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Food Safety and Inspection Service's Controls Over Declaring Allergens on Product Labels

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OFFICE OF INSPECTOR GENERAL

Food Safety and Inspection Service's Controls Over Declaring Allergens on Product Labels
Audit Report 24601-0005-31

OBJECTIVE

Our objective was to evaluate whether FSIS has sufficient controls in place to ensure allergens are properly disclosed on product labels under the Federal Meat, Poultry and Egg Inspection Acts.

REVIEWED

We reviewed FSIS policies and procedures; interviewed officials from FSIS, FDA, academia, and a trade group; performed data analysis on FSIS verification activities; and observed FSIS monitoring activities in five meat, poultry, and egg production plants.

RECOMMENDS

Overall, OIG recommends collaborating with stakeholders to develop a more robust approach to preventing food allergen illnesses. We also made recommendations to help FSIS improve how it currently verifies that labels accurately disclose allergen presence in food products.

OIG assessed if FSIS had sufficient controls to ensure that allergens are properly disclosed on product labels.

WHAT OIG FOUND

The Food Safety Inspection Service (FSIS) regulates food ingredients used in the production of meat, poultry, and egg products, including verifying the accuracy of labels and ingredients statements.

We found that FSIS inspectors currently perform reviews designed to determine if products are mislabeled and contain undeclared allergens. When the agency finds that a processing plant has released food with an undeclared allergen, FSIS requests a recall. In this report, we detail how the agency can improve its current approach to regulating undisclosed allergens:

- FSIS needs to be more consistent in how it completes verification tasks.
- FSIS needs to consider additional ways to indicate which plants use ingredients containing allergens.
- FSIS needs to more thoroughly address the possibility for cross-contact between products containing different allergens on the same production floor.
- FSIS needs to better document how they control data from complaints of undisclosed allergens.

Overall, OIG commends FSIS for taking steps to address undeclared allergens as a food safety concern.

FSIS generally agreed with our findings and recommendations, and we accepted management decision on all 12 recommendations.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: June 12, 2017

AUDIT NUMBER: 24601-0005-31

TO: Alfred V. Almanza
Acting Deputy Under Secretary, Office of Food Safety
Administrator, Food Safety and Inspection Service

ATTN: Steven Fisher
Chief Financial Officer
Food Safety and Inspection Service
Office of the Chief Financial Officer

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Food Safety and Inspection Service's Controls Over Declaring Allergens on Product Labels

This report presents the results of the subject audit. Your written response to the official draft report, dated May 18, 2017, is included in its entirety, at the end of the report. Your response and the Office of Inspector General's position are incorporated into the relevant sections of the report. Based on your written response, we are accepting your management decision for all the audit recommendations in the report and no further response to this office is necessary.

In accordance with Departmental Regulation 1720-1, final action needs to be taken within one year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Although the estimated completion dates for Recommendations 8, 9, and 10 extend more than one year from the date of your audit reply, we agree to extend final action for these three recommendations until June 30, 2018. Please follow your internal agency procedures in forwarding final action correspondence to Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

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Background and Objectives

Background

The Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection Acts authorize the Food Safety and Inspection Service (FSIS) to regulate food ingredients used in the production of meat, poultry, and egg products.[1] According to these acts, any food intended for human consumption must have proper labeling declaring major allergens in any amount[2]—even trace amounts. Therefore, all additives used in producing meat, poultry, and egg products and intended for human consumption must, by law, clearly declare the inclusion of any of the eight major ("Big 8") allergens defined by the Federal Food, Drug, and Cosmetic Act[3]—milk, eggs, fish, crustacean shellfish, wheat, soybeans, peanuts, and tree nuts. Currently, FSIS inspects meat, poultry, and egg products at approximately 5,200 plants where such processing actions occur.[4]

The "Big 8" allergens account for 90 percent of serious allergic reactions in the United States. According to the Food and Drug Administration (FDA), food allergies are responsible for an estimated 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year. Foodborne allergic reactions result in significant health care costs of more than $2,500 per incident, and the annual monetary loss is about $1.1 billion.[5]

The proper labeling of allergens in meat, poultry, and egg products is a critical issue to an increasing number of Americans, especially children. Approximately 15 million Americans with these types of allergies have no choice but to avoid allergens in the foods they eat, which means they must rely on a full disclosure of allergenic substances on a product label.

Additionally, the economic impact for allergen-related recalls can be significant to the industry and FSIS. The information we obtained on actual allergen recalls from two plants we visited showed the cost of a recall from one plant was a few thousand dollars and the cost of a recall from the other plant was about $450,000 for two recalls. FSIS estimated that the agency's overall cost for it to oversee allergen recalls was approximately $0.5 million in 2014.

A review of recall data from the last four years shows undeclared allergens have become the leading cause of FSIS' product recalls (see the table below).

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[1] 21 United States Code §§ 10, 12, and 15.

[2] Food allergens are specific components of food or ingredients within food (typically proteins) that are recognized by allergen-specific immune cells and cause specific immunologic reactions, resulting in characteristic signs and symptoms.

[3] Federal Food, Drug, and Cosmetic Act, 21 U.S.C., §§ 301-399h.

[4] Processing is defined to have occurred when the plant further manipulates raw meat, poultry, and/or eggs into processed food products.

[5] Annual losses for foodborne allergic reactions are those totals from direct medical expenditures and the implicit value of lost quality-adjusted life days, which are considered estimates of the willingness to pay to reduce health risks. Risk Analysis, Vol. 35, No. 6, 1126, 2015 *The Per Case and Total Annual Costs of Foodborne Illness in the United States*.

FSIS Summary of Recall Cases for Calendar Years 2012 to 2015

		Reason For Recall							
Year	Total Recalls	STEC[6]	Listeria	Salmonella	Undeclared Allergen	Extraneous Material	Processing Defect	Undeclared Substance	Other[7]
2012	82	5	16	2	**29**	13	1	7	9
2013	75	9	9	4	**25**	10	2	2	14
2014	94	5	7	4	**43**	6	4	2	23
2015	150	8	6	3	**58**	11	4	5	55

FSIS published guidance to the industry that outlined best practice recommendations in November 2015. According to FSIS officials, one reason for the increase in recalls for calendar year 2015 was that FSIS instituted ongoing verification tasks in the plants and required the in-plant inspectors to perform ongoing allergen verification tasks.

Plants are responsible for implementing Hazard Analysis and Critical Control Points (HACCP) systems in their plants that indicate where food allergens could be introduced into a product, such as where ingredients are added and where cross-contact may occur from another product production line. HACCP is a preventative, logical, scientific approach to controlling hazards in food production.

In order to ensure that plants' HACCP plans are operating effectively and identifying the possible presence of undeclared allergens,[8] FSIS inspectors perform food safety tasks to monitor plant operations. As part of the food safety inspection tasks, on a monthly basis, inspectors perform the "Big 8" inspection task,[9] which includes ongoing verification of product formulation and ensuring labels are accurate for the "Big 8" allergens in the Plant Health Inspection System (PHIS).[10] To assess the overall effectiveness of the processing plants' food safety systems, inspectors also perform Hazard Analysis Verification (HAV) procedures to verify a plant is meeting its regulatory requirements and has addressed the relevant food safety hazards for all the plant's processes, products, and intended uses. Inspectors also perform non-food safety tasks such as observing plant product formulation, verifying the accuracy of labeling, and reviewing plant records, which may identify the possible presence of allergens.

[6] STEC includes recalls due to Shiga toxin-producing E. coli (STEC). STEC organisms include *E. coli* O157:H7, E. coli O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121, and *E. coli* O145.

[7] "Other" includes producing without inspection, failure to present for import inspection, and labeling issues, among others.

[8] HACCP plans are plant-specific and are designed to monitor and control plant operations, as part of a HACCP system. HACCP is a process control system designed to prevent microbial and other hazards in food production. It includes steps designed to prevent problems before they occur and to correct deviations as soon as they are detected.

[9] FSIS Directive 7230.1, Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("Big 8") Food Allergens, Mar. 10, 2015.

[10] The Public Health Information System is a comprehensive data-driven inspection system used by FSIS in-plant inspectors to record the results of their inspection activities.

FSIS provided OIG with a general product label demonstrating the eight elements of a product label, which is shown below. The label illustrates the various elements–product name, handling statement, net weight statement, address line, ingredients statement, nutrition facts, safe handling instructions, and inspection legend and establishment (plant) name (see Image 1).

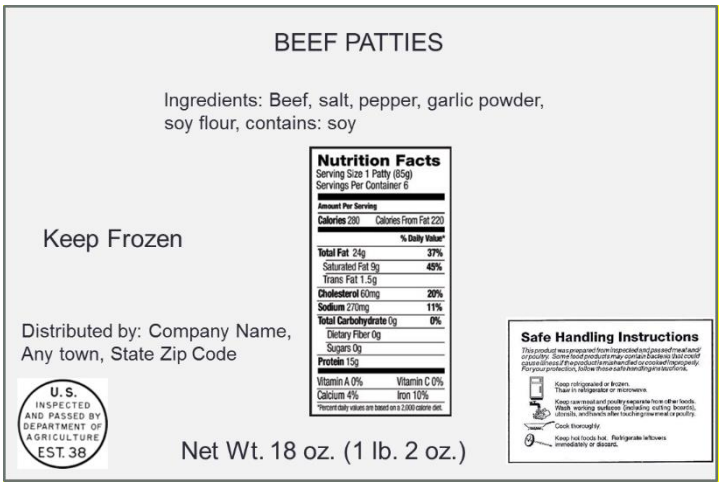

Image 1: This product label illustrates the information included to inform the consumer.

Finally, consumers who feel they have been sickened by consuming an undeclared allergen in a meat, poultry, or processed egg product can make a complaint directly to FSIS. FSIS operates the Consumer Complaint Monitoring System (CCMS), where details of allergic reactions can be submitted online, or consumers can call the Department of Agriculture (USDA) Meat and Poultry Hotline, operated by FSIS employees. A consumer complaint is any consumer-initiated complaint reported to FSIS, or by someone on behalf of a consumer. This includes consumer complaints reported to FSIS by a State or local health department, or another Federal agency, such as the Food and Nutrition Service, the Agricultural Marketing Service, or FDA. It also includes complaints that involve imported products. FSIS employees, with access to CCMS, enter the complaint information regarding the consumer, the product, and the nature of the complaint into the appropriate CCMS data entry fields. If the CCMS staff determines that a complaint should be investigated, it will inform the FSIS District Office where the complainant resides and request an investigation. Additionally, CCMS serves as an integral part of the FSIS bio-defense strategy.

Objectives

Our objective was to evaluate whether FSIS has sufficient controls in place to ensure allergens are properly disclosed on product labels under the Federal Meat, Poultry, and Egg Inspection Acts.

Section 1: FSIS' Approach toward Allergens

Finding 1: FSIS Needs to Collaborate with Stakeholders and Improve its Approach to Undeclared Allergens

Processing plants are required to list allergenic and non-allergenic ingredients on the product label so that consumers can be aware of the make-up of the product they are purchasing. In order to provide greater oversight of allergens, in 2015, FSIS issued Directive 7230.1, which required inspectors to verify plants are accurately controlling and labeling the eight most common food allergens. These verifications are designed to determine if products are mislabeled and contain undeclared allergens[11] and according to FSIS officials, has led to an increase in allergen-related recalls. When the agency finds that a processing plant released food with an undeclared allergen on a product label, FSIS may request that the plant conduct a recall. Although OIG commends FSIS for taking the initiative to address allergen issues as a food safety concern, for future consideration, the agency should move towards ways of developing a more robust approach to enhance its monitoring of processing plants and reducing recalls. To accomplish this goal, FSIS should cooperate with the wide range of stakeholders involved in emerging issues related to allergens—including other public health authorities, consumer groups, the food industry, and academia—to help the agency formulate a more forward-thinking policy potentially reducing severe allergic reactions among those with food allergies.

In its 2017 through 2021 Strategic Plan, FSIS established goals such as preventing foodborne illness and protect public health as well as modernizing inspection systems, policies, and using scientific approaches, such as reducing the number of undeclared allergen-related recalls, to enhance its food safety and public health mission.[12]

FSIS' current approach to allergens essentially places assurance of allergen identification on ingredient documentation, which could be inaccurate. To move towards a more accurate method for identifying allergens in FSIS-regulated products, the agency should consider ingredient testing for its future endeavors. Industry, academia, and other governmental agencies are currently developing testing methods that could identify allergenic ingredients actually in the product. Because undeclared allergens are an emerging food safety concern and allergen-related recalls are on the rise, FSIS should consider meeting with stakeholders to gain knowledge of advances in research for ingredient testing and other methods for detecting allergens in foods. Based on the information obtained from the meeting, the agency may make better informed policy decisions to support a more robust approach to control allergens in processing plants.

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[11] Product formulation and label verification reviews include record reviews and observation of the production process to determine whether processing plants accurately control and label the major food allergens. The record review verifies the label contains all required information, ingredient statements are accurate, and an FSIS-approved label is on file at the processing plant. For general labeling verification reviews, observing the plant's formulating process is required for restricted ingredient requirements.

[12] FSIS Strategic Plan. https://www.fsis.usda.gov/wps/wcm/connect/317d14d6-1759-448e-941a-de3cbff289e5/Strategic-Plan-2017-2021.pdf?MOD=AJPERES.

OIG acknowledges FSIS' efforts to ensure its inspectors verify that products are correctly labeled to disclose allergens. In this report, we detail several steps the agency can take to improve its current approach to undisclosed allergens:

- FSIS needs to be more consistent in how it completes verification tasks (see Finding 2).
- FSIS needs to consider ways to indicate which plants are using allergens (see Finding 3).[13]
- FSIS needs to more thoroughly address the possibility for cross-contact[14] between products containing different allergens on the same production floor (see Finding 4).
- FSIS needs to better document how they control data from complaints of undisclosed allergens (see Finding 6).

However, we maintain that FSIS faces a challenge in moving from an approach that focuses mostly on verifying that labels are accurate and conducting recalls when they are not, to a more robust approach that should reduce the likelihood that undisclosed allergens are present in food products. A move to this approach would involve research into such topics as testing for allergens and statistical modeling, which we address in Finding 5.

In addressing other emerging issues, USDA has held meetings with stakeholders to consider and make determinations about future approaches. For example, in May 2012, USDA held a three-day workshop for stakeholders from industry, consumer groups, and other governmental departments to help develop a plan for addressing antimicrobial resistance. Similarly, FSIS should hold a seminar with stakeholders to address emerging issues related to food allergens.[15] After dialogue with stakeholders, FSIS should draft an action plan to guide future efforts. Agency officials agreed it would be beneficial if academia, consumer groups, industry, and all other interested stakeholders meet with governmental health agencies to discuss the current state of allergen research and concepts. A separate advisory group could assist FSIS with policy development so the agency could make more informed policy decisions to actively monitor allergen controls.

Recommendation 1

Sponsor a public meeting on food allergen issues that offers FSIS and collaborators an opportunity to engage with other public health authorities, consumers, health professionals, the food industry, academia, and other stakeholders to gain greater appreciation for the regulatory, practical, clinical, and analytical challenges present in allergen control. Based on the

[13] A PHIS plant profile provides information to FSIS such as products produced, processes performed, HACCP systems utilized, and other general information for a processing plant. FSIS uses the data in the plant profile to assign inspection tasks to its inspectors.

[14] Cross-contact is the term used to describe the condition of ingredients from one production line coming into contact with ingredients on another separate production line.

[15] On March 16, 2017, FSIS hosted a public meeting to address, specifically, the continued occurrence of product recalls due to undeclared allergens and the best practices for prevention and control of allergens as a public health threat in FSIS-regulated plants. Topics focused on FSIS action and enforcement of undeclared allergens, labeling compliance, prevention, and emerging issues.

information presented at the public meeting, draft an action plan that can be used by FSIS management to improve the Agency's approach to food allergens.

Agency Response

FSIS stated that it sponsored a public meeting on March 16, 2017 with attendance from over 100 individuals from academia, the general public, public health and regulatory agencies, the food industry, and other stakeholders. The public meeting allowed for discussion of best practices, challenges, and opportunities for collaboration. An action plan will be used by FSIS management to improve our approach to food allergens is under development, along with several other allergen-focused projects, and is being initiated as a result of the successful FSIS-sponsored meeting. The action plan will be completed by February 28, 2018.

OIG Position

We accept management decision for this recommendation.

Section 2: FSIS' Current Monitoring of Allergens

Finding 2: FSIS Needs to Improve Implementation of Product Formulation and Label Verification Tasks for Identifying the "Big 8" Allergens

We found that FSIS' implementation of the product formulation and label verification task for identifying the "Big 8" allergens could be improved. For example, FSIS provided us with task related data for a 10-month period. Based on our analysis of the data, we determined there were almost 5,200 processing plants where FSIS monitors the "Big 8" formulation verification task. These tasks were assigned to the inspectors almost 65,700 times; however, only about 41,700 of those tasks were completed— meaning inspectors did not complete this task about 24,000 times.[16] Additionally, when completing the "Big 8" task, inspectors are to complete a series of questions; however, we found inspectors answered these questions inconsistently.[17] While FSIS recently released a directive to FSIS inspectors providing general instructions for verifying that products with allergens are properly labeled, we determined these issues occurred for a number of reasons. For example, we found inconsistencies between FSIS' directive and the instructions within PHIS and the agency did not provide adequate training to help inspectors understand the new requirements.[18] Unless inspectors perform these tasks correctly, FSIS will not have assurance that plants are labeling products correctly.

PHIS is a system developed for FSIS to collect, consolidate, and analyze data at the plant level. PHIS allows FSIS to provide inspection personnel the frequencies to perform verification tasks, such as for allergens, and it generates tasks assigned to inspectors.[19] In March 2015, FSIS released Directive 7230.1, which states PHIS will assign each FSIS shift at a plant, a monthly "Big 8" product formulation and label verification task in which FSIS inspectors are to verify that all ingredients in the product formulation are appropriately declared on the meat, poultry, or egg product labels. Within PHIS, tasks are assigned,[20] and inspectors report the task when

[16] FSIS also completed an analysis of the "Big 8" verification tasks in November 2015, and found that the percentage of plants that completed the "Big 8" task at least once increased over time to 96 percent between April and October 2015. This indicates that FSIS has some information on most of its plants although the frequency of the "Big 8" task performance was not as often as planned.

[17] The "Big 8" formulation verification task includes a record review, observation of the production process, and responding to specific task-related questions to verify that processing plants are accurately controlling and labeling the eight most common food allergens.

[18] FSIS Directive 7230.1, *Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("BIG 8") Food Allergens*, Mar. 10, 2015.

[19] PHIS provides information about the appropriate tasks for each plant, their relative priorities based on their expected impact on public health, and their expected frequencies.

[20] PHIS assigns inspection tasks based on information in the plant profile.

completed.[21] When an inspector opens a "Big 8" formulation verification task, PHIS provides instructions to inspectors on how to perform it.

Completing the "Big 8" Formulation Verification Task

At the almost 5,200 processing plants where FSIS monitors for allergens, our analysis of data showed inspectors may not have routinely completed the "Big 8" formulation verification task. We received task-related data from FSIS that covered a 10-month period. The data showed PHIS assigned FSIS inspectors the "Big 8" task almost 65,700 times. However, we determined that inspectors only completed approximately 41,700 of those assigned tasks. This means the "Big 8" formulation verification task was completed approximately 63 percent of the time. Even at the 92 plants that experienced allergen related recalls in 2014 and 2015, inspectors were assigned almost 1,400 tasks, and these tasks were not completed almost 400 times. Our analysis of the data suggests that the inspectors at plants where allergen recalls had occurred were more likely to complete the task; however, it was still not completed about 28 percent of the time.[22]

When we discussed this concern with FSIS officials, they explained that they made their best efforts to assign the "Big 8" formulation verification task to only those plants that could possibly have allergens as ingredients by selecting the most likely HACCP[23] categories from PHIS.[24] In some cases, plants may slaughter and process, but not add any ingredients. Therefore, FSIS inspectors would receive the task because of the plant's processing component, but would not need to complete the task because the plant was not adding any ingredients to the final product. Officials also explained that they wanted all processing plants adding ingredients to the meat products to complete the "Big 8" formulation verification task whether or not there are known allergen ingredients. They explained that a plant adding ingredients might believe they do not have allergens to report on its label; however, inspectors performing the task might discover that the plant is unknowingly using allergens.

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[21] In a prior OIG audit report, Audit 24601-0001-23, *Implementation of the Public Health Information System for Domestic Inspection*, August 2015, OIG reviewed PHIS to determine if the system was meeting FSIS' needs. OIG found that inspectors were not always utilizing a function in PHIS that let them record reasons inspection tasks were incomplete. The audit team for this report discussed this concern with FSIS national officials who told us that agency management decided it is not critical for FSIS inspectors to properly code every task that is not completed because inspectors' priority is monitoring food safety in the plants.

[22] To determine the completion rate, OIG analyzed completed tasks over a 10-month period as a cumulative number or percentage. Of those PHIS assigned tasks, OIG defined completed tasks as those tasks FSIS inspectors finished or did not perform the task and provided a reason code justifying why the task could not be completed.

[23] According to FSIS, HACCP regulations require inspected plants to evaluate whether a chemical hazard, including allergens, are reasonably likely to occur in the final product, and if so, develop a plan of control.

[24] PHIS assigns the "Big 8" formulation verification task based on HACCP categories such as raw – non-intact, raw – intact, not heat treated, shelf stable, fully cooked not shelf stable, etc. The corresponding guidance, Directive 7320.1, applies to inspectors in meat, poultry, and egg product plants that produce product in HACCP categories specified in the directive. According to FSIS, this applies to non-slaughter only plants. This includes raw products, but does not specifically delineate between plants that process products by adding ingredients and those that do not add any ingredients but only fabricate raw product (such as grinding meat into hamburger). These plants may have products with allergens and without allergens.

Additionally, FSIS officials explained that there are reasons why inspectors do not complete the "Big 8" verification task in a given month. They explained that some small plants do not always have product to inspect. OIG acknowledges that there may be situations where inspectors cannot complete the task—such as unavailable product, a staffing problem, or the plant not operating every day—but we maintain that the inspectors should complete the task when possible and applicable.[25] While these situations exist, we question that these explanations would account for the 63 percent completion rate.[26] Following up on the actual completion rate would allow FSIS management to better identify problem areas in completing the task.

When we discussed completing the "Big 8" formulation verification task with an FSIS inspector at one of the plants we visited, we were told some inspectors may not realize that "Big 8" formulation verification tasks are considered a relatively high priority. PHIS ranks tasks by priority from 1 to 6, with 1 being the highest priority and 6 the lowest. Prior to the issuance of Directive 7230.1, verifying that products are properly labeled was included in the priority 6 general labeling task identified in PHIS Directive 13,000.1.[27] However, when Directive 7230.1 was issued, PHIS was updated to include the "Big 8" formulation verification task. According to FSIS, PHIS identifies the priority of the "Big 8" formulation verification task as a 3, however, one FSIS inspector told us that inspectors might still consider the "Big 8" task as a general labeling task. This inspector said additional FSIS education and training would help correct the problem. FSIS officials said additional training was not part of the implementation of the directive; although when FSIS added new Consumer Safety Inspectors, they did receive training on completing the "Big 8" formulation verification task. In addition, FSIS should issue revised directives to indicate that the "Big 8" formulation verification task is a priority 3 and ensure all other directives that relate to the priority of allergen tasks are consistent.

Errors When Completing the "Big 8" Formulation Verification Task

Even when inspectors completed the "Big 8" formulation verification task, we found that they did not always follow the directive and sometimes made errors.

- Directive 7230.1 states inspectors are to consider any product processed in the plant for the "Big 8" formulation verification task, however, through an interview and analyzing survey questions, we found inspectors did not consider all products in making their risk-based selection. This occurred, in part, because of

[25] By "possible," OIG refers to situations such as FSIS inspectors have constraints on their time because of the individual operational characteristics of their assigned plants, necessary travel for patrol assignments, unforeseen issues that arise, and other factors. "By "applicable," OIG refers to the "Big 8" task for inspectors at plants which could possibly have allergenic ingredients compared to those at processing plants that do not add any ingredients.
[26] The completion rate of 63 percent is from OIG's data analysis. OIG did not verify FSIS inspectors' reasons for not completing the "Big 8" task. However, OIG agrees with FSIS' conclusion in their "Big 8" Verification Task Rates report, which showed that tasks were performed not as often as planned.
[27] FSIS Directive 13,000.1, *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)*, August 31, 2012.

inconsistent directions from the directive and PHIS instructions.[28] The directive instructs inspectors to select any product in the plant even though a product may not contain an allergen, whereas PHIS instructs inspectors to only select a product containing a known allergen for the task.

- Directive 7230.1 instructs inspectors to coordinate with each other to avoid selecting the same product in multiple shift processing plants. However, in two of the three plants we visited that had multiple shifts, FSIS inspectors did not coordinate between shifts on product selection for the "Big 8" formulation verification task. In one plant we visited, an inspector told us he did not consult with the other shift inspectors to ensure they did not select the same product for the verification task. In another plant, we found that a lack of coordination occurred between two shifts because inspectors from different shifts selected the same product on the same day for the "Big 8" formulation verification task. This duplication of efforts results in a smaller population sampling size, reducing food safety assurance.

- Directive 7230.1, according to FSIS officials, was written so that all products should be eligible for the "Big 8" formulation verification task. The directive's instructions have a priority flowchart that should ensure that the same product is not being selected month after month.[29] However, at one of the processing plants we visited, FSIS inspectors recorded 19 "Big 8" formulation verification tasks during the 10-month period we reviewed. We noted the inspectors chose a turkey sausage product 17 of the 19 times. For the remaining two selections, they choose a beef product once and a pork product once even though during our week at the plant we reviewed a weekly production schedule that showed a significant amount of beef, chicken, and pork products as well as the turkey sausage.

  Varying the product selection is important because large recalls could occur if not all products are being reviewed. In November 2016, a processing plant recalled almost 119 tons of pork products due to mislabeling and undeclared allergens that went undetected for 24 months.

Completing the "Big 8" Formulation Verification Task Questionnaire

According to Directive 7230.1, when completing the "Big 8" formulation verification task, FSIS inspectors are to answer eight specific questions related to the products at the plant and the product selected. However, we determined that inspectors did not answer these questions consistently. For example, inspectors responding to a question about

[28] PHIS provides inspection task guidance information to assist the FSIS inspectors in performing the "Big 8" formulation verification task. The guidance states "Using the guidance in FSIS Directive 7230.1, IPP are to select one product containing a "big 8" allergen for verification."

[29] Potentially, a product may be selected more than once based on certain conditions detailed in the flowchart. For example, the product had a change in supplier of ingredients, a change in ingredients, or a change in formulation within the past "six months." This can occur if the product incorporates a multi-ingredient component produced outside the plant.

which allergens were present indicated that only soy was present, when the plant also processed a product containing dairy and wheat. Some inspectors treat seasoning packets or spice mixes as one ingredient, while others would document each ingredient in the packet or mix. We noted that if inspectors do not respond consistently to these types of questions, FSIS decision-makers would not have access to accurate data about the processing plants and how they are handling allergens.

FSIS national officials stated that they are currently analyzing the data from April 2015 through March 2016 of the "Big 8" formulation verification task. The results from the analysis may be used to identify potential problems with the task and directive. The results from these analyses would provide meaningful data to determine whether FSIS inspectors fully understand Directive 7230.1's requirements for implementing the "Big 8" formulation verification task. FSIS should determine if inspectors need additional guidance or training, if instructions need to be revised, or if guidance needs to be updated.

Recommendation 2

Clarify Directive 7230.1, and provide additional guidance as necessary to ensure that FSIS inspectors accurately implement the "Big 8" formulation verification task, including product selection.

Agency Response

FSIS stated that Directive 7230.1, Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("Big 8") Food Allergens, has been instrumental in raising awareness of allergens among FSIS-regulated establishments with indispensable communication by inspection program personnel to establishment personnel about the importance of preventing undeclared allergens. The directive has also led to the early identification of establishment issues, which likely prevented the release of products containing undeclared allergens into commerce. FSIS will revise the directive to clarify the instructions to inspection program personnel. A workgroup to revise FSIS Directive 7230.1 will be put in place by August 31, 2017, with a list of items for revision completed by November 30, 2017. The draft revision of the directive will be completed by February 28, 2018 with a final issuance expected by April 30, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 3

Review the "Big 8" formulation verification task instructions in the Public Health Information System (PHIS) and, if necessary, update the instructions to ensure consistency with Directive 7230.1.

Agency Response

FSIS stated it will review the PHIS task instructions for the "Big 8" formulation verification task and if necessary, update the instructions in PHIS to be consistent with FSIS Directive 7230.1. A review of PHIS task instructions and a comparison against FSIS Directive 7230.1 will be completed by September 30, 2017. An update to the task instructions, as needed, will be completed by January 31, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 4

Determine if inspectors are completing the "Big 8" formulation verification task as required. Based on the determination, take appropriate corrective action such as providing additional training to inspectors.

Agency Response

FSIS stated it will continue periodic reviews of the "Big 8" formulation verification task, and will use the results to inform any decisions about additional training or clarification of instructions. Previously completed analyses will be used to inform the revision of FSIS Directive 7230.1. The review of FSIS data for the "Big 8" formulation task will be completed by November 30, 2017 with results informing the revision of FSIS Directive 7230.1 as outlined in the response to recommendation 2. The determination for additional training needs and clarification of instructions will be completed by March 31, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 5

Determine which additional directives and notices provide instructions regarding allergens to FSIS inspectors. Review and update the material as necessary to ensure consistency among the documents and consider stating that allergen verification is a priority 3 task.

Agency Response

FSIS stated it will determine which directives and notices provide instructions to inspection program personnel regarding allergens and review those policy issuances. As appropriate, FSIS will state that allergen verification is a priority 3 task and update instructions to ensure

consistency. The initial review of directives and notices will be completed by October 31, 2017. If needed, updates to policy issuances will be completed by April 30, 2018.

OIG Position

We accept management decision for this recommendation.

Finding 3: FSIS Should Better Identify Plants Handling Allergens

FSIS' method of assigning the "Big 8" formulation verification allergen task[30] limits the agency's ability to analyze data from allergen-specific plants and limits the assigning of potential future tasks specifically related to allergens. When FSIS developed the "Big 8" formulation verification task within PHIS, the agency did not have a precise method to identify and select processing plants that add allergens. Instead, FSIS made assumptions regarding which processing plants were likely to add ingredients, including allergens, during the production process, and which plants might provide additional processing to the meat without adding ingredients, for example cutting larger primals of meat or poultry into consumer products such as steaks, roasts or grinding meat and poultry. Those assumptions were based on HACCP categories recorded in the PHIS profile. This occurred because the PHIS plant profile did not include a specific indication, such as a "yes/no" checkbox, for allergens. FSIS officials were reluctant to require that inspectors perform additional work regarding ingredients in developing a plant's profile data due to the time involved,[31] and because adding a "yes/no" allergen checkbox would require a software modification. As a result, some processing plants may be assigned allergen-related inspection tasks even when these plants do not handle allergens, which could affect the data FSIS compiles in its efforts to manage allergens. Ultimately, the agency is unable to precisely identify the plants that use allergenic ingredients in PHIS.

Directive 7230.1 provides instructions to FSIS inspectors for verifying that processing plants are accurately controlling and labeling common food allergens.[32] The directive also states that FSIS will analyze PHIS data from this verification activity on a quarterly basis, and these analyses will be used to determine if additional policy instructions are needed.

When FSIS designed the "Big 8" formulation verification allergen task, it needed to distinguish between plants that would be likely to add allergens and those plants that would perform additional production of the meat or poultry without adding any new ingredients. To make this distinction, the agency relied on information in the plant's PHIS profile. FSIS then assigned the "Big 8" formulation verification allergen task to the plants the agency considered likely to be adding allergens to products.

Despite FSIS' best efforts, agency officials acknowledged that there were still probably a "few hundred" plants being assigned the task on a monthly basis even though these plants were not working with allergens. Likewise, agency officials could not be certain that every plant that worked with allergens received the task.

OIG maintains that, if FSIS cannot accurately identify plants that add allergenic ingredients, the agency's ability to monitor the accuracy of product labels is diminished. Currently,

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[30] The "Big 8" formulation verification allergen task is intended to be performed in processing plants that handle allergenic ingredients as well as those plants that do not handle allergenic ingredients.

[31] Processing plants could be adding, deleting, or changing ingredients frequently; therefore, it could be time consuming for the inspectors to constantly change the plant's profile to update allergenic ingredients.

[32] FSIS Directive 7230.1, *Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("BIG 8") Food Allergens*, Mar. 10, 2015.

Directive 7230.1 requires FSIS inspectors to verify all products in a processing plant because allergen related recalls have occurred in plants where allergens were not known to be in any FSIS regulated products. As FSIS focuses more resources on product labeling, it may become more important to precisely identify those plants that add allergenic ingredients to their products in order for FSIS to facilitate certain tasks—for example, some types of allergen testing in specified plants. By determining which establishments use allergen-containing ingredients, FSIS would be able to perform more meaningful data analysis and better utilize its inspection resources. This could be accomplished by including a "yes/no" checkbox in the PHIS plant profile designating allergens are present in the plant.

Adding a "yes/no" checkbox to PHIS would enhance FSIS' management and oversight of the "Big 8" formulation verification allergen task. The intention of the checkbox is not directed towards FSIS plant-level operations; however, the information may assist the agency in the future when new allergen-related tasks are performed. When we discussed with FSIS officials the idea of adding to PHIS plant profiles a "yes/no" checkbox that would indicate if plants used allergens, they stated that they were reluctant to add another inspection duty for their inspectors to perform, especially if it involved tracking allergenic ingredients in the plant profile. We suggested that FSIS only needed to indicate whether or not a plant was using allergenic ingredients. However, FSIS also explained that adding the "yes/no" check box would require a PHIS software modification. Nevertheless, adding a "yes/no" allergen checkbox would enhance the accuracy of FSIS data related to label verification activities. FSIS officials agreed that they should evaluate if adding a "yes/no" checkbox in the PHIS plant profile would be worthwhile.

Recommendation 6

Determine if plants with allergenic ingredients need to be identified in PHIS with a "yes/no" checkbox in the plant profile. If not, then implement another method that will allow the agency to improve its data analysis by accurately identifying plants that add allergenic ingredients and develop measureable timeframes and milestones for the agency to implement its decision.

Agency Response

FSIS stated it will use the responses from the "Big 8" allergen formulation verification task questionnaire to categorize establishments that produce products containing "Big 8" allergens. FSIS will develop a plan to add this information to the establishment profile in PHIS. Initial categorization of establishments and developing a plan to add the information to the establishment profile in PHIS will be completed by February 28, 2018.

OIG Position

We accept management decision for this recommendation.

Finding 4: FSIS Inspectors Need to Examine Potential Allergen Cross-Contact

At three of the five processing plants that we visited, OIG found that meat and poultry were being processed in an open environment where multiple production lines operated in the same open room, potentially allowing allergenic cross-contact to occur. At one plant, for example, we identified that food from one production line that contained an allergenic powdered substance, such as powdered milk or wheat flour, was operating next to another line that did not have the same allergenic ingredients. Although FSIS inspectors had performed in-depth reviews at these plants, we determined inspectors did not properly consider the potential for allergen cross-contact situations as part of their analysis.[33] We made this determination based on discussions with plant management who said they had not performed any scientific assessment to support that allergen cross-contact was not likely to happen. This occurred because FSIS has not properly advised its inspectors on how to evaluate the role that allergen cross-contact issues play in these production situations. As a result, the FSIS inspectors in these plants did not consider the potential risk for allergen cross-contact when they performed their HAV inspection tasks. Since FSIS does not test end products for various allergens that might have been introduced through cross-contact, FSIS and plant management could only become aware of any allergenic cross-contact after consumers reported adverse allergic reactions.

FSIS Directive 5000.6 states that FSIS inspectors will perform the HAV task to verify that a plant meets the regulatory requirements for the development and implementation of the hazard analysis, and that the plant has addressed the relevant food safety hazards for all the plant's processes, products, and intended uses.[34] Inspectors will identify obvious cases of noncompliance and other issues of concern that may require further consideration. Plants provide a flowchart to show where potential hazards are likely to occur, and inspectors are to verify whether the plant's flowchart illustrates that the production process and hazard analysis meet regulatory requirements. Additionally, the inspector determines whether the processing plant considered all the possible hazards for each process step. Inspectors are to conduct an HAV task that includes a document review and, when possible, direct observation. FSIS Directive 7230.1 instructs inspectors to observe that all ingredients used in the production of the product are present, all ingredients in the product formulation are declared in the ingredients statement and the appropriate label is applied to the product. Ultimately, as FSIS inspectors do their inspection tasks, they continuously verify that the plant has management controls in place to address allergen cross-contact concerns.

At the first processing plant, we found three production lines together in a large common area. Poultry products were being processed in all three lines, each with a different batter mixture containing different allergens. Plant employees dumped large bags of dry ingredients into the production equipment to coat the raw poultry products. As the dry ingredients from the bags were added to the food processing equipment, fine powder clouded the air, dusted the production equipment, and coated the floor. As the processing equipment ran, additional dry and moist coating fell to the floor around the production equipment. Plant equipment and some plant

[33] These reviews are known as hazard analysis verification tasks.

[34] FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task*, Mar. 4, 2014.

employees with powdered coated smocks moved between the different production lines. Additionally, plant management told us that the plant did not use specialized air handling equipment on the production floor to control or reduce particles that might be in the air.

When we asked plant management for scientific support that cross-contact was not likely to occur in their open plant production area, they could not produce any evidence to demonstrate cross-contact was not likely to occur, even though FSIS inspectors should have requested scientific support when they performed the HAV task or "Big 8" task.[35] Although plant documentation showed that allergens were considered as a potential food safety hazard, plant management said it never occurred to them that there could be a problem with allergens from one line getting into products produced on another production line. However, the managers acknowledged they would consider whether it would be prudent to obtain the necessary scientific support.

When we discussed our observations with FSIS officials, they stated it would be difficult to comment without having more information from the in-plant inspection staff. Further, FSIS officials indicated that the conditions we observed at this plant were probably the industry norm for these types of processing plants. In contrast, we observed another processing plant where the dry ingredients were controlled differently. This plant had three production lines operating together in a large common area. The ingredients for the products made on each product line varied and included differing allergens. However, the ingredients used during production were much better controlled, with little or no spillage on the floor from the equipment and no noticeable ingredients floating in the air. We observed that dry ingredients were prepared in small tubs in another area of the plant and then moved to staging areas near the production equipment where the tubs were covered with plastic until the ingredients were added to the process. Even though there appeared to be reduced allergen cross-contact risks at this second plant, the plant management could not provide us with scientific support[36] to show that three production lines in a common area did not result in cross-contact between lines.

Also, FSIS inspectors handled potential allergenic cross-contact differently at the two plants. At the first plant, the FSIS inspection staff did not express any concerns to us regarding the potential cross-contact issues we observed. However, at the second plant, we found that the FSIS inspection staff was alert for cross-contact issues. We found that an inspector wrote a noncompliance record that faulted a plant employee who was working on a production line using soy for having "clumps of product residue and staining" on the employee's coat, which could potentially cause a cross-contact situation. This was in contrast to the production environment we observed at the first processing plant, where FSIS inspectors allowed the plant to operate normally, even though there was visible allergenic residue throughout the entire production area.

[35] FSIS officials stated that its analysis of recall data shows there have been no FSIS recalls in the last two years due to undeclared allergens being introduced through environment cross-contact, airborne, or otherwise.

[36] OIG reviewed the plant's hazard analysis documentation, which did not address the potential for cross-contact in the production environment. Plant officials confirmed that they did not consider cross-contact between production lines as a potential hazard and therefore the hazard was not included in the plant's hazard analysis documentation.

We also visited and observed production conditions at an egg processing plant. This plant generally produced liquid eggs with no other allergic ingredients; however, on occasion, they produced an egg product with milk in a dedicated room with physical barriers, which prevented most opportunities for allergen cross-contact with normal production.

However, we noted that the same frocks were worn by the production operators when they worked inside and outside this dedicated production area. We discussed our observation with plant management, and they informed us they had not considered using the same frock to be a hazard that could facilitate allergen cross-contact. As a result of our observation, plant managers decided the staff who worked in the dedicated production room would wear disposable frocks so there would be less of a chance that the powder form of non-fat dry milk residue could escape the dedicated room.

Although we were not aware of any reports of illnesses or adverse allergic reactions caused by the food produced in any of these plants, we were concerned that FSIS in-plant inspectors had inconsistent approaches to the potential for cross-contact. We were also concerned that FSIS in-plant inspectors did not identify cross-contact as a potential issue on the HAV tasks. FSIS should determine how many production plants it inspects that have more than one production line co-located in a common production area. If a significant number of these types of facilities exist, then FSIS should ensure that HAV tasks that focus on the issue concerning allergen cross-contact are done in all these plants. We discussed our recommendations with FSIS officials, and they agreed these were viable options for the agency.

Recommendation 7

Develop a plan with measureable timeframes and milestones to revise FSIS Directive 7230.1 or Directive 5000.6 to address the issue of potential allergen cross-contact, including whether a plant has sufficient scientific evidence to support that allergen cross-contact is properly prevented or controlled among the products within a plant's production environment.

Agency Response

FSIS stated it will develop a plan to review existing data and FSIS Directives 7230.1 and 5000.6, Performance of the Hazard Analysis Verification (HAV) Task, to determine whether it is necessary to address potential allergen cross-contact in the verification instructions to inspection program personnel. FSIS will develop a plan to review existing training and educational materials to determine whether it is necessary to further address potential allergen cross-contact. FSIS will review and make a determination as to whether potential allergen cross-contact will be included in the revision to FSIS Directive 7230.1 by February 28, 2018. The review,

determination, and inclusion of cross-contact information in FSIS Directive 7230.1 and education/training materials, if necessary, will be completed by April 30, 2018.

OIG Position

We accept management decision for this recommendation.

Section 3: Research into Future Regulation of Allergens

Finding 5: FSIS Should Perform an Allergen Risk Analysis and Propose Research into Allergen Testing and Modeling

FSIS is not a research agency; therefore, it does not perform research of its own and must instead rely on other Federal agencies and universities to perform research that will advance FSIS' ability to perform food safety inspections. Every year, FSIS officials propose a set of research priorities for these other entities to pursue. We reviewed FSIS' research priorities for fiscal years (FYs) 2015 and 2016 and found that although the agency is aware that the number of recalls related to allergens has increased in recent years and it has issued guidance and instructions to its inspectors. However, it has not listed any allergen-related research projects on its research priority list, despite the increasing number of recalls occurring due to food products formulated with allergenic ingredients not included on the label. In addition, agency officials explained that they have not performed a comprehensive assessment of risk to evaluate potential allergen-related problems. This occurred because FSIS did not consider undeclared allergen contamination research a high priority. Although food allergens affect millions of consumers each year,[37] the pathogen *E.coli*[38] affects only a few thousand consumers[39] each year; however, FSIS has made *E.coli* research requests. As a result, FSIS, consumers, and industry are not benefitting from the latest scientific research concerning food allergens, which affect a large number of consumers.

In general, food recalls have trended upward over the last few years with twice as many allergen recalls in 2015 than in 2012. In 2014 and 2015, meat and poultry plants had 101 recalls totaling over 16 million pounds. According to the American Chemical Society, one contributing factor to the increase in recalls is an increasingly complex supply chain with an "ever-widening variety of ingredients, compositions, and processing methods as well as more suppliers with global distribution."[40] These facts represent a significant challenge for the food industry and the food safety regulatory agencies that provide and ensure accurate food allergen labeling.

Although FSIS does not conduct its own research and has no funding for performing research, evaluating emerging science on foodborne illness and trends is essential for implementing effective policies for risk response. Actual research projects are done by USDA scientists from

[37] More than four million children experienced food allergen issues in 2012, according to the Centers for Disease Control and Prevention (this would include FDA and FSIS regulated food products). CDC-National Center for Health Statistics, *Summary Health Statistics for U.S. Children: National Health Interview Survey, 2012,* 15 (Series 10, Number 258).
[38] *Escherichia coli* (*E. coli*) O157:H7.
[39] According to the National Institute of Allergy and Infectious Diseases, there are about 70,000 cases of *E. coli* infections each year. National Institute of Health, https:www.niaid.nih.gov/topics/ecoli/Pages/default.aspx.html (last visited January 28, 2016.) However, according to FSIS officials, in FY 2015 only 7,451 of these E.*coli* illnesses were from FSIS-regulated food products.
[40] Journal of Agricultural and Food Chemistry, *Summary of the ACS Symposium on Advances in Food Allergen Detection*, 5621, Published: Nov. 20, 2012.

the Agricultural Research Service or the National Institute of Food and Agriculture based on the priority requests made by FSIS. FSIS also provides its research list to universities and educational facilities as part of FSIS' outreach, and educators are encouraged to take on some of the research as well. For example, professors may request grants for research on food safety or suggest topics to graduate students.

Risk Assessment

FSIS officials stated that one of the goals for conducting research is to collect information to fill gaps for future risk assessments related to undeclared allergens. Additionally, agency officials told OIG that one necessary precursor to FSIS requesting allergen-related research is to explore and identify the data gaps that need to be filled in order to conduct a risk assessment or other analysis. Finally, FSIS officials informed us that using this risk gap assessment, agency managers would be able to determine which testing and modeling research projects could provide the necessary inputs for future risk assessments, which could point to risks and risk management approaches that would result in immediate benefits for food safety.

While FSIS performed more than one detailed risk assessment in response to *E. coli* outbreaks, it has not performed a detailed risk assessment for food allergens. When we spoke to FSIS officials about performing a risk assessment for undeclared allergens, they informed us that they are in the initial stages of evaluating the state of the science and other information available for conducting an allergen risk assessment. FSIS can begin the process of identifying this missing data by conducting the public stakeholder's meeting discussed in Finding 1.

OIG maintains FSIS can determine which critical information is available and what data gaps exist to perform an in-depth allergen risk assessment similar to those it performed in the past for *E. coli*. This analysis should provide direction on how the agency might proceed in requesting meaningful research into allergens. Such research could include expanding capacity to test for allergens in food products or developing statistical modeling.

Testing

At present, FSIS does not have the necessary technology in place to routinely test for the presence of undeclared allergens in food products. Instead, FSIS in-plant inspectors use record reviews and observations to verify that labels declare the eight food allergens if present. The agency can perform some testing for allergens, but currently does so only on a "for cause" basis, such as investigating a consumer complaint. However, FSIS does not have the methodologies to test for all of the "Big 8" allergens. FSIS management indicated there was no substantial public safety need that justified devoting additional agency resources into developing testing methodologies for all of the "Big 8" allergens;

therefore, FSIS can only test for three of the "Big 8" allergens, and those tests can only be run for one allergen at a time.[41]

In the future, FSIS may want to test for allergens more often, more comprehensively, and more dynamically. The FSIS Deputy Under Secretary noted that testing is a key part of FSIS' food safety efforts. Testing, for example, would greatly improve oversight of allergens in imports. Testing of import products would be FSIS' best means to independently verify the accuracy of the labels for about 4.4 billion pounds of imported meat, poultry, and egg products.[42] Since FSIS inspectors are not onsite in foreign countries to do daily record reviews and observations, the only way FSIS can independently verify the accuracy of the labeling of imported products is to proactively conduct allergen testing, which the agency does not and cannot do at this time.

During our work, we learned that FDA is in the process of validating a multi-test method for 14 allergens.[43] While any testing method developed by FDA would have to be modified for FSIS' use, a similar test could prove efficient and yield comprehensive results for FSIS. Furthermore, officials from an industry trade group stated that, if FSIS had the technology in place to start a robust allergen testing program (similar to the robust pathogen testing programs already implemented for *E.coli*), this decision would encourage plants to adopt their own testing programs as well, thereby improving consumer safety.

When we discussed testing with FSIS officials, they stated that expanded proactive allergen testing by the agency would be a major investment of agency resources. They agreed, however, that the agency should consider more comprehensive and robust testing for food allergens. Further, FSIS officials noted that it is important that FSIS take a data-driven, scientifically valid approach to any effort of encouraging the development of, validating and implementing the testing of allergens in FSIS-regulated products. FSIS officials informed OIG that such an effort would likely take several years. Such testing would support one of the goals of FSIS' 2017 through 2021 Strategic Plan, which is to modernize inspection systems, policies and the use of scientific approaches to enhance FSIS' food safety and public health mission.

Statistical Modeling

Another advancement that FSIS should consider is statistical modeling. Some research entities are currently studying statistical modeling to supply data about allergens in food products. Modeling is a technique that can provide information on the levels or exposure,

[41] FSIS informed us that its laboratories could test for soy, non-fat dried milk-lactose, and cereal (wheat). FSIS conducted only 36 allergen tests in a 2-year span (2014 and 2015). When FSIS laboratories cannot test for allergens in a food product, FSIS will work with plant management to verify if the product was mislabeled.
[42] 2015 FSIS import inspection data for meat, poultry and egg products. USDA-FNS, *2015 Import Data*, https://www.fsis.usda.gov/wps/wcm/connect/0b68597b-7b0d-4b02-9538-5ac40c88227c/2015-Import-Data.pdf?MOD=AJPERES (last visited July 6, 2016)
[43] According to FDA officials, this new FDA multi-allergen testing method will detect most common allergens plus some specific varieties of nuts.

of allergenic ingredients in foods and the threshold, which is the amount of allergen where there is negligible risk of an ingredient causing an allergic reaction.[44] Modeling has the potential to increase consumer safety by helping to prevent "recall fatigue" and the wasting of otherwise safe food. Recall fatigue is where consumers no longer heed recall warnings because they perceive the warnings to be an overreaction by the industry; in other words, too many recalls can result in consumers ignoring such warnings. In addition, because modeling is a technique that could give FSIS the ability to determine safe levels of undeclared allergens in food products, modeling may provide consumers with a much higher level of accuracy when it comes to labeling and recalls, thereby increasing consumer safety. There are three classes of recalls plus market withdrawals.[45] Modeling could be used by the agency to downgrade the level of the recall or prevent a company from recalling a harmless product, thus relieving the level of consumer recall fatigue.

Industry representatives told us about a situation where modeling was done by an outside consultant in a recall situation. The data from the model showed that an individual consumer would have to eat thousands of pounds of the product to have an allergic reaction. Even when FSIS was provided with this evidence, the company was still requested to recall the product. We do not dispute that FSIS made the appropriate determination in requesting that the firm in question conduct a product recall since public safety is of the utmost importance. OIG acknowledges that there may be situations in the future where the potential for an adverse allergic reaction may be negligible, and the company may be able to demonstrate that it has acted in good faith; in such a situation a product recall might serve no immediate public health benefit and only act to cause consumers and industry to discard and waste otherwise safe food products. A well thought out regulatory process where FSIS is receptive to accepting scientifically sound modeling data from industry, FSIS' staff, academia, or other stakeholders may help to prevent this type situation.

OIG recognizes that applying the results of current research to FSIS' practices will require investment of agency resources, but partnering with stakeholders could make this goal achievable. Senior FSIS officials agreed that the agency needs to work with other stakeholders to develop the science necessary to meet FSIS' regulatory mission. FDA is one potential partner, who has been working on new allergen testing and modeling research. FSIS can immediately

[44] For OIG's purposes, we define threshold as the level a food allergen must reach in an individual's system before a life-threatening reaction occurs. We define exposure as the amount of allergens in the food that the individual consumed. Therefore, when an individual is exposed to food allergens in excess of their individual threshold level, the individual may have an allergic reaction.

[45] There are three types of recalls. Class I is a health-hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Class II is a health-hazard situation where there is a remote probability of adverse health consequences from the use of the product. Class III is a situation where the use of the product will not cause adverse health consequences. A market withdrawal occurs when a firm's removal or correction, on its own initiative, involves a minor infraction that would not result in the product being adulterated or misbranded.

benefit from advancements FDA has already made in these areas as well as any future accomplishments.

When we spoke to FSIS officials, they expressed an interest in proactively responding to the issues of food allergens. Senior FSIS officials stated that they are aware of this emerging food safety concern. They acknowledged the science behind testing and modeling is constantly evolving and expressed willingness to work with stakeholders toward the future prevention of allergen related illnesses.

Recommendation 8

Develop a plan with measureable timeframes and milestones to identify the available data and data gaps related to examining the risks from "Big 8" allergens in meat, poultry, and egg products.

Agency Response

FSIS stated it will follow standardized food safety risk analysis guidelines to evaluate regulatory concerns related to allergens in FSIS-regulated products. In FY 2017, FSIS will seek public and stakeholder input related to allergens in meat, poultry and egg products. FSIS will use this input to define risk management options and questions which will serve as the basis for a risk assessment plan. The plan will provide a regulatory and public health context for the assessment and include a summary of the key risk management issues and proposed analytic approaches. The plan will also include a measurable timeframe and milestones for identifying available data and critical data gaps to conduct the appropriate type(s) of risk assessment(s). Those data gaps will inform FSIS FY 2018 Research Priorities. The plan will be completed by June 30, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 9

Develop a plan with measureable timeframes and milestones to identify when research may be beneficial related to allergen testing systems and/or modeling methodologies for FSIS-regulated products, taking into consideration the work already conducted by the Food and Drug Administration (FDA), academic researchers, and others.

Agency Response

FSIS acknowledges that there is a need for additional research to clearly identify the allergenic hazards and the risks they may pose. FSIS will propose that identifying or developing an analytical method to monitor allergens in FSIS-regulated products be an official FSIS research priority. This proposed priority will be evaluated through review of FSIS research priorities through the FSIS Governance Process. Method development for allergen testing may also be considered as part of the action plan resulting from the March 2017 allergen public meeting. In

addition, collaboration with FDA is currently underway to better understand how FDA has approached the challenge with the products they regulate, and how that information might transfer over to products FSIS regulates. One vital step in understanding the risk is to have the proper laboratory methodology in place, so as to identify the hazard, if present, and assess the magnitude of the effect. FSIS and Agricultural Research Service (ARS) are proposing to identify analytical methods to test allergens in FSIS-regulated products. FSIS would then develop a plan, with measurable timeframes and milestones, for modification and validation of these analytical methods. Allergen testing as an agency research priority will be reviewed by July 30, 2017. The action plan arising from the allergen public meeting will be completed by February 28, 2018. Additionally, the joint FSIS and ARS plan will be developed by June 30, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 10

Develop a plan with measureable timeframes and milestones to periodically assess how testing and/or modeling concepts could be used in the future by the agency to improve areas, such as regulatory oversight, educational efforts and improve the agency's approach to undeclared allergen prevention and control.

Agency Response

FSIS stated in Recommendation 8, FSIS will develop a risk assessment plan that will identify and evaluate various risk assessment approaches to address risk management questions and develop potential risk management strategies. FSIS will evaluate approach(es), including modeling, based on risk management questions, available and expected data, and the timeframe for decision-making. The plan will be completed by June 30, 2018.

OIG Position

We accept management decision for this recommendation.

Section 4: Data Analysis

Finding 6: FSIS Needs to Improve How It Analyzes Data Related to Reports of Foodborne Illnesses

When consumers and other public health agencies contact FSIS to report illnesses, such as allergic reactions, the agency creates a case in FSIS' CCMS database.[46] We found, from our review of the CCMS directive and discussions with FSIS officials, that FSIS did not adequately follow requirements to ensure FSIS staff analyzed foodborne reactions or illnesses for an annual presentation to management. In addition, the directive requires the agency to develop artificial intelligence models that would analyze CCMS data to identify non-routine patterns of data, which might indicate "grave or potentially grave threats to public health;" however, we found that FSIS had neither prepared nor shared the data analysis on reactions to foodborne allergens or other potential health related issues. In addition, officials explained that FSIS had not integrated CCMS with the Department of Homeland Security (DHS) National Biosurveillance Integrations System (NBIS). The officials said this occurred because FSIS did not have the artificial intelligence data analysis tools necessary to process and analyze the CCMS database information. As a result, FSIS' Data Coordination Committee (DCC) may not have access to all the pertinent data they need to make informed safety decisions, or to disseminate this information to DHS and other stakeholders.

FSIS has procedures to investigate reports of foodborne illness associated with the products it inspects. After receiving a report of illness, FSIS creates a case in its CCMS database, as required by FSIS' Consumer Complaints Directive.[47] This directive serves an integral part in FSIS' biodefense strategy and states that the system should be integrated with the Department of Homeland Security National Biosurveillance Integrations System (DHS NBIS). In addition to integrating CCMS with NBIS, the directive also notes that the agency is responsible for developing artificial intelligence models that support identifying non-routine incident patterns imbedded in CCMS data. FSIS' Foodborne Illness Directive instructs FSIS to analyze the data contained in its foodborne illness investigation database, compile it annually, and provide annual briefings to FSIS' DCC, and other FSIS officials, and also to post its reports on its DCC website.[48] DCC is responsible for coordinating agency activities involving the collection, analysis, and use of FSIS or other data. DCC reviews significant data issues for the agency and the policy ramifications of those issues.

We found that FSIS was not using CCMS to analyze the non-routine data. The system was supposed to identify non-routine incident patterns embedded in the CCMS data; however, FSIS officials stated the computer did not find trends any faster or more accurately than FSIS staff.[49]

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[46] CCMS is an electronic database used by FSIS to record, analyze, and track all consumer complaints reported to the agency.

[47] FSIS Directive 5610.1, *Procedures to Implement the Consumer Complaint Monitoring System*, Aug. 8, 2005.

[48] FSIS Directive 8080.3, Foodborne *Illness Investigations*, Sept. 4, 2013.

[49] FSIS Directive 5610.1 describes a "non-routine incident" essentially as those complaints that are not routine and made references to grave threats to public safety involving an FSIS-regulated product or deliberate contamination of FSIS-regulated product.

FSIS informed us that the agency "took a different approach with CCMS than in this outdated directive [Directive 5610.11]…." FSIS officials went on to explain that FSIS follows up on every food related complaint it receives whether illness, injury or reaction and it reviews this data annually. FSIS uses CCMS not only for documenting food hazard incidents, but also for monitoring trends, coordination of investigations, communication with field staff and consumers. The system currently allows in-depth query of data for analysis. An artificial intelligence model previously existed in CCMS but ceased to exist in 2014 after system updates did not allow the model to function properly. From 2008 through 2014, the model assisted with reviews of trends among similar cases for the items returned on query; however, it matched what could be found by CCMS analysts just as quickly as using other system features. FSIS officials also explained that planned upgrades would include tools that help to further support data analysis and reporting.

In addition, FSIS informed us that CCMS was not integrated with NBIS. DHS is in charge of integrating and analyzing information from various monitoring systems across the Federal government and supporting the interagency biosurveillance community via the National Biosurveillance Integration Center (NBIC).[50] FSIS officials informed us they believe it is not advisable to integrate their systems with DHS[51] based on a Government Accountability Office audit report that indicates that NBIC faces challenges that limit its ability to enhance national biosurveillance.[52] For example, the report identifies that NBIC faces challenges obtaining data and creating meaningful new information.

FSIS also informed us that they had not followed their reporting and posting requirements in the agency's foodborne illness directive that required it to annually analyze the data from the foodborne illness investigation database, provide annual briefings, and post the reports on the DCC website. When we asked FSIS personnel for copies of the annual foodborne illness investigation reports, they informed us that neither the FY 2013 nor the FY 2014 report had been presented to DCC as required. As a result of our request, the agency realized they had not followed their reporting and posting requirements, and subsequently these reports were posted to the DCC website. Additionally, FSIS personnel conducted a January 2016 briefing with its management regarding the FY 2014 foodborne investigation data. FSIS officials said they agreed they need to improve how they prepare and post the DCC report. They stated that they would track this requirement in the future. These reports may identify similar foodborne illnesses or be an indicator for an emerging foodborne illness.

FSIS officials should set up a formal reporting process to assure that foodborne illness reports are prepared and presented to FSIS management, as required. FSIS officials indicated they were willing to evaluate whether a formal tracking system would enhance the agency's efforts to

[50] The National Biosurveillance Integration Center was established within DHS to address the Implementing Recommendations of the 9/11 Commission Act of 2007. Implementing Recommendations of the 9/11 Commission Act of 2007, Pub. L. No. 110-53, tit. XI, 121 Stat. 375, 476.
[51] FSIS officials explained that when the directive was written they anticipated that the agency would soon be able to integrate CCMS with DHS NBIS; however, as time progressed, FSIS realized that the two systems could never be integrated under their current designs. The FSIS directive has never been revised to delete this requirement.
[52] Audit Report GAO-15-793, *Challenges and Options for the National Biosurveillance Integration Center*, Sept. 24, 2015.

ensure that reports of foodborne illness outbreaks are timely prepared and shared annually with FSIS management.

Recommendation 11

Revise the Consumer Complaint Monitoring System (CCMS) directive to update the description of how FSIS identifies patterns of illness and the most appropriate means to share the data with appropriate stakeholders, especially public safety agencies.

Agency Response

FSIS stated that the CCMS directive addresses all consumer complaints reported to FSIS, including illness. The directive is currently under revision and will clarify how complaints are evaluated to identify patterns and similar cases. The directive will also include language that the information contained within the system for the respective proceeding year will be analyzed on an annual basis and made available to the public. The updated directive will be issued by December 30, 2017.

OIG Position

We accept management decision for this recommendation.

Recommendation 12

Implement controls to ensure reports of foodborne illness outbreaks, including reactions to allergens, are prepared and shared annually with the Data Coordination Committee (DCC) and FSIS management, as required.

Agency Response

FSIS stated that on an annual basis, Office of Public Health Science (OPHS) will provide briefings on foodborne illness investigations and CCMS data (including reports of allergic reaction) to the DCC and FSIS management. Controls aimed at ensuring this is done will be inclusion of these activities in staff performance metrics, systematic planning to ensure briefings are regularly scheduled, and the development of an internal tracking mechanism to document when such briefings are administered and by whom. FSIS has already started implementing most of these activities, with the exception of the tracking document, which will be developed by August 30, 2017.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

To complete our audit of FSIS' controls over products containing allergens, we performed audit steps at the FSIS national office located in Washington, D.C., and five meat, poultry, and egg processing plants across the United States. The facilities we visited were located in Arkansas, Iowa, Pennsylvania, and Tennessee.

FSIS has approximately 5,200 processing plants it monitors for allergens. To select the processing plants we visited, we used a non-statistical basis with selection criteria based on factors such as plant size, number of allergen recalls, volume of recalled product, and type of products processed.

To meet our audit objectives, we reviewed FSIS and plant records;[53] interviewed personnel and officials from multiple FSIS national and field office locations, officials from a Federal Government agency, trade association, and allergen researchers; and visited selected processing plants. Among those visited and interviewed were:

- FSIS national office representatives—we discussed issues related to allergen control, data analysis integration, allergen recalls, allergen research, and inspection activities related to allergens.
- Office of Field Operations—we conducted interviews with senior-level officials who manage national inspection activities.
- Office of Policy and Program Development—we conducted interviews with senior-level officials who provide leadership in the identification of policy needs and develop policy solutions.
- Office of Data Integration and Food Protection—we conducted interviews with senior-level officials who coordinate FSIS' data collection, analysis, and integration activities across all program areas. This group is responsible for evaluating individual FSIS data streams, ensuring data analyses are consistent and of high quality, and conducting data analyses for the agency's decision-makers.
- Office of Public Health Science—we conducted interviews with senior-level officials who oversee the development of scientific information related to meat, poultry, and egg products, and use that information to assess potential human health risks. We also conducted interviews with officials from Laboratory Services and CCMS. Laboratory Services coordinates and conducts laboratory analytical services in support of the agency's farm-to-table strategies. CCMS is a surveillance system that is designed to document and track all consumer complaints that are reported to FSIS.
- FDA—we conducted interviews with senior-level officials from the Center for Food Safety and Applied Nutrition who oversee the agency's allergen testing programs. FDA is responsible for protecting the public health by assuring that foods are safe, wholesome, sanitary, and properly labeled.

[53] Our record reviews consisted of information and data from calendar years 2014 and 2015 up to the time of our plant visit. The last plant visit concluded in June 2016.

- Trade group—we conducted an interview with representatives of an industry trade group. The interview included discussions about the trade group's collaboration with academia on a guidance document for industry as well as reasons why allergen recalls are on the rise.
- Allergen researchers—we conducted an interview with researchers from the Food Allergy Research and Resource Program, University of Nebraska-Lincoln about ongoing allergen research. This group collaborates with research institutions, governmental authorities, consumer groups, and scientific societies to improve the safety of food products for consumers with food allergies.
- Processing facilities—we conducted fieldwork at five plants in four States to gain an understanding of how they control allergens within their processes. At each plant, we conducted interviews with both FSIS inspectors and plant management. We also reviewed data and information from the plant and FSIS records. Both the records reviews and interviews were used to determine the extent of FSIS inspection and oversight, as well as to verify aspects of FSIS and processing plant allergen control activities.
- Media sites—we reviewed industry, consumer safety, and various news sources to stay current on relevant industry issues.

We obtained data from FSIS regarding completion rates for the "Big 8" formulation verification task. We performed analysis on these data and compared data to plant documents from the five plants we visited.

During the audit, we focused on whether FSIS has sufficient controls in place to ensure allergens are properly disclosed on product labels. Our audit fieldwork was conducted from October 2015 to October 2016.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions, based on our audit objectives. The evidence obtained provided a reasonable basis for our findings and conclusions based on our audit objectives.

Abbreviations

ARS ..... Agricultural Research Service
CCMS ..... Consumer Complaint Monitoring System
DCC ..... Data Coordination Committee
DHS ..... Department of Homeland Security
E. coli ..... *Escherichia coli* O157:H7
FDA ..... Food and Drug Administration
FSIS ..... Food Safety and Inspection Service
FY ..... Fiscal Year
HACCP ..... Hazard Analysis and Critical Control Point
HAV ..... Hazard Analysis Verification
NBIC ..... National Biosurveillance Integration Center
NBIS ..... National Biosurveillance Integration System
OIG ..... Office of Inspector General
OPHS ..... Office of Public Health Science
PHIS ..... Public Health Information System
STEC ..... Shiga toxin-producing *E.coli*
USDA ..... Department of Agriculture

USDA'S
FOOD SAFETY AND INSPECTION SERVICE'S
RESPONSE TO AUDIT REPORT

United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW, Washington, D.C. 20250

TO: Gil H. Harden
Assistant Inspector General
Office of Inspector General

FROM: Alfred V. Almanza **/ s /** **May 18, 2017**
Acting Deputy Under Secretary, Food Safety
Administrator, Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Food Safety and Inspection Service Controls Over Declaring Allergens on Product Labels

We appreciate the opportunity to review and comment on this Official Draft report. The Food Safety and Inspection Service (FSIS) reviewed the Official Draft report and has general comments followed by a response to each recommendation.

FSIS' General Comments

FSIS acutely understands the significance of preventing undeclared allergens in meat, poultry, and egg products. Our colleagues, friends, and family are among the millions of Americans with food allergies, many of whom meticulously take precautions to avoid known allergens to maintain their health and avoid potentially life-threatening exposures. We take our public health mission, to ensure that FSIS-regulated products are accurately labeled in addition to being safe and wholesome, very seriously. While FSIS appreciates the work that OIG has done in assessing FSIS controls over declaring allergens on products labels, FSIS would like to take this opportunity to clarify some statements made within the report.

First, FSIS is in the plant every day and can verify that products are appropriately formulated, both through observation and record review, while FDA does not have this ability. OIG has suggested that FSIS consider ingredient testing for allergens. This may offer another verification tool for FSIS, but cannot be the central approach to verifying the accuracy of product labels that is, by statute, FSIS' primary focus of ensuring allergens are accurately disclosed on product labels.

Second, the report states that reactions to food allergens affect millions of consumers each year but fails to emphasize that due to FSIS' increased vigilance in verifying ingredients on product labels and strengthening of enforcement of allergens in the plant and on labels very few people have actually been adversely affected by undeclared allergens in FSIS-regulated products.

Finally, a multidisciplinary team of FSIS leaders has been addressing the issue of undeclared allergens for years. We have utilized education and enhanced training, implemented additional verification procedures, and increased communication to reduce the increased level of undeclared allergen recalls seen in recent years. Ongoing collaboration with our partners, most recently with a public meeting in March 2017, has led to a number of opportunities to address the challenges we face. Our actions have

resulted in successes, yet we are continuing to enhance our efforts to implement significant solutions.

FSIS' Response to OIG's Recommendations

Recommendation 1:
Sponsor a public meeting on food allergen issues that offers FSIS and collaborators an opportunity to engage with other public health authorities, consumers, health professionals, the food industry, academia, and other stakeholders to gain greater appreciation for the regulatory, practical, clinical, and analytical challenges present in allergen control. Based on the information presented at the public meeting, draft an action plan that can be used by FSIS management to improve the Agency's approach to food allergens.

FSIS Response:
FSIS sponsored a public meeting on March 16, 2017 with attendance from over 100 individuals from academia, the general public, public health and regulatory agencies, the food industry, and other stakeholders. The public meeting allowed for discussion of best practices, challenges, and opportunities for collaboration. An action plan that will be used by FSIS management to improve our approach to food allergens is under development, along with several other allergen-focused projects, and is being initiated as a result of this successful FSIS-sponsored meeting.

Estimated Completion Date:
An action plan will be completed by February 28, 2018.

Recommendation 2:
Clarify Directive 7230.1, and provide additional guidance as necessary to ensure that FSIS inspectors accurately implement the "Big 8" formulation verification task, including product selection.

FSIS Response:
FSIS Directive 7230.1, Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("Big 8") Food Allergens, has been instrumental in raising awareness of allergens among FSIS-regulated establishments with indispensable communication by inspection program personnel to establishment personnel about the importance of preventing undeclared allergens. The directive has also led to the early identification of establishment issues which likely prevented the release of products containing undeclared allergens into commerce. FSIS will revise the directive to clarify the instructions to inspection program personnel.

Estimated Completion Date:
A workgroup to revise FSIS Directive 7230.1 will be put in place by August 31, 2017 with a list of items for revision completed by November 30, 2017. Thedraft revision of the directive will be completed by February 28, 2018 with a final issuance expected by April 30, 2018.

Recommendation 3:
Review the "Big 8" formulation verification task instructions in the Public Health Information System (PHIS) and, if necessary, update the instructions to ensure consistency with Directive 7230.1.

FSIS Response:
FSIS will review the PHIS task instructions for the "Big 8" formulation verification task and if necessary, update the instructions in PHIS to be consistent with FSIS Directive 7230.1.

Estimated Completion Date:
A review of PHIS task instructions and a comparison against FSIS Directive 7230.1 will be completed by September 30, 2017. An update to the task instructions, as needed, will be completed by January 31, 2018.

Recommendation 4:
Determine if inspectors are completing the "Big 8" formulation verification task as required. Based on the determination, take appropriate corrective action, such as providing additional training to inspectors.

FSIS Response:
FSIS will continue periodic reviews of the "Big 8" formulation verification task, and will use the results to inform any decisions about additional training or clarification of instructions. Previously completed analyses will be used to inform the revision of FSIS Directive 7230.1.

Estimated Completion Date:
The review of FSIS data for the "Big 8" formulation task will be completed by November 30, 2017 with results informing the revision of FSIS Directive 7230.1 as outlined in the response to recommendation 2. The determination for additional training needs and clarification of instructions will be completed by March 31, 2018.

Recommendation 5:
Determine which additional directives and notices provide instructions regarding allergens to FSIS inspectors. Review and update the material as necessary to ensure consistency among the documents and consider stating that allergen verification is a priority 3 task.

FSIS Response:
FSIS will determine which directives and notices provide instructions to inspection program personnel regarding allergens and review those policy issuances. As appropriate, FSIS will state that allergen verification is a priority 3 task and update instructions to ensure consistency.

Estimated Completion Date:
The initial review of directives and notices will be completed by October 31, 2017. If needed, updates to policy issuances will be completed by April 30, 2018.

Recommendation 6:
Determine whether plants with allergenic ingredients need to be identified in PHIS with a "yes/no" checkbox in the plant profile. If not, then implement another method that will allow the agency to improve its data analysis by accurately identifying plants that add allergenic ingredients and develop measureable timeframes and milestones for the agency to implement its decision.

FSIS Response:
FSIS will use the responses from the "Big 8" allergen formulation verification task questionnaire to categorize establishments that produce products containing "Big 8" allergens. FSIS will develop a plan to add this information to the establishment profile in PHIS.

Estimated Completion Date:
Initial categorization of establishments and developing a plan to add the information to the establishment profile in PHIS will be completed by February 28, 2018.

Recommendation 7:
Develop a plan with measureable timeframes and milestones to revise FSIS Directive 7230.1 or Directive 5000.6 to address the issue of potential allergen cross-contact, including whether a plant has sufficient scientific evidence to support that allergen cross-contact is properly prevented or controlled among the products within a plant's production environment.

FSIS Response:
FSIS will develop a plan to review existing data and FSIS Directives 7230.1 and 5000.6, Performance of the Hazard Analysis Verification (HAV) Task, to determine whether it is necessary to address potential allergen cross-contact in the verification instructions to inspection program personnel. FSIS will develop a plan to review existing training and educational materials to determine whether it is necessary to further address potential allergen cross-contact.

Estimated Completion Date:
FSIS will review and make a determination as to whether potential allergen cross-contact will be included in the revision to FSIS Directive 7230.1 by February 28, 2018. The review, determination, and inclusion of cross-contact information in FSIS Directive 7230.1 and education/training materials, if necessary, will be completed by April 30, 2018.

Recommendation 8:
Develop a plan with measureable timeframes and milestones to identify the available data and data gaps related to examining the risks from "Big 8" allergens in meat, poultry, and egg products.

FSIS Response:
FSIS will follow standardized food safety risk analysis guidelines to evaluate regulatory concerns related to allergens in FSIS-regulated products. In FY2017, FSIS will seek public and stakeholder input related to allergens in meat, poultry and egg products. FSIS will use this input to define risk management options and questions which will serve as the basis for a risk assessment plan. The plan will provide a regulatory and public health context for the assessment and include a summary of the key risk management issues and proposed analytic approaches. The plan will also include a measurable timeframe and milestones for identifying available data and critical data gaps to conduct the appropriate type(s) of risk assessment(s). Those data gaps will inform FSIS FY2018 Research Priorities.

Estimated Completion Date:
The plan will be completed by June 30, 2018.

Recommendation 9:
Develop a plan with measureable timeframes and milestones to identify when research may be beneficial related to allergen testing systems and/or modeling methodologies for FSIS-regulated products, taking into consideration the work already conducted by the Food and Drug Administration (FDA), academic researchers, and others.

FSIS Response:
FSIS acknowledges that there is a need for additional research to clearly identify the allergenic hazards and the risks they may pose. FSIS will propose that identifying or developing an analytical method to monitor allergens in FSIS-regulated products be an official FSIS research priority. This proposed priority will be evaluated through review of FSIS research priorities through the FSIS Governance Process. Method development for allergen testing may also be considered as part of the action plan resulting from the March 2017 allergen public meeting. In addition, collaboration with FDA is currently underway to better understand how FDA has approached the challenge with the products they regulate, and how that information might transfer over to products FSIS regulates. One vital step in understanding the risk is to have the proper laboratory methodology in place, so as to identify the hazard, if present, and assess the magnitude of the effect. FSIS and ARS are proposing to identify analytical methods to test allergens in FSIS-regulated products. FSIS would then develop a plan, with measurable timeframes and milestones, for modification and validation of these analytical methods.

Estimated Completion Date:
Allergen testing as an Agency research priority will be reviewed by July 30, 2017. The action plan arising from the allergen public meeting will be completed by February 28, 2018. Additionally, the joint FSIS and ARS plan will be developed by June 30, 2018.

Recommendation 10:
Develop a plan with measureable timeframes and milestones to periodically assess how testing and/or modeling concepts could be used in the future by the agency to improve areas such as regulatory oversight, educational efforts, and the agency's approach to undeclared allergen prevention and control.

FSIS Response:
As stated in response to Recommendation 8, FSIS will develop a risk assessment plan that will identify and evaluate various risk assessment approaches to address risk management questions and develop potential risk management strategies. FSIS will evaluate approach(es), including modeling, based on risk management questions, available and expected data, and the timeframe for decision-making.

Estimated Completion Date:
The plan will be completed by June 30, 2018.

Recommendation 11:
Revise the Consumer Complaint Monitoring System (CCMS) directive to update the description of how FSIS identifies patterns of illness and the most appropriate means to share the data with appropriate stakeholders, especially public safety agencies.

FSIS Response:
The CCMS directive addresses all consumer complaints reported to FSIS, including illness. The directive is currently under revision and will clarify how complaints are evaluated to identify patterns and similar cases. The directive will also include language that the information contained within the system for the respective proceeding year will be analyzed on an annual basis and made available to the public.

Estimated Completion Date:
The updated directive will be issued by December 30, 2017.

Recommendation 12:
Implement controls to ensure reports of foodborne illness outbreaks, including reactions to allergens, are prepared and shared annually with the Data Coordination Committee (DCC) and FSIS management, as required.

FSIS Response:
On an annual basis, OPHS will provide briefings on foodborne illness investigations and CCMS data (including reports of allergic reaction) to the DCC and FSIS management. Controls aimed at ensuring this is done will be inclusion of these activities in staff performance metrics, systematic planning to ensure briefings are regularly scheduled, and the development of an internal tracking mechanism to document when such briefings are administered and by whom.

Estimated Completion Date:
FSIS has already started implementing most of these activities, with the exception of the tracking document, which will be developed by August 30, 2017.

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