

SPECIAL GUEST EDITOR SECTION: FOOD ALLERGENS MANAGEMENT

Allergens: An Enhanced Focus

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Food Allergy Awareness Week was created with the purpose of placing a spotlight on the seriousness of food allergies. Recognized in the United States in mid-May every year, Food Allergy Awareness Week serves as a reminder of the over 15 million Americans who suffer from food allergies. The importance of allergies and allergen labeling can be seen when looking at U.S. Food and Drug Administration recall data: of the 764 recalls in 2016, 305 (representing more than 40%) were due to undeclared allergens. However, recalls for undeclared allergens are a complex issue with numerous factors. The implementation of prevention-based systems with the necessary management components and further error-proofing the systems, along with allergen awareness embedded throughout a company's food safety culture, can likely help reduce the number of recalls for undeclared allergens. As a resource to manufacturers, the Grocery Manufacturers Association and the Food Allergy Research and Resource Program have developed several resources to assist with developing robust allergen management programs. By reducing the number of recalls for undeclared allergens, the food industry will likely increase and maintain consumer confidence and trust of the food-allergic community. This enhanced consumer confidence and trust could eventually open the door for further collaboration with the food-allergic community and, potentially, advance allergen-related policies.

Food Allergy Awareness Week was created with the purpose of placing a spotlight on the seriousness of food allergies. Recognized in the United States in mid-May every year, Food Allergy Awareness Week serves as a reminder of the over 15 million Americans who suffer from food allergies (1). Some manufacturers in the food industry use this week to promote food allergy awareness throughout their company and communities.

Although Food Allergy Awareness Week raises the awareness of those who suffer from food allergies, the fact remains that there is currently no cure and, thus, strict avoidance of the particular food is essential. However, this remains challenging for consumers when undeclared food allergens continue to be the top recall reason. [The Reportable Food Registry (RFR) is an

electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences (2).] In 2016, there were 764 recalls by the U.S. Food and Drug Administration (FDA) and, of that, 305 (40%) were due to undeclared allergens (3). The other recalls for FDA-regulated foods in 2016 were predominantly associated with foreign material and microbiological contaminants, along with other reasons for recalls. Clearly, the primary driver for recalls was undeclared allergens. In addition, from the chart in Figure 1, it is evident that undeclared allergens continue to be the top reason for reports to the FDA's RFR.

Furthermore, recalls for Food Safety and Inspection Service (FSIS)-regulated food show a similar trend, with the leading cause of recalls being undeclared allergens. In 2016, there were a total of 122 recalls for FSIS-regulated products, 34 (28%) of which were due to undeclared allergens. The other 2016 FSIS recalls were distributed among the following reasons: other (23%), which includes production without inspection; extraneous material (17%); shigatoxigenic *Escherichia coli* and verotoxigenic *E. coli* (11%); *Listeria monocytogenes* (9%); undeclared substances (5.7%); processing defects (4%); and *Salmonella* (1.6%; 4).

It is critical for food manufacturers to understand the facts regarding food allergens and how food allergens are addressed in the Food Safety Modernization Act (FSMA)'s Preventive Controls for Human Food final rule.

How Allergens Are Addressed in FSMA

FSMA is the most dramatic food safety law in over 70 years and was signed into law by President Barack Obama on January 4, 2011. FSMA aims to ensure the U.S. food supply is safe by shifting its focus from responding to contamination events to creating a prevention- and risk-based system (5). With FSMA, there are seven foundational rules. Allergens are addressed in two of these final rules:

(1) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; and

(2) Foreign Supplier Verification Programs

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule adds new preventive control provisions as required by FSMA and updates and revises certain requirements in the existing current good manufacturing practice (cGMP) regulations, which are now codified in 21 CFR Part 117. The FDA made several changes to the terminology used in the cGMPs, including the use of the term "allergen cross-contact" to describe the inadvertent incorporation of an allergen into food. Prevention against allergen cross-contact is now explicitly mentioned numerous times throughout the cGMPs. A key requirement of the Preventive Controls for Human Food rule is to have a written food safety plan, which includes a written hazard analysis. When conducting a hazard analysis, known or reasonably foreseeable hazards must be considered. This includes the identification of

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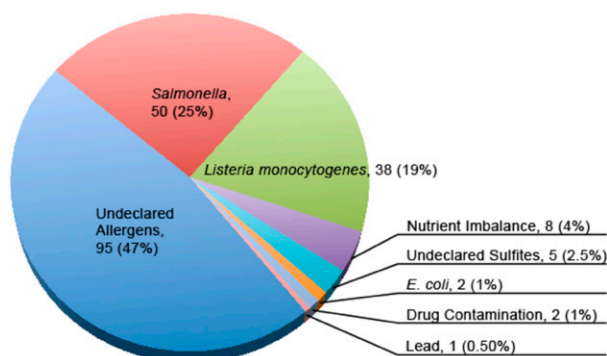


Figure 1. Distribution of entries from the Reportable Food Registry annual report. The entries pictured are from year 5 (September 8, 2013–September 7, 2014; 13).

chemical (including radiological), biological, and physical hazards. Allergens are considered a type of chemical hazard. The hazard analysis must include an evaluation of the severity of illness or injury if the hazard were to occur and the probability injury or illness will occur in the absence of control. Some elements the hazard analysis must consider include the formulation of the food; condition, function, and design of the facility and equipment (i.e., sanitary design of the equipment and the facility); raw materials and processing aids; manufacturing/processing procedures; packaging and labeling activities; and sanitation, including employee hygiene.

When conducting a hazard analysis, consideration also must be given to the examination of not only the food being analyzed, but also the allergen profile of the other foods manufactured in the same facility, other allergens managed by suppliers, and how these foods can contribute to the overall allergen risk profile. What is the likelihood of allergen cross-contact with multiple allergens in a facility? Are the production lines shared or are there separate lines for food containing a specific allergen? (The final rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food does not require separate lines for facilities that process allergens. Instead, this risk—shared lines between allergen-containing foods and nonallergen-containing foods—needs to be assessed in a facility's hazard analysis.) What is the proximity of different lines? What is the material flow and traffic pattern throughout the facility? Is it a well-constructed facility or are sanitary operations difficult to maintain due to a challenging facility design? In addition, other factors the cross-functional food safety team might need to consider are the number of changeovers involving allergens, use of shared equipment or dedicated lines, labels preprinted from label supplier(s) versus labels printed on-demand in production, visual similarity of labels for allergen-containing versus nonallergen-containing products, and whether labeling equipment is shared between allergen and nonallergen lines.

Thorough examination of the data analyzed by a facility's food safety team during the process of conducting a hazard analysis can lead to determining the need to implement one or more allergen-preventive controls to reduce or eliminate the risk of allergen cross-contact or mislabeled product [i.e., misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act]. (In 21 CFR 117.3, "preventive controls" means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe

manufacturing, processing, packing, or holding of food would use to significantly minimize or prevent the hazard.) During the hazard analysis process, it might be determined that certain allergen controls cannot be managed as a cGMP, but instead need to be managed to the rigor of a preventive control. Examples of allergen-preventive controls could include allergenic ingredient management, label management procedures upon receipt, rework management, label reconciliation process, barcode scanners in packaging, and sanitation of shared equipment (possibly a sanitation preventive control). [21 CFR 117.135(c)(2) states, "food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes used for (1) ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and (2) labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act."]

So, how does industry begin to reduce the number of recalls for undeclared allergens? First and foremost, food manufacturers need to critically review their food safety system as it relates to allergens: both prevention of allergen cross-contact and proper labeling. Many food manufacturers will find steps in their process in which allergen cross-contact cannot be managed solely through cGMPs. Instead, many manufacturers will find, through their hazard analysis, aspects of their process in which allergens are a reasonably foreseeable hazard that require implementation of one or more preventive controls with the required management components, which include monitoring, verification, corrections, corrective actions, and records, as appropriate, to either minimize or prevent those hazards. The key is that cGMPs cannot be used to control a reasonably foreseeable hazard. Rather, a hazard, such as undeclared allergens, can only be controlled through the application of one or more preventive controls.

Next, consideration should be given to all aspects of a facility's allergen management program and to which ones have previously had failures or near-misses. This data can be used when assessing the likelihood of occurrence of the hazard during the process of conducting the written hazard analysis. Most allergen-related recalls can be traced back to product in the wrong package. Fundamentally, it is packaging errors and not allergen cross-contact, despite what many in the industry incorrectly believe. This is evident by examining the allergen recalls from 2007 to 2012 (6). Of the allergen recalls in this period with a known root cause, over 60% were caused by failure in label control and not allergen cross-contact, even though many in the industry focus most of their resources on allergen cross-contact prevention.

Finally, manufacturers might want to consider additional measures to mitigate the risk of human error (e.g., employees placing the incorrect labels into the labeler) and further error-proofing a facility's allergen management system. Eliminating the possibility of undeclared allergens through error-proofing, as much as possible, and enhanced engineering controls throughout the manufacturing process should be the desired goal. Detecting an error (e.g., mislabeled product) after it has occurred is too late; the system has already failed, representing an actualized risk if the product leaves the control of the facility. In addition, from a business perspective, there are now substantial costs associated with reworking the product, which include lost productivity, increased waste (e.g., product, labels, and packaging material),

increased usage of utilities, and delays of the product to the marketplace. Over-reliance on the human factor and the visual inspection of the safety of the product is clearly flawed and not working. The cost of reworking product, or worse, the liability of a product recall, along with the intangible cost of eroding consumer confidence and impact to the marketplace, will likely be significantly more than the cost of enhanced engineering controls, barcode scanners, or equipment with enhanced sanitary design. Integration of a prevention-based food safety system is not only integral to protecting the consumer, but is also the cornerstone of FSMA. A prevention-based food safety system also makes good business and financial sense.

Once allergen-preventive controls have been identified through hazard analysis, management components, such as monitoring, verification, corrections, and corrective actions, as appropriate, must be implemented to ensure the effectiveness of the preventive control(s). [21 CFR Part 117.150(c)(1) and 21 CFR Part 117.150(c)(2) are the provisions pertaining to corrections versus corrective actions in the context of sanitation and allergen-preventive controls. When timely action is taken, “corrections” are adequate, and a full corrective action is not required. For sanitation and allergen-preventive controls, the exact nature of the correction depends on the specific situation.] As appropriate, to ensure the effectiveness of the preventive control, records must be maintained for monitoring, corrective actions and corrections, and verification of activities (including record review). These records have to be made available to the FDA within 24 h of verbal request.

For monitoring an allergen-preventive control or any other type of preventive control, the regulation does not require a specific monitoring frequency, but instead the monitoring must be performed at an adequate frequency to ensure the preventive controls are being performed consistently (7). In addition, the facility should determine the monitoring frequency based on the amount of product they are willing to risk should a nonconformance be detected.

Verification activities, as appropriate to the nature of the preventive control and its role in the facility’s food safety system, must be conducted to ensure the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazard (i.e., undeclared allergens; 8). Examples of verification might be an independent check or record review. There has been a common misconception that the FDA requires testing for allergens as a verification activity. Testing of either the finished product or of previously cleaned food contact surfaces for allergens is not required in the final rule for Preventive Controls for Human Food. (Per FDA Response 317, in the preamble to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule, “Testing is not always required. The provision provides flexibility for an establishment to test when appropriate, such as when a facility determines that it is necessary to.”) However, if a firm includes testing as a verification measure in its food safety plan, then the firm should expect that the FDA will review those testing records during a regulatory inspection. Also, a key concept is testing cannot be used to *control* a hazard; hence, testing is not a control measure. If testing is incorporated into a food safety plan, it is a verification measure, and these records are subject to FDA review.

Fundamentally, the facility has the flexibility to determine whether to conduct testing for allergens based on the preventive control (i.e., allergen-preventive control) and, as appropriate to the facility, the food and nature of the preventive control and its role in the facility’s food safety system (9). Also, prior to the firm deciding to test for allergens in either the previously cleaned surface and/or finished product, the firm should ensure it’s has a robust program for holding the product, including any associated rework product, prior to the receipt and review of the results.

In addition, because the FDA never codified a requirement for finished product or surface testing after sanitation for allergens, there is no preferred test method outlined in the regulation. [Per 21 CFR 117.165(b)(2), testing must be scientifically valid. AOAC INTERNATIONAL is an example of one organization that publishes scientifically valid methods of testing. ELISAs are currently the method of choice for the detection of residues of allergic foods that might contaminate other foods. However, prior to selecting a specific test method, a firm needs to consider that food matrix effects, as performance of a test, may vary depending on the matrix being analyzed, in addition to considering inherent variability in the results. For additional information on testing of allergens in food products, *see* information from the Food Allergy Research and Resource Program (FARRP; University of Nebraska-Lincoln, Lincoln, NE).] Instead, the standard in preventive controls for human food for food contact surfaces is “visibly clean.” The FDA explains in the preamble to the Preventive Controls for Human Food that “visibly clean can be a minimum standard that a facility could apply during verification of food allergen controls by visual observation.” (Response 465 in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule.) The first edition of the Food Safety Preventive Controls Alliance curriculum, which is the standardized curriculum recognized by the FDA, states, “if you can see residue on the equipment, the equipment is not clean. This includes the presence of films or protein sheen” (10).

Lastly, there is no requirement in the final rules for validation of sanitation or allergen-preventive controls. According to 21 CFR 117.160(c), “you do not need to validate: (1) the food allergen controls in §117.135(c)(2); (2) the sanitation controls in §117.135(c)(3)” [§117.135(c)(2) refers to food allergen-preventive controls and §117.135(c)(3) refers to sanitation preventive controls.]. This is further articulated in the preamble to the final rule in which the FDA states, “we have acknowledged that it is premature to require validation of food allergen controls” (per FDA Response 429, in the preamble to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule). However, although validation of allergen-cleaning procedures is not a regulatory requirement, it may be useful especially in the following cases: complex equipment is involved, first time a unique allergen is introduced on a production line, or when major formulation changes are made to determine whether the cleaning procedures are still adequate (10).

Reducing the number of undeclared allergen recalls is complicated. The number of recalls for undeclared allergens is a multifaceted problem with challenges from farm to fork. It is only through a complete written hazard analysis, which includes an assessment of all the supply chain risks, and implementation of one or more preventive controls with strong management commitment that we might begin to see a reduction in the number of allergen-related recalls. Furthermore, the topics of allergens

and the risk of undeclared allergens must be embedded into an organization's food safety culture from top management down to the operational level. Food allergen management must be related on a personal level to all the employees throughout the organization so they are intrinsically motivated to own their part in the company's allergen management program.

Conclusions

Recalls for undeclared allergens are a complex issue with numerous factors. The implementation of prevention-based systems with the necessary management components and further error-proofing the systems, along with allergen awareness embedded throughout a company's food safety culture, can likely help reduce the number of recalls for undeclared allergens. As a resource to manufacturers, the Grocery Manufacturers Association (see their allergen manual, *Managing Allergens in Food Processing Establishments*; 11) and FARRP (12) have developed a number of resources to assist in the development of robust allergen management programs. By reducing the number of recalls for undeclared allergens, the food industry will likely increase and maintain consumer confidence and trust of the food-allergic community. This enhanced consumer confidence and trust could eventually open the door for further collaboration with the food-allergic community and, potentially, advance allergen-related policies.

References

- (1) FARE - Food Allergy Research & Education Facts and Statistics, Facts and Statistics, <https://www.foodallergy.org/facts-and-stats> (accessed on August 31, 2017)
- (2) U.S. Food and Drug Administration (2016) Reportable Food Registry for Industry, <https://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>
- (3) Maberry, T. (2017) A Look Back at 2016 Food Recalls, *Food Safety Magazine*, <http://www.foodsafetymagazine.com/enewsletter/a-look-back-at-2016-food-recalls> (accessed on June 19, 2017)
- (4) U.S. Department of Agriculture, Food Safety and Inspection Service (2017) Summary of Recall Cases in Calendar Year 2016, <https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-summaries> (accessed on June 30, 2017)
- (5) U.S. Food and Drug Administration (2017) Food and Drug Administration Food Safety Modernization Act (FSMA), <https://www.fda.gov/food/guidanceregulation/fsma> (accessed on June 16, 2017)
- (6) Gendel, S.M., & Jianmei, Z. (2013) *J. Food Prot.* **76**, 1933–1938, <https://doi.org/10.4315/0362-028X.JFP-13-171>
- (7) U.S. Code of Federal Regulations, (2015) Monitoring, 21 CFR Part 117.145(b)
- (8) ———. (2015) Verification, 21 CFR 117.155(a)
- (9) ———. (2015) Verification of implementation and effectiveness. 21 CFR 117.165(a)
- (10) Food Safety Preventive Controls Alliance (2015) *Food Safety Preventive Controls Alliance course for Preventive Controls for Human Food*, Chap. 10, 1st Ed., pp 10–6–10–7
- (11) GMA - Grocery Manufacturers Association (2010) Featured Publications, GMA Washington, DC. <http://www.gmaonline.org/forms/store/CommercePlusFormPublic/search?action=Feature> (accessed on November 17, 2017)
- (12) University of Nebraska-Lincoln (2017) Food Allergy Research and Resource Program, <http://farrp.unl.edu> (accessed on November 17, 2017)
- (13) U.S. Food and Drug Administration (2016) The Reportable Food Registry: A Five Year Overview of Targeting Inspection Resources and Identifying Patterns of Adulteration: September 8, 2009–September 7, 2014, Reportable Food Registry Fifth Annual Report, <https://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM502117.pdf> (accessed on June 30, 2017)