In response to recent recalls involving foreign material found in meat and poultry products, the Food Safety and Inspection Service (FSIS) is taking a closer look at how establishments are handling foreign material complaints from consumers/customers, and findings between establishments. Based on its evaluation, the agency may decide whether there is a need to make policy changes, issue a new regulation, or issue compliance guidelines for the industry.

On June 8, 2016, FSIS issued Notice 40-16, “Questionnaire on Consumer Complaints Involving Foreign Material.” Pursuant to the Notice, inspection program personnel (IPP) are to complete a questionnaire between July 11 and August 11, 2016 regarding how official establishments respond to foreign material complaints. Although the questionnaire has not yet been released, the Notice indicates establishments will be asked, among other things: (1) whether they have a written process to gather and evaluate all consumer complaints regarding foreign material, (2) whether they have a written description of the actions they take for complaints, including when no action is taken and why, and (3) whether they make these written documents available to IPP. Information collected from the questionnaires will be used “to determine the next phase and to inform policy development.”

The agency is currently concerned that establishments do not have a documented process for determining whether consumer complaints are legitimate, and if so, for determining whether adulterated product may be in commerce. According to the agency, this documented process is necessary to determine whether the establishment is required to notify the FSIS District Office of foreign material complaints in accordance with 9 C.F.R. § 418.2. This regulation requires an establishment to notify the District Office within 24 hours when it has reason to believe adulterated or misbranded product is in commerce.

With regards to what elements should be part of a documented process for evaluating consumer complaints, FSIS has shared the following issues.

- Does the establishment/company have a written protocol for tracking incoming complaints?
- Is there written decision criteria for determining:
  - Whether a complaint is legitimate?
  - Whether the foreign material is isolated or systemic; if isolated:
    * Whether the establishment has a process for reviewing any remaining product; and
    * Whether the establishment considers “repeat isolated incidents” from the same source?

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FSIS Focuses on Foreign Material Contamination (cont.)

◊ Whether the foreign material is visible to the consumer or incorporated into the product?
  * Even if visible, FSIS noted that establishments should carefully consider whether product has been shipped to schools, military, hospitals and other institutions.
◊ Whether the foreign material renders product “adulterated?” and
◊ Whether FSIS will be notified?
  • If corporate headquarters is doing the analysis, does headquarters provide feedback to the producing establishment and provide updates regarding repetitive contamination?
  • Is the process for evaluating complaints regarding foreign material in a form that IPP can review?
  • Does the establishment provide updates to IPP regarding foreign material complaints?

FSIS will be assessing whether establishments are currently considering these factors in determining whether additional regulatory initiatives are warranted.

Another policy issue under consideration is when establishments are required to notify the District Office (DO) when foreign material is found between official establishments. FSIS is concerned that establishments are not checking incoming product frequently enough to detect foreign material contamination. Furthermore, when foreign material is detected, the agency is concerned that many establishments simply determine that contamination is inherent in the product process, remove the foreign material, and further process the remaining product without determining if the contamination was more prevalent. The agency believes that establishments should have a decision-making process for determining the extent of contamination when any foreign material is found.

During a conference call with industry members, a question was asked whether establishments are required to notify the DO pursuant to 9 C.F.R. § 418.2 each time foreign material is found upon receipt of food (e.g., blue glove, metal hook). The agency stated it does not currently expect notification to the DO provided the following conditions are met:

  • The establishment finds the foreign material;
  • The establishment follows procedures to evaluate the incoming product to ensure the foreign material is an isolated incident and not more prevalent;
  • The establishment notifies its supplier; and
  • The establishment notifies IPP.

If these conditions are met, FSIS would currently allow the foreign material finding to be handled in accordance with FSIS Directive 8140.1. Although quite old and recognized by the agency as in need of updating, this Directive sets forth procedures it will follow when an establishment receives adulterated product from a supplier. Procedures include completing a Form 8140.1 and notifying agency personnel in the District in which the supplier resides.

In the next few months, FSIS will be evaluating how establishments are assessing, responding to, and reporting foreign material complaints and findings and developing policy based on this assessment. Establishments should reassess their procedures to ensure they are meeting agency expectations if they have not already done so.
Quarterly Establishment Information Letter

Currently, FSIS provides establishments with the individual sample results of all agency testing.¹

FSIS will continue to provide establishments with individual results.² Beyond that, FSIS is developing “Quarterly Establishment Information Letters” to provide establishments with more information on the sample results. FSIS intends to implement the Letters nationwide by the end of next year. Once implemented, these Letters will be automatically generated and sent every quarter to the establishment in the same way that individual results are conveyed now.

The Letters will include the results of the agency’s sampling programs for pathogens and residues for the past year. The letter will provide both summary results and detailed results for the establishment, including, in the case of pathogens: serotype, PFGE, and antimicrobial resistance.

The Letters will also provide industry averages (percentage of positive samples) for *Salmonella* and *Campylobacter*. At present, FSIS does not plan to provide other industry-wide data in the Letters. FSIS may otherwise provide industry-wide information as to serotypes, PFGE, and antimicrobial resistance through its website, in the same manner that the agency issues its [quarterly residue report](#) for residues.

The Letters will have an Appendix providing information on:

- Serotypes commonly associated with human illness,
- PFGE pattern recurrence over the last 5 years at the establishment,
- FDA's Antimicrobial Drug Classification, and
- Harborage and Cross-contamination.

Consistent with FSIS’ increasing focus on pathogens of public health significance, the Letters will not be limited to data. The Letters will also discuss further FSIS actions based on the results, such as increased testing or a Food Safety Assessment. In discussing the Letters, FSIS officials have made clear that the agency expects establishments to consider the information presented in the Letter to aid in the evaluation of their process control and any potential improvements to increase food safety.

The Letters will have a phased implementation. FSIS will issue a Notice and then start sending letters to establishments in one Circuit (the pilot circuit has not been selected yet), then to one District, before rolling out nationwide. As always, we encourage establishments to continue to use the data available to them, through their own testing programs as well as FSIS sample results to maintain the best programs possible.

¹ Previously, FSIS also had provided “End of Set” letters to establishments subject to a *Salmonella* Performance Standard. However, since FSIS has transitioned from a set to a moving window in determining compliance with the performance standards, there is no longer a “set” to end.

² [FSIS Directive 5300.1](#). Chapter II, Part II, provides instruction to inspection program personnel (IPP) on how to update the establishment’s contact information to include an email address for receiving FSIS lab sample results.
For the past several years, the recalls related to allergens have been increasing. Allergen recalls top the list for the number of recalls of meat and poultry products regulated under USDA’s Food Safety and Inspection Service (FSIS), recalls for all other types of food products regulated under the Food and Drug Administration (FDA), and for foods regulated by the Canadian Food Inspection Agency and the Australian Food Inspection Agency as well.

In order to determine what can be done to control the process and prevent the risk to the consumers; it is important to understand what is happening at the establishment that results in products being manufactured or labeled improperly. It is easy to “blame” all of the increase in recalls on undeclared allergens coming to the establishment from the supply chain. This has led to recalls in products regulated by both agencies such as the recalls for peanut in cumin powder. However, there is much we can do at our facilities to ensure products are not only produced correctly, but also labeled correctly.

In an analysis of food allergen recalls of FDA-regulated products conducted by Gendel and Zhu, it was determined that bakery products were the most frequently recalled food type and milk was the most frequent undeclared allergen. This analysis also demonstrated that the use of the wrong package or label was the most frequent reason a food was involved in an allergen recall.

In reviewing the details of the Gendel and Zhu analysis, it is important to note that in approximately 28% of the allergen recalls no root cause was identified or reported. If the establishment does not determine what caused the problem – they will never be in a position to prevent it from reoccurring. The root cause that was identified most frequently was use of the wrong package or label. In a report by the North American Meat Association (Rachel L. Murphy, 2015), the most common reason for an allergen recall is described as “a change in product formulation or a change in the supplier’s ingredient formulation.” The use of the wrong label and a change in product formulation are both situations that can be addressed in an establishment’s allergen control plan.

In conducting a more in-depth analysis, it was determined that for those FDA recalls caused by failures in label control: control of the labels is as important as are the controls for the foods and food contact surfaces. When determining what may have failed with the label control, Gendel and Zhu determined that the main concerns were failure to actually provide the allergen information on the label (including carrying through the information from a supplier) and ensuring proper terminology for the allergen in the product (e.g., use of the term “milk” rather than “dairy”). These examples provide good support for all establishments to re-evaluate their allergen control program and ensure it is up-to-date and effective.

Allergen control programs are essential to prevent the concerns with allergen mislabeling as well as cross contact. There are many guidance documents available to the industry to assist in the development or enhancement of allergen control programs. Documents that establishments may wish to review include the FSIS Compliance Guidelines for Industry (FSIS, 2015), NAMI Allergen Control Guidance (Rachel L. Murphy, 2015) and the Food Allergy Research and Resource Program (FARRP, 2008). Regardless of the products made, key elements an establishment should consider in an allergen control plan include:

**Supplier programs**
- Letters of guarantee and on-going communication with suppliers to ensure knowledge of any changes that take place at the supplier level.
  - Ensure your suppliers have an allergen control program.
  - Require suppliers to notify you of changes to the allergen status of ingredients.
Allergen Recalls: How Can We Prevent Them? (cont.)

Receiving Procedures
- Review of labels on incoming ingredients. Spice blends have been a particularly high risk item for changes. The use of transparencies of the correct label of the expected item as it can easily be laid over the incoming ingredients for comparison. This makes this an easy task at receipt in determining whether or not a label has changed.
- Tag incoming ingredients that contain allergens. Make certain that the “tagging” is not removed when the product is used, e.g., a sticker on the outside of shrink wrap that will be removed when the shrink wrap is removed.
- Review of labels at receipt. Were they properly printed? The use of transparencies also works very well for this task.

Storage of Ingredients
- Storage of ingredients with properly labeling and in a manner to prevent cross-contact contamination.
  - Like allergens should be stored with like allergens.
  - Use of closed containers.
  - Employees should be trained to know what to do if there is a ripped bag or spillage from a container.
  - Color coding may be useful in this area.

Research and Development
- When formulating new products, ask if the allergenic ingredient is really necessary? Too often we use an allergenic ingredient in new product development that offers no difference in the taste or function of the product.

Scheduling
- Schedule production runs for products that contain allergens last in order to minimize changeovers.
- Ensure allergen cross contact sanitation occurs immediately after production of foods containing allergenic ingredients.

Processing
- Ensure current batch sheet is being used. The batch sheets should be dated.
- Consider color-coded tools, containers and utensils to identify allergenic ingredient or products.
- Consider personnel working on different processing lines.
- Provide a means to identify which employees are working on a line that contains allergens such as different colored hairnets or different colored frocks.
  - As a side note – consider employee outer garments in break rooms. Are allergens available in the breakroom, e.g., peanuts? Do employees wear their uniform into the breakroom? Do they wash their hands when leaving the breakroom?
- Consider ventilation and the possibility of dust from one processing line to another.

Sanitation
- Is the equipment easy to clean (at pre-op and between production runs)?
  - Are there rough welds or parts of the equipment that cannot be easily accessed?
- Are there hollow areas or recessed areas on the equipment in which allergens can accumulate?
- When validating allergen cross contact procedures, ensure product is held pending results.

Labelling
- Ensure accurate label is applied to product – have employees read the label “out loud” – we see what we expect to see.
- Maintain label controls.
  - Discard out of date labels or ensure they are maintained under lock and key.
- Ensure finished product label carries forward any allergen statements from suppliers.

These are only a few points that might be included in your program. However, it should be clear that the program must be comprehensive – supplier to finished product. If there is failure in the allergen program, then a root cause analysis should be conducted to assist in bolstering the program. Preventing allergen recalls is not simply a matter of checking the label on the product on the way out of the door. The key is to have a comprehensive allergen program and ensure it is implemented and effective.
FSMA – Sanitary Transportation Final Rule Affects Both FDA and FSIS-regulated Facilities

Under the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) has issued seven foundational regulations. These regulations are intended to address the products produced by FDA-regulated facilities and shift the focus of federal regulators from responding to contamination to preventing it.

The Sanitary Transportation of Human and Animal Food final rule, which implements key provisions of the Sanitary Food Transportation Act of 2005 (2005 SFTA), was issued April 6, 2016. This is the only regulation under FSMA that applies to all food products, those regulated by FDA as well as the Food Safety and Inspection Service (FSIS). The final rule requires those engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food unsafe. Compliance dates are April 6, 2017 for most businesses and April 6, 2018 for “small businesses” which are those having less than 500 full time employees and for motor carriers that are not also shippers and/or receivers with less than 25.5 million in annual receipts. Additional information, including a Fact Sheet and Questions and Answers, is available on FDA’s Sanitary Transportation webpage.

The final rule applies to shippers, receivers, loaders, and carriers engaged in the transportation of human or animal food by motor or rail vehicle in the United States. It does not apply to transportation of food by air or ship. It establishes new requirements for shippers, receivers, loaders, and carriers of food “in addition to any other [FDA] requirements applicable to the transportation of food.” For example, the current good manufacturing practice (CGMP) regulations for human food (21 C.F.R. Part 117) generally require transportation of human food to be under conditions that will protect food against allergen cross-contact and contamination.

Exemptions

Exemptions include the following:

• Transportation of live food animals, except molluscan shellfish;
• Transportation activities performed by a farm;
• Transportation of human food byproducts intended for animal food and not further processed (the rule otherwise does apply to animal food);
• Transportation of food completely enclosed in a container (unless the food requires temperature control for safety);
• Transportation of food by air or ship; and
• Food when it is located in a facility that is regulated, throughout the entire facility, by USDA. Note: When the food leaves the USDA-regulated facility, it appears to lose its exemption. The preamble to the final rule states that FSIS does not “directly” address transportation and that this rule “complements” their regulations.

Key Requirements

Key components of the final rule include that vehicles and transportation equipment must be designed and maintained to prevent food from becoming unsafe. They must be stored to prevent contamination or pest infestation. If used to transport food that requires temperature control for safety, it must be designed, maintained, and equipped to provide adequate temperature control. Transportation operations will be required to be conducted under conditions and controls determined necessary to prevent food from becoming unsafe.

\[ \text{---continued on page 7} \]
FSMA – Sanitary Transportation Final Rule Affects Both FDA and FSIS-regulated Facilities (cont.)

The final rule has specific requirements for each entity involved in the transportation of food. Shippers are required to develop, implement and provide written specifications to the carrier (and the loader, where appropriate) that include sanitary specifications for transportation vehicles and equipment and, where appropriate, operating temperature. Loaders are required to ensure the supplier specifications are met for foods that are not fully enclosed in packaging and to verify cold storage containers are adequately prepared and meet sanitary conditions. Receivers are required to assess that the food was not subjected to significant temperature abuse.

It should be noted that carriers may be made responsible for the sanitary conditions during transportation by a written agreement with the shipper. Any of the parties involved in the transportation of food may reassign its responsibilities to another party using a written contract. If responsibilities are assigned to another party that is not covered by the final rule (e.g., a carrier contracts with a truck wash station to wash a bulk tanker), FDA will hold the party covered by the final rule responsible for compliance.

Training will be required for carriers that agree in writing to be responsible for sanitary conditions during transportation. The carrier’s personnel engaged in the actual transportation operations must receive adequate training regarding any potential food safety problems, basic sanitary transportation practices, and the carrier’s responsibilities. FDA has indicated it intends to develop an online course to address this training element.

As is required in all of the various FSMA regulations, FDA expects records to be maintained supporting the requirements of the regulation. These will need to be made available to the FDA upon verbal or written request for review and/or copying.
MEET THE USDA TEAM

Dennis R. Johnson — a Principal with the firm who specializes in food safety law and regulation, representing large and small meat and poultry companies and trade associations before the United States Department of Agriculture's Food Safety and Inspection Service. Mr. Johnson is a certified HACCP instructor and is the author of HACCP and U.S. Food Safety Law. Mr. Johnson has been a frequent speaker on numerous topics, including food safety and regulatory compliance under the Federal Meat Inspection Act and the Poultry Products Inspection Act. Mr. Johnson received his law degree from Columbus School of Law and his Masters of Law degree from the National Law Center, where he was a Food and Drug Law Institute Fellow.

Brett T. Schwemer — Brett is a principal who concentrates his practice in food and labeling law, representing meat and poultry companies and trade associations before USDA's Food Safety and Inspection Service (FSIS), and in the case of dual jurisdiction establishments and other food companies, before the Food and Drug Administration (FDA). Brett counsels clients on a variety of food law issues, such as FSIS and FDA inspectional and enforcement authorities, labeling requirements, export and import requirements, recalls, and HACCP, hazard analyses and preventive control requirements under the laws administered by FSIS and FDA. He has spoken and written extensively on these subjects and is a certified HACCP trainer. In addition to food safety and labeling law, Brett specializes in regulatory, compliance, and enforcement matters before other USDA agencies, such as the Grain Inspection, Packers and Stockyards Administration (GIPSA).

Jolyda (Jody) O. Swaim — a Principal with the firm who focuses on United States Department of Agriculture's Food Safety and Inspection Service and Food and Drug Administration regulatory matters, as related to meat and poultry production and high risk FDA regulated foods. She assists clients with issues regarding meat and poultry product labeling, HACCP and SSOP, as well as quality assurance and sanitation. Ms. Swaim also has experience in the areas of import and export of meat and poultry products. Prior to becoming an attorney, Jody had extensive experience in the meat, poultry, and food industry—specifically working for Sara Lee Corporation, ConAgra Foods, Inc., and The Campbell Soup Company. Her work has included high-risk bakeries, various prepared or frozen food operations, as well as vegetable manufacturing companies. She has experience in all matters relating to food production, gained from direct control of departments such as food safety, sanitation, quality assurance, consumer affairs, and operations. Jody received her B.S. in Biology from Mercyhurst University in Erie, Pennsylvania and her J.D. cum laude from Thomas M. Cooley Law School in Lansing, Michigan.

Barbara (Barb) J. Masters — a Senior Policy Advisor with the firm who provides guidance on all areas of food safety, regulatory process and animal welfare. She has expertise in meat and poultry slaughter and processing. Prior to joining OFW Law, Dr. Masters served as Acting Administrator, and then Administrator, for the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from March 2004 through January 2007. During her tenure as FSIS Administrator, she worked to establish a solid infrastructure of science-based policies and data analysis. Dr. Masters graduated from Mississippi State University with a Doctor of Veterinary Medicine degree. Additionally, she participated in the Food Animal Internship at Kansas State University. She continued to further her education by taking advanced coursework in biotechnology at Texas A&M University.
The U.S. Food and Drug Administration (FDA) regulates 25% of the gross domestic product (GDP) of the United States. The United States Department of Agriculture (USDA) governs a substantial percentage as well. Whether companies under FDA or USDA jurisdiction are bringing a new product to market, responding to an agency enforcement action, or attempting to challenge a new regulatory initiative, businesses regulated by FDA or USDA must know how to navigate the regulatory process. They must also clearly understand the legislative process and how new legislation can impact their businesses. Our attorneys are well situated to anticipate legislative initiatives before Congress, to communicate with our clients about proposed changes, and to lobby Congress on their behalf. The Washington, DC, law firm of Olsson Frank Weeda Terman Matz PC is the nation’s premier FDA, USDA, and health care law firm, serving clients before federal agencies, courts, and Congress.

Founded in 1979 as Olsson and Frank, P.C., and known for many years as Olsson Frank & Weeda, P.C., our lawyers have built a solid reputation for depth and expertise. Providing legal and government affairs representation to companies and trade associations in the food, drug, medical device, and agricultural industries, we work to remove obstacles that our clients face.

With over 30 years of combined legal and public service experience, as well as backgrounds in government, medicine, and industry, we have an established reputation for finding solutions to client problems. At Olsson Frank Weeda Terman Matz PC, we bring a wealth of knowledge and experience to every client we represent.