FSIS is conducting this sampling program to expand its verification of industry's compliance with the Agency's labeling regulations. Labeling claims are required to be truthful and not misleading (9 CFR 317.8(a), and 381.129). Labels are also required to display a complete listing of ingredients (9 CFR 317.2(c)(2), and 381.118) to protect consumers from misbranded and economically adulterated meat and poultry products.

IV. AWARENESS MEETING WITH ESTABLISHMENT MANAGEMENT

When IPP receive an LV_ALG request in the Public Health Inspection System (PHIS), they are to include the following information at the next weekly meeting with establishment management:

1. FSIS will collect samples for the allergen verification sampling program conducted at establishments that produce ready-to-eat (RTE) products with labeling claims for 14 food allergens and gluten;

2. These samples will be collected at the same time and from the same lot of product as a concurrent RTEPROD sample;

3. FSIS Directive 7000.6 provides instructions for this sampling program (IPP will provide a web link or printed copy); and

4. Establishments are not required to hold or control product selected for sampling under this sampling program. However, IPP are to inform establishment management that sampled product that tests positive for the allergen ingredient(s) on the claim would be subject to regulatory action as outlined in Section X. Establishments are still required to hold RTE sampled product in accordance with FSIS Directive 10,240.3, *FSIS Ready-to-Eat Sampling Programs.*

V. ELIGIBILITY

A. The establishment eligibility is determined based on information collected through multiple data sources. Establishments that are eligible for the "Big 9" Formulation Verification task and produce RTE products labeled with a labeling claim(s) for one or more allergen ingredients (e.g., no soy added, milk-free, does not contain eggs) will be eligible for sampling. Eligible establishments will be randomly selected for sampling tasks.

B. IPP are to be familiar with the establishment's production schedule to determine when it is producing eligible product. IPP at eligible establishments may receive a sampling task with the sampling code LV_ALG. Products eligible for sampling are RTE products that may be sampled under the RTEPROD sampling projects, as described in FSIS Directive 10,240.3, and labeled with a claim for allergen ingredients.

VI. ORDERING SAMPLING SUPPLIES

A. IPP are to only use sampling supplies provided by FSIS laboratories when collecting samples.

B. If IPP have not received sample supplies at least 72 hours prior to the scheduled sample collection, they are to request sampling supplies through PHIS by right-clicking on the scheduled sampling task on the Task Calendar, selecting "Order Supplies," and entering information in the fields provided. Information can also be found in IPP Help, *Sample Handling and Packaging*.

C. If IPP are unable to request supplies via PHIS, they are to request sampling supplies via Outlook to the FSIS Eastern Laboratory (EL)(SamplingSupplies-EasternLab@usda.gov).

D. IPP are to include the following information in their email request for supplies:

1. The sampling project code (LV_ALG);

2. The establishment number and establishment name;

3. The IPP's name and contact phone number; and

4. The specific supplies needed, including name and quantity to be ordered.

E. Sample supplies for the allergen verification sample include:

1 – Shipping Box (M-USDA20) with packing materials
1 – Two-gallon zipper lock bag, non-sterile
1 – 6"x12" Plastic Bags
1 – FedEx Billable Stamp for the EL
1 – FSIS Form 7355-2A/2B

VII. SCHEDULING THE SAMPLE

When IPP receive an LV_ALG request in PHIS, they are to schedule sample collection within the sampling window timeframes given. IPP are to schedule and collect LV_ALG samples at the same time as a RTEPROD sample on the PHIS calendar on days that eligible product will be produced.

1. IPP are to add the sampling task to the task calendar and set up a collection date and parcel pickup date, in accordance with FSIS Directive 13,000.2, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*. Any rescheduled or canceled sampling tasks are to be recorded in PHIS.

2. IPP are not to wait until the end of the sampling window to schedule the sample. Scheduling the sample at the beginning of the sampling window will allow more time to ensure that the sample is available, and that capacity is available at the labs during the sampling window.

3. To schedule the sample, IPP are to randomly select a day, shift, and time within the sample window timeframe and from shifts in which the establishment will be producing RTE products with a label claim. There should be an equal chance that sampling will occur during any shift where eligible product is produced.

4. After selecting the day, shift, time, and product to collect a LV_ALG sample, IPP are to schedule a RTEPROD of the same product from the same lot following instructions in FSIS Directive 10,240.3. The LV_ALG sample is to be packaged and shipped separately to the FSIS EL for analysis. See Section VII: *Scheduling the Sample* for instructions.

VIII. CONDUCTING SAMPLING TASKS

A. IPP are to notify establishment management before collecting the samples. IPP are to discuss sample scheduling with the establishment and document the discussion in a Memorandum of Interview , as described in FSIS Directive 5,000.1, *Verifying an Establishment's Food Safety System*. As part of this discussion, IPP are to determine the types of RTE products produced by the establishment, whether they are labeled with any claims, and when they are produced.

B. IPP are to collect one pound of eligible product. The labs require at least one pound of product for the LV_ALG sample to analyze the sample, and failure to collect the minimum amount will result in a sample discard. IPP are to collect either one pound of meat or poultry only or one pound of a complete product, including meat or poultry and non-meat or poultry components when the ingredients are commingled. IPP are to separately collect one pound of eligible product from the same lot for the RTEPROD task following instructions in FSIS Directive 10,240.3.

C. When the product contains meat or poultry and non-meat or poultry ingredients, IPP are to review IPP Help, *Multi-component RTE Product Sampling*, which contains examples of how to determine how much product to collect; IPP Help also includes photos of comingled (in contact) and non-comingled (not in contact) ingredients in final packaging (i.e., packaging that is normally shipped by the establishment into commerce). For allergen verification, IPP are to ensure that:

1. If the meat or poultry and non-meat or poultry ingredients are commingled in the final package (e.g., a salad with meat or poultry mixed in, bread product stuffed with meat), IPP are to collect a one-pound sample of the complete final product (including the meat or poultry and non-meat or poultry component).

2. If the meat or poultry and non-meat or poultry ingredients are not commingled in the final package (e.g., an entree with separate compartments for meat or poultry and vegetables), then IPP are to collect enough final packages to reach the one-pound sample weight for the meat or poultry component, or the establishment may slack-fill the meat or poultry component only into the final package. Other components that are non-meat or poultry do not count towards the sample weight in non-commingled products. Generally, multiple entrees are necessary to ensure there is sufficient meat or poultry available for laboratory testing.

D. IPP are to submit the samples to the laboratory for allergen analysis in the final package. The laboratory does not supply sterile bags or gloves for sampling because IPP are not to have direct contact with the exposed, unpackaged RTE product as allergens and other contaminants may be present in the environment and could be transferred to the product if an exposed product is collected.

NOTE: Final packaging may include butcher paper, wax paper, plastic wrap, or any packaging that is not sealed.

E. If the final package or product container is too large, heavy, or costly to ship to the laboratory or the establishment only ships product in bulk, IPP can contact the laboratory through PHIS to request a larger shipping container or ask the establishment to slack-fill or short-weight a product for a one-pound sample and send it in the usual establishment packaging, such as the container liner. IPP are not to cut the product to fit it inside the shipping container. The following are additional instructions regarding slack-filling or short-weighting:

1. If possible, IPP are to ensure the establishment slack-fills or short-weights a one-pound sample in the usual establishment packaging and seal it (e.g., vacuum seal).

2. If the product is shipped in bulk using a liner bag inside a box, IPP are to ensure the establishment slack-fills or short-weights a one-pound sample into the container liner. IPP are to tie off the liner bag (e.g., by knotting the bag or using a rubber band) so smaller particles (e.g., shredded meat pieces) or liquid does not spill into the shipping container. IPP are to place the slack-filled package in a secondary bag. The laboratory will discard the sample if it contains spilled or leaking products.

3. If the product is shipped in bulk and there is no liner bag (e.g., a wax-lined box), IPP are to ensure the establishment slack-fills or short-weights a one-pound sample using its bulk packaging (e.g., the wax lined box with no liner bag), or the establishment may use food-grade packaging or sterile packaging such as Whirl-Pak bags. Laboratory-supplied bags (e.g., zip top bags) are for secondary containment to protect the shipping container from possible sample leakage and are not sterile. The laboratory-supplied bag protects the box in case the primary container leaks.

4. IPP are not to slack-fill the sample and are not to supply the establishment with a laboratory-supplied bag as the primary wrap or container for the sample. The establishment is responsible for slack-filling the product in packaging that they supply.

5. When IPP document the sampling task in PHIS, under the *Additional Info* tab, they are to click "yes" to the question "Is this sample short-weighted/slack-filled?" to ensure that the sample is not discarded by the laboratory. Per this directive, IPP are to ensure the sample is short-weighted or slack-filled by the establishment employees or equipment in establishment-supplied packaging.

NOTE: There is no sampling questionnaire to complete for this sampling project.

IV. SAMPLING PACKING AND SHIPPING

A. IPP are to safeguard the integrity of samples during submission according to FSIS Directive 7,355.1, *Use of Sample Seals for Laboratory Samples and Other Applications*.

B. IPP are to ship samples to the designated laboratory as soon as collected and during the next available FedEx pickup. IPP are to ship samples refrigerated or frozen, depending on establishment practices. IPP are to use sufficient frozen gel packs to keep samples cold during transit. IPP are to ship samples Monday through Friday. IPP are not to ship samples on Saturdays or on the day before a federal holiday, or as directed by an Agency user notice via e-mail notification.

C. According to FSIS Directive 13,000.2, IPP are to submit information through PHIS to transfer electronic records to the lab. To submit samples to the lab, IPP are to apply the bar code label from the sample seal set to the designated location at the top of the lab form and sign and date the form before placing it in the shipping container. Additional information on the use of sample seals can be found in FSIS Directive 7,355.1.

D. IPP are to respond in a timely manner to any requests from the FSIS laboratories regarding sample or form information (e.g., if the sample is missing a form that IPP need to submit) to avoid the sample being discarded.

X. TEST RESULTS AND FURTHER ACTIONS

A. Test results for the LV_ALG sampling project will be reported in PHIS as "acceptable" or "unacceptable." In the event that FSIS testing reports as "unacceptable" because it is positive for the presence of the allergen ingredient(s) on the claim, IPP are to document the finding in a noncompliance record (NR) and cite 9 CFR 317.8(a) and 317.2(c)(2) (for meat products) or 381.129 and 381.118 (for poultry products).

1. If the unacceptable result is for a "Big 9" allergen (soy, crustacean shellfish (e.g., crab, lobster, shrimp), eggs, peanuts, milk, tree nuts (almond, Brazil nut, cashew, coconut, hazelnut, macadamia, pine nut, pistachio, and walnut), IPP are to conduct a directed Big 9 Formulation Verification task and document the findings in PHIS in accordance with FSIS Directive 7,230.1, *Ongoing Verification of Product Formulation and Labeling Targeting the Nine Most Common ("Big 9") Food Allergens.*

2. If the unacceptable result is for gluten, IPP are to conduct a directed general labeling task according to the instructions in FSIS Directive 7,221.1, *Prior Labeling Approval,* to verify that the ingredients list is compliant with 9 CFR 317.2(f).

B. Establishments are not required to hold or control product selected for sampling under this sampling program; however, if any of the product represented by the unacceptable lab results has been shipped into commerce, IPP are to verify that the establishment has accounted for all product in the affected lot and has taken appropriate corrective actions under 9 CFR 417.3. If the establishment fails to take appropriate action or fails to demonstrate that it is fulfilling the claim stated, FSIS may take further action, including but not limited to, recommending a recall of affected product remaining in commerce, rescinding label approval for labels bearing the claim, and not approving any labels with similar claims, until the establishment can demonstrate its ability to ensure the accuracy of its labels. In the event IPP become aware that adulterated or misbranded products have entered commerce, IPP are to inform their supervisor, per instructions provided in FSIS Directive 8,080.1, *Managing Adulterated or Misbranded Meat, Poultry, and Egg Products.*

XI. QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select **Sampling** as the Inquiry Type.

NOTE: Refer to FSIS Directive 5,620.1, *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator
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