

The FDA, ConAgra, Coca-Cola Share Food Allergen Control Strategies

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Recalls of foods that contain undeclared allergens are rising noticeably. Food allergens like milk, wheat and nuts are being considered for a list of high-risk foods that the Food and Drug Administration (FDA) is compiling for the Food Safety Modernization Act (FSMA). Experts recommend food manufacturers position themselves against allergen-related risk by coordinating company policies and procedures.

Allergen practices fall under the proposed FSMA rule known as Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. Published as a proposal in January 2013, the rule is under FDA revision. It's expected to be reintroduced and opened for more comment by early summer 2014. To clarify allergen-related policy and practices, industry experts from the FDA, Johns Hopkins University, ConAgra and the Coca-Cola Co. presented in a Food Safety Summit workshop, "Food Allergen Control Update," April 10 at the Baltimore Convention Center.

"The number of recalls caused by undeclared allergens over the last six years has generally been going up. It's clear that there's an increasing number," said Steven Gendel, food allergen coordinator, FDA. According to Reportable Food Registry reports, undeclared allergens are the second-leading cause of food recalls at 34 percent, surpassed only by salmonella's 36 percent.

However, the recalls are easily avoidable.

"It's very clear that those recalls are caused by very simple issues: not paying attention to details, not thinking about the problem on an ongoing basis," Gendel said.

Under FSMA rules, allergens are identified as elements that must be considered in hazard identification and sanitation controls, he said. After the rule is finalized, the FDA will issue a guidance document. In the meantime, food manufacturers must take stock of their responsibility to protect consumers with allergies.

"[Consumers'] only risk management option is avoidance. Before they can do that, they need to be able to trust labels — that whatever is not intended to be there is not actually there," Gendel said.

The recent influx food allergy diagnoses of has upped the ante on research regarding reactions to these foods.

Corrinne Keet, assistant professor of pediatrics at Johns Hopkins School of Medicine, defined allergies as an immunologic response to a food, as opposed to an intolerance. With allergies, very small amounts of the allergen may cause reactions, which can be severe and life threatening.

“Right now the only real treatment is to carefully avoid the allergen and treat accidental exposures as they happen,” Keet said.

At least 11 million Americans suffer from allergies, Keet said. Data show that up to \$25 billion is lost annually in the United States due to reactions to food allergens. This sum includes direct medical costs and loss of pay from missing work for treatment. Young children suffer from food allergies most often — as many as 5-10 percent of kids. Three to 4 percent of adolescents and adults suffer from food allergies. The prevalence of allergies appears to be rising, she said. The most common allergens, by prevalence, are milk, eggs, peanuts, tree nuts, fish and shellfish. Sesame is increasingly being recognized as a common allergen, Keet said.

Food manufacturing experts are growing hyper-vigilant of allergens from their facilities and throughout their corporate structure.

ConAgra’s Allergen Control Strategy



Steven Gendel

In a food processing environment, allergens can be strategically managed, said Leslie Skybo, manager of quality, frozen foods platform for ConAgra Foods. All levels of the organization, from corporate to floor employees, must understand the importance of food allergen control. Receiving, storage, scheduling and sanitation

are elements of manufacturing where allergenic ingredients must be sequestered. Plants need specific policies that comply with regulations and support HACCP practices, she said.

At the receiving stage, Skybo recommends containing allergens with a sampling plan for incoming materials to verify that suppliers deliver exactly what they contracted to send. Incoming and outgoing materials should also be identified regarding allergenic contents, she said.

“If you are running a lot of products and you know that mispack is one of your risks, you might want to store those separately or label what’s in those containers,” Skybo said. Pallet labels can easily be marked with colors that symbolize specific allergens, she said, such as yellow for peanuts.

In terms of scheduling, non-allergen products should be produced first.

“Line segregation, for many of us, is not possible,” Skybo said.

That’s where sanitation and testing come in. Good sanitation practices include flushing lines after running a recipe with allergenic ingredients, Skybo said. A complete sanitation cycle should be run and then validated at changeover. During changeovers, the line must be cleared. An employee should then walk the line to verify that all packaging and food material are cleaned from the line. For validation, she recommended a visual inspection, swabbing of parts of the line, and following up with ATP and allergen-specific testing, followed by product testing.

“Depending on the form of the allergen, testing may not pick up its presence,” Skybo said.

Employees can help avoid product contamination by swapping out hairnets and other articles of clothing when the line is changed over, Skybo said. A specific color of utensils should be assigned to each allergen, alerting employees to seafood, for example, with the color purple.

“It really raises the awareness around all of the associates at the facility about allergens,” Skybo said.

After production, packaging and label verifications are another line of defense to keep allergens where they belong. She advised checking for correct packaging material and check labels during the product run. A master of each label should be filed for daily comparison to a new label from the line. Labels for new products should be reviewed and scrutinized by an internal third party. Skybo noted that sale samples and seasonal items are just as important as year-round products. Additionally, obsolete packaging should be removed from the facility to ensure it’s not confused with other packaging, which could result in mislabeling.

“It’s all about continuous improvement,” Skybo said.

Coca-Cola Co.’s Global Ingredient Management



Craig Llewellyn

The ingredients in most manufactured beverages, excluding dairy, typically make them immune from allergen content concerns. But the trend toward protein in drinks is changing the game for companies like Coca-Cola, said Craig Llewellyn, director of ingredient safety, global scientific and regulatory affairs, for the company. The Coca-Cola Company is present in 207 countries and estimates that 1.9 billion servings of their products are consumed daily. Many of those countries' regulatory schemes are not in harmony. In addition, the allergen portfolio of each country may vary.

"We take [food safety] very seriously because our risk is huge," Llewellyn said.

Llewellyn stressed that allergen contamination risks occur throughout the lifetime of a product. Understanding this risk must be an element of every stage of a product's life cycle, from research and development, engineering and system design, raw materials, labeling and packaging, production scheduling/changeovers, rework and sanitation. In the production facility, manufacturers can reduce cross-contamination with allergens by simply limiting the use of allergenic ingredients, he said. Once the product leaves the facility, allergen labeling and advisory statements must be appropriate and consistent.

"This is the way we communicate with our customers," Llewellyn said.

The recent trend of including of solids as beverage ingredients creates challenges to the standard changeover and sanitization procedures for fluid products, he said. In addition, product offerings in larger sizes allow for an increased concentration of

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allergens, which could lead to more of a risk for allergen exposure in beverages than, for instance, in confectionary products, he said.

Possible errors and oversights often occur during the cleaning of shared equipment, rework, switching ingredients, formulation, labeling and packaging. Suppliers may fail to disclose allergens.

“The biggest risk of all is human error,” Llewellyn said.

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