

the ALLERGEN piece

Allergen control requires well-designed equipment and facilities, processing and sanitation strategies, and buy-in from the entire team.

by M. Hikmet Boyacioglu, PhD

Food allergy is the condition caused by a reaction to naturally occurring protein in a food or a food ingredients. In the US, the eight major allergens are milk, eggs, fish, crustacean shellfish (shrimp, crab, lobster), peanut, soybean, tree nuts (almond, walnut, cashew, etc.) and wheat.

While FSMA is transforming food production to create a safer supply, allergens still pose a significant health concern in the food industry, which has seen little reduction in allergen recalls since the introduction of FSMA, according to Gina Reo, president of quality assurance strategies and advisor to the American Bakers Association. The US Food & Drug Administration (FDA)'s Food CGMP Modernization Report outlined six allergen control components with cleaning procedure validation of food-contact equipment particularly concerning to investigators on plant visits. Further, bakery customers and consumers are driving manufacturing vigilance to provide clean, accurate labels.

According to Allie Sequera-Denyko, food safety professional, AIB International, not long ago allergen awareness and control were not as widely discussed in the US food industry or around the globe. "However, over the last decade, the Reportable Food Registry (RFR) has uncovered a startling outcome in relation to allergens," she explained. According RFR's report "A Five-Year Overview of Targeting Inspection Resources and Identifying Patterns of Adulteration: Sept. 8, 2009,

As the population of people affected by allergens continues to rise, the food industry works diligently to respond and make food safer for those affected.

©Yulia Furman - stock.adobe.com



Implementing a FSMA-compliant sanitation program and allergen control plan will only be successful with adequate training of employees.

to Sept. 7, 2014,” undeclared allergens increased from 30 to 47% with baking- and snack-related commodities accounting for a large majority.

“Allergens also accounted for the largest amount of recalls,” Ms. Sequera-Denyko said. “With this startling information, progress to avoid such outcomes is vital, and it starts at our plants’ frontlines.”

In a globalized food supply, allergens can fall through the cracks. “Verification of ingredients from international sources can be challenging,” said Richard Goodman, PhD, research professor, University of Nebraska Food Allergy Research and Resource Program (FARRP). “In developing or modifying products, companies must consider allergenic sources including purified or concentrated proteins.”

Sanitation strategies

Bakers and suppliers must work together to meet consumer demand for allergen-free food. “Accomplishing

and meeting consumer expectations starts with teamwork at the plant level and understanding allergen assessment risks, processes and associated sanitation procedures. It is a team effort,” said Brandon Smith, quality assurance manager, The Bakery Cos., Nashville.

When evaluating raw ingredients and their risk, baking companies can ask suppliers these questions: What ingredients are being used? What’s the baker’s percent used? How will allergens be transferred during production? What’s the impact of tool cross-contamination? And what current tests and validation steps are available to the industry?

High-priority cross-contamination risk sites must be tested with a scientifically proven method for the presence of allergens. Validation tests performed by swabbing multiple risk areas throughout the process will ensure no allergen contamination exists.

Once risks of cross-contamination are evaluated,

Routine swabs of equipment after sanitation cycles ensure that production lines are truly clear of any allergen residue.
Peter Valli





Allergen control often starts in the ingredient receiving and storage area. Allergen ingredients should be stored in an isolated and controlled way to prevent cross-contamination.

Peter Valli

Ms. Sequera-Denyko said there are several tips for controlling allergens. She recommended using simple tools such as a flashlight, scrapers and drain lifters to visually assess cleaning efficacy. In addition, operators should not just rely on eye-level inspection of lines but also bend down and climb up them, which can often reveal areas that are missed in the sanitation process.

Facilities with numerous allergens, or those that don't use allergen swabbing, can use protein tests. Optimized scheduling of allergen and non-allergen runs can reduce sanitation burdens. Or if common allergens are used in various product runs, operators can focus on those allergens that are unique or harder to remove. Dedicated equipment and tools for allergen runs vs. non-allergen runs engineer out the added allergen risk.

"Alongside FSMA, product recall due to allergen cross contamination is a major driver for plants to segregate ingredients and equipment. Dust control, sorting equipment, receiving/storing and scanners are some of the options that can keep allergens from being passed on to the consumer," said Rowdy Brixey, president and CEO, Brixey Engineering Strategies & Training.

The role of sanitary design

Proper design of the plant or equipment is a prerequisite for an effective HACCP program. "Hygiene, hygienic design and the subsequent monitoring of their effectiveness are of critical importance in establishing and maintaining a safe food supply as well as contributing to the overall success of a food-handling facility," said Matilda Freund, PhD, senior

director, global quality, Mondelez International.

Potential health hazards and good manufacturing practices (GMPs) should all be considered at the design stage of both plant and equipment to eliminate cross-contamination and make cleaning easier. "The design and construction of allergen production lines has changed rapidly in the last few years," said Stuart Jernigan, director of preconstruction for A M King. According to Mr. Jernigan, design considerations have evolved from simply sanitizing a line that contained allergens to total separation with physical and environmental barriers. Allergen raw materials are often stored in separate rooms, employee smock up and wash areas are segregated, and physical walls are now constructed around processing lines dedicated to the production of products containing allergens.

Air pressure and quality is monitored and controlled with separate air handling systems. Process waste streams are now segregated from other processes within the plant to prevent cross contamination in case of a blockage or leak. Security is integrated into the allergen area to prevent unauthorized employee access. In many instances, different color smocks and color schemes for flooring are used to clearly identify allergens. "The combination of these steps is intended to clearly and measurably separate the entire allergen area with regard to production and sanitation," Mr. Jernigan noted.

For equipment, stainless steel designs for easier cleaning can have an impact on preventing cross-contamination. Indentations or dead areas where dirt may collect are avoided. Rounded supports and diagonal planes all



G&I PRODUCTS
GLAZES | ICINGS | AND MORE

Visit Our Booth!
IBIE'19 - Las Vegas
Booth 713

GLAZES

High Gloss, Specialty

ICINGS

Donut | Roll | Pastry | Specialty

CAKE ICINGS

Real Buttercream | Buttercrème Style

FILLINGS

Cream | Crème | Fruit

TOPPINGS, SMEARS & SPREADS

PURITY CLEAN LABEL

Preservative Free | Natural Flavors & Colors

1-480-558-5155

sales@gandiproductions.com

gandiproductions.com



FOOD SAFETY SERIES

“Production and sanitation personnel must partner to provide the safest production run schedule to minimize impact to all products.”

Brandon Smith, The Bakery Cos.

keep excess allergens from accumulating and hiding from sanitation teams. Hygiene-critical components that need to be cleaned separately are often easily removed without tools.

Best practices during processing

Once a baking facility is designed for maximum allergen security and sanitary designed equipment is installed, cleaning prevents cross-contamination between production runs. “Production and sanitation personnel must partner to provide the safest production run schedule to minimize impact to all products,” Mr. Smith said. “The effective cleaning of food-contact surfaces must routinely occur to remove the presence of an allergen on all product contact areas. Production’s obligation is to maintain clean environmental surfaces that are allergen-free and to adhere to all allergen controls and good manufacturing practices.” He emphasized that sanitation plans provide the structural procedures to verify proper allergen cleaning.

Where dry cleaning is common, bakers and snack producers should establish validated cleaning protocols and verify them frequently. This most likely will include disassembly of equipment, clean-out-of-place practices and hand-cleaning with dedicated allergen-free cleaning utensils. But success comes down to the people.

“If there’s one thing I learned very early in my bakery career is that it doesn’t cost a lot of money to be clean,” Mr. Brixey said. Operator ownership and attention to maintenance practices can do more to control sanitation risks than anything else, he explained.

“Sanitation is everyone’s responsibility, not just the sanitation department,” Mr. Brixey continued. “Management must instill these behaviors and drive ex-

pectations. Regardless of the age of your equipment, these actions will be the key to your success in many areas. You get what you allow. Don’t expect what you don’t inspect.”

To ensure sufficient removal of allergenic material from equipment, validation with scientifically proven, allergen-specific tests are often required under most auditing schemes. According to Mr. Brixey, a machine can appear to be clean and still the surface tests positive for an allergen. Allergen test kits can keep the possible contamination risk to a minimum. “A solid plan, training, multiple checks and concern for the consumer can go a long way to eliminate risk,” he said. Fortunately, test kit manufacturers have developed simple, inexpensive test strips that can be used for validation and verification of cleaning practices.

Planning ahead

Dr. Goodman advised food companies to develop an allergen control plan (ACP) and employee training focusing on acquisition, storage, handling, processing, packaging and identification of allergenic foods and ingredients. All ingredient suppliers should also have an ACP and understand allergen controls.

Scheduling manufacturing non-allergenic and gluten-free foods first in complex factory lines reduces risks and minimizes changeover following sanitation. Packaging and appropriate labels are frequently cited for deficiencies. Standard operating procedures and protocols should be clearly written and easy to follow and understand. Employee training should be ongoing and involve all levels of company personnel. Other considerations include the physical form (liquid or solid) of allergens, concentrations, type of food contact surfaces, equipment

FOOD SAFETY SERIES



Employees must be properly trained in a company's allergen control plan in order for it to be implemented effectively to protect consumers.

Peter Valli

design and age as well as the most effective type of cleaning methods (wet or dry).

"Several tools are available to food manufacturers to aid in and customize effective sanitation strategies," said Jamie Kabourek, dietician and resource manager, FARRP. "These include visual inspection, ATP swabs, total protein, PCR-based methods or immunochemical testing."

The allergen mitigation program or ACP should be a part of the company's larger FSMA plan. "Robust plans are composed of matrix checks within one's supply chain, from ingredients, cross-contact points, hazard characterization and finally control measures covering sanitation programs," Ms. Reo said. Controls may include production scheduling, dedicated equipment, color coding, trafficking, solid barriers and, perhaps most importantly, cleaning.

Sanitation programs must include documented monitoring, verification and, above all, validation for FSMA preventive controls. Such validation includes qualitative ongoing assessments performed each cleaning, periodic qualitative, pre-defined cleaning assessments every two to three years, and a quantitative cleaning cross-contact assessment study of three sample sets, according to Ms. Reo.

"Validation should focus on risk-based sampling to detect allergen protein or contaminant presence. Review the possible distribution of targeted allergen," she said. "Spot-check methods are not sufficient, and accredited laboratory testing is recommended."

Training and sanitation services

Implementing a FSMA-compliant sanitation program and ACP will only be successful with adequate training of employees. "The goal of any sanitation program should be to provide a clean manufacturing operation capable of producing wholesome and safe products," said John Traylor, John A. Troiler, Inc. "The program should provide guidance and training for employees in good

"Allergens also accounted for the largest amount of recalls. With this startling information, progress to avoid such outcomes is vital, and it starts at our plants' frontline."

Allie Sequera-Denyko, AIB International

sanitary practices and should be able to identify process stages that are pivotal in producing acceptable products. Last, the program should keep management informed of the sanitary condition of the plant and its workers."

Recognizing this need, FDA staggered compliance dates according to the size of the business to give the food industry time to develop plans and train employees. "While members of the food industry are ultimately responsible for getting the training, they need to comply with the FSMA rules, the FDA recognizes the importance of its role in facilitating that training," the agency said in a statement. "For the agency, this means joining with public and private partners in state, federal, tribal and international governments, industry, and academia in the development and delivery of training."

AIB International contributes sanitation services throughout the supply chain. "We're focused on providing unparalleled service and food safety expertise, so companies can confidently focus on growth," said Jeff Wilson, vice-president of operations Europe, Asia, and Africa, AIB International. "To support businesses and implement sanitation best practices, AIB International provides consolidated standards, GMP inspections and consulting, temporary sanitarian placements and online and in-person sanitation training.

"Our in-person GMP workshop is the ideal place to start for individual's new sanitation issues and is scheduled several times a year" he said. The right actions along the food supply chain, from farmers to consumers, as well as good governance and regulations, are essential to food safety."

Food safety contributes to food security, human health, economic prosperity, agriculture, market access, tourism and sustainable development. ●

Editor's Note: This is the final installment of a four-part food safety series. The three previous installments can be found in the May, June and July issues of Baking & Snack.