

MEMORANDUM

From: Steven B. Steinborn
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Re: FSIS Updates Compliance Guidelines on Allergen Control and Prevention

FSIS has revised its Compliance Guidelines for Allergens and Ingredients of Public Health Concern, which provide recommendations for identifying and preventing many of the allergen-related hazards that have led to a number of recent recalls. FSIS first released the guidelines in April 2014 and issued the revision in response to comments received from industry and other stakeholders. ^{1/} FSIS plans to provide outreach to the meat and poultry industry on the Compliance Guidelines by conducting webinar sessions. This memorandum summarizes the key changes made in the revised guidelines.

Background

FSIS issued the original guidelines in 2014 to address what the agency described as “a sustained increase in the number of recalls of FSIS-regulated product that contained undeclared allergens.” FSIS expressed its view that many of those recalls were “preventable as many had been the result of ingredient changes, product changes, products in the wrong package, or products with misprinted labels.” According to FSIS, an allergen recall likely indicates a failure of the establishment to properly implement its hazard analysis and critical control point (HACCP) program in that the establishment has either failed to address the allergen in its hazard analysis, failed to support a decision made in its hazard analysis, failed to reassess its hazard analysis, or failed to implement effectively controls to support the decisions made in its hazard analysis.

The April 2014 guidelines provided meat and poultry establishments with recommendations on how to identify hazards with respect to allergens and other ingredients of public health concern when conducting their hazard analysis, how to prevent and control these hazards through HACCP plans, sanitation standard operating procedures (SOPs), and other prerequisite programs, and how to properly declare allergens on labels. Though the guidelines are nonbinding, FSIS recommended that establishments incorporate the practices detailed in the guidelines into their HACCP plan or sanitation SOPs.

^{1/} See Hogan Lovells memorandum dated April 22, 2014, *FSIS Releases Compliance Guideline on Allergen Control*.

Letters of Guarantee

The revised guidelines highlight the detail and substance of a letter of guarantee (LOG) furnished by a supplier. FSIS draws a distinction between a LOG and a Certificate of Analysis (COA) and focuses on the communication and coordination between an establishment and its suppliers that should take place when an establishment relies on LOGs. Establishments must be aware of the ingredients they are using in the production of their products, and they must determine whether they have considered and employed the necessary in-plant controls to prevent cross contact and assure accurate label declarations. FSIS explains in the revised guidelines that establishments should seek out information about the allergens and ingredients of public health concern their suppliers use, as well as information on their suppliers' production practices, and that this information may come in the form of a LOG.

Whereas a COA includes test results associated with a specific lot, a LOG may describe the ingredients used in the production of products. However, the contents of a LOG can vary significantly, ranging from a general statement to a more detailed description of the supplier's process (e.g., ingredient components, processing aids, rework, processing steps, environmental conditions, product carry over). FSIS advises that if a LOG is only a general statement, the establishment should consider initiating a dialogue with its supplier to ensure the establishment understands ingredient information or to recommend that the supplier include more specific information in LOGs. FSIS also recommends that establishments review and update LOGs regularly to ensure that decisions they make in their hazard analysis are supported and to ensure that the establishment detects any changes a supplier makes in its formulation before the establishment incorporates the ingredient into its production process.

Clarified Focus and Purpose

FSIS edited the guidelines to clarify that the focus of the document is on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the "food processing plant" definition, as defined in the Food and Drug Administration's (FDA's) "2013 Food Code." FSIS also revised the guidelines to emphasize the purpose of hazard analysis is not just to assess the food safety hazards reasonably likely to occur in the production process but also to identify the measures through Critical Control Points (CCPs) that the establishment can apply to control those hazards. The updated guidelines explain that the hazard analysis must consider food safety hazard that can occur before, during, and after entry into the establishment.

Ingredients of Public Health Concern

FSIS received comments from industry requesting that the agency clarify that certain substances identified in the guidelines are not allergens and arguing that monosodium glutamate (MSG) should not be included in the guidelines. Research confirms that MSG does not cause adverse reactions, even when tested in people who claim to have a sensitivity to MSG. In response FSIS revised the guidelines to make clear that sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and MSG are ingredients that may result in an adverse reaction in certain susceptible individuals, even though they are not considered allergens. FSIS maintained that it is concerned about all foods or food ingredients that may cause adverse health effects, and therefore that MSG remains an ingredient of public health concern.

Revised Appendices

FSIS also revised the guidelines' appendices, adding one new appendix and revising others. FSIS added "Allergenic Ingredients and Foods," a listing of allergenic ingredients and foods that may contain them. This document is based on "Tips for Avoiding Your Allergen," published by Food Allergy Research and Education (FARE), and it previously was Attachment 3 to FSIS Notice 29-13, which is now expired. For each of the "Big Eight" allergens, the document lists foods that likely contain the allergen, as well as foods that sometimes contain the allergen (e.g., peanuts may sometimes be found in chili or enchilada sauce, milk can sometimes be found in hot dogs, lunch meat, and sausages).

Allergen Testing

In the *Federal Register* notice announcing the revised guidelines, FSIS responded to two trade organizations that commented that the original guidelines suggested that allergen testing is the only way to meet the guidelines and that the guidelines therefore are regulatory requirements that should adhere to rulemaking procedures. The groups also argued that establishments should only test ingredients in cooperation with the supplier. FSIS responded that establishments may use allergen testing to verify and document sanitation effectiveness, but that testing is not required, nor is it the only way to demonstrate that allergens are not present on a production line, on equipment, or in product. When an establishment conducts allergen testing of ingredients, FSIS encourages establishments to communicate with their suppliers and to hold the product tested for allergens until they receive results.

Recommendation to Prevent Mislabeling

FSIS also added the suggestion that establishments conduct simulations with inaccurate product labels to test systems, checklists, and procedures to prevent mislabeling during packing, labeling, and storage of final product.

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Establishments and suppliers alike will find the Compliance Guidelines valuable in providing insight into the expectations of FSIS in how allergen risks should be managed. Please let us know if you have questions or if we can be of any further assistance.