

“Big 9” Formulation Verification Task Job Aid

Instructions: Review this Job Aid and policy documents, regulations, and inspection methodologies with a mentor.

Acronyms/Definitions

- Food Allergen – An ingredient that may cause an allergic reaction.
- Gluten – Protein found in wheat, rye, and barley. Gluten is not an allergen but may cause an insensitivity/intolerance reaction.
- RTE – Ready-to-eat products are edible without additional preparation to achieve food safety.
- CCP – Critical Control Point used to control a food safety hazard that is determined by the establishment-while performing a hazard analysis-to be reasonably likely to occur.
- HAV – Hazard Analysis Verification task is performed by IPP to assess if the establishment has performed and documented a hazard analysis that meets applicable regulatory requirements and addresses all relevant food safety hazards associated with the processes and products and the intended use per [9 CFR 417.2\(a\)](#).

Task Overview

- IPP verify that establishments are accurately controlling and labeling the nine most common (“Big 9”) food allergens, as well as gluten, when included in a product formulation.
- “Big 9” allergens:
 - Milk
 - Eggs
 - Peanuts
 - Tree nuts
 - Soybeans
 - Sesame
 - Wheat
 - Fish
 - Crustacean shellfish
- Previous voluntary recalls connected to undeclared allergens have occurred due to:
 - Changes in ingredient suppliers.
 - Products in the wrong package or with misprinted labels.
 - Changes to a product or ingredient formulation.
- If a product is shipped into commerce with an undeclared allergen, the establishment’s food safety system failed to control the chemical food safety hazard associated with that allergen.
- The “Big 9” Formulation Verification task applies to establishments that produce products other than single ingredient products in all HACCP processing categories, except slaughter.
- IPP also collect samples when assigned in PHIS to verify accurate labeling claims for 14 food allergens and gluten.

Task Basic Procedure

- [Schedule the routine “Big 9” Formulation Verification task](#) in PHIS.

- If the task is on the task list in an establishment that produces single ingredient products or only combines various species, IPP are to cancel the task and ensure the establishment profile is up to date.
- IPP may schedule directed “Big 9” Formulation Verification tasks if indicators suggest an increased risk of undeclared allergens, per supervisory instruction.
- In a multiple shift assignment, complete the task on each shift, rotating through all applicable product categories.
- Select one product on the establishment’s production schedule using the prioritization flow chart in [FSIS Directive 7230.1](#).
 - Refrain from selecting the same product for consecutive tasks unless the establishment only produces one product subject to the task.
- Review the formulation for the selected product.
- Use both the record review and review & observation components to verify:
 - All ingredients used in the production of the product are on the formulation record. This will include reviewing labels of incoming ingredients.
 - All ingredients in the formulation are declared in the ingredients statement on the label using the ingredients’ common or usual names in descending order of predominance.
 - The applied label is consistent with the label approval on file for the product.
- Complete the task related questions in the “questionnaire” tab of the task in PHIS (see Attachment 2 of [FSIS Directive 7230.1](#)).
- If noncompliance is observed:
 - Notify supervisor immediately, especially if products with undeclared allergens may have entered commerce. This product would be considered adulterated
 - Follow FSIS Directive 5000.1 to document the noncompliance under the “Big 9” Formulation Verification Task in PHIS, citing the relevant hazard analysis and labeling regulations:
 - Hazard Analysis –
 - The hazard analysis does not address allergens as a food safety hazard and the allergens are not declared on the product label: cite 9 CFR 417.2(a)(1) and verify corrective actions per 9 CFR 417.3(b) and (c).
 - The hazard analysis addresses allergens as a food safety hazard not reasonably likely to occur due to a prerequisite program and the allergens are not declared on the product label: cite 9 CFR 417.2(a)(1) and 417.5(a)(1) and verify corrective actions per 9 CFR 417.3(b) and (c).
 - The hazard analysis addresses allergens as a food safety hazard that is reasonably likely to occur controlled with a CCP and the allergens are not declared on the product label: cite 9 CFR 417.2(c)(4) and verify corrective actions per 9 CFR 417.3(a) and (c).

- Labeling –
 - Undeclared allergen– document food safety labeling noncompliance citing 9 CFR 317.2, 381.118, or 590.411(c)(1)
 - Other labeling issues – document noncompliance under General Labeling task citing 9 CFR 317.2, 381.118, or 590.411(c)(1)
 - Determine what the findings show about the overall effectiveness of the establishment’s food safety system.
- Document and complete the verification task in PHIS.

Sampling Procedure

- *Allergen Verification Sampling Program (LV_ALG) – [FSIS Directive 7000.6](#)*
 - Collect samples for allergen verification sampling at establishments that produce RTE products with **negative** labeling claims.
 - Use of a negative labeling claim (e.g., ‘no soy added’, ‘milk-free’, ‘does not contain eggs’) is voluntary.
 - Products without negative labeling claims are not eligible for this sampling project.
 - Collect samples at the same time and from the same lot of product as a concurrent RTEPROD sample.
 - When LV_ALG sampling tasks appear in the PHIS task list, follow the instructions in [FSIS Directive 7000.6](#) to collect the sample.

Discussion Points

- How does the establishment address the use of allergenic ingredients or gluten in their product formulation(s), including spice/flavoring mixes purchased from a supplier?
- How are IPP to verify the establishment has all ingredients listed in the ingredients statement on the label per the labeling requirements?
- What should be included in the formulation file and the labeling file by the establishment?

Knowledge Check

- What are the “Big 9” allergens?
- What makes an RTE product eligible for the Allergen Sampling Verification Program?

Resources

- [FSIS Directive 7230.1](#) – *Ongoing Verification of Product Formulation and Labeling Targeting the Nine Most Common (“Big 9”) Food Allergens*
- [FSIS Directive 7000.6](#) – *Allergen Verification Sampling Program*