Facility Design for Allergen Control
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Recent statistics regarding the increase in food allergies for Americans point to the need for greater scrutiny of the processes and equipment used to make foods that contain allergens. Consumers that are allergic to certain foods must avoid those allergens to which they experience reactions – potentially deadly ones – and thus must be able to rely on the accuracy of the packaging labels provided by the food manufacturers.

One of the greatest risks to consumers is exposure to allergens resulting from the inadvertent contamination of products during handling, storing, and processing. The regulations and standards regarding allergen control in food manufacture designate food allergens, mandate the declaration of food allergens, and require companies to have programs in place to manage food allergens. However, they do not give clear direction for facility design and processing that will aid in reducing the risk of allergen contamination.

As regulatory focus on allergens has led to a dramatic increase in allergen-related recalls, food manufacturers are focusing more on understanding and complying with regulatory requirements for facility design: Proper facility design and processing practices can help reduce the risk of allergen contamination. In this paper, we will examine the requirements and guidance given by the U.S. Food and Drug Administration (US FDA), the U.S. Department of Agriculture (USDA), and the American Institute of Baking (AIB). Additionally, some design and manufacturing recommendations are provided for handling and processing allergenic material in GMP facilities.

Regulatory Requirements

Requirements addressing food allergens were created by the FDA in the Food Allergen Labeling Consumer Protection Act of 2006 (FALCPA) and the Food Safety Modernization Act of 2011 (FSMA).

- **FALCPA.** Allergens are directly addressed in the FALCPA. These requirements designate food allergens of greatest public health concern and mandate the declaration of these major food allergens with consideration of format, naming, and inclusion of major and minor ingredients. As noted in the FALCPA, allergens of greatest health concern in the U.S. are milk, eggs, peanut, soy, fish, shellfish, wheat and tree nuts. When naming these allergens, the FALCPA requires the use of the food source’s “common” name. For example, naming “milk” when “casein” is the actual ingredient. This declaration is also required for flavorings, colorings and incidental additives that incorporate major food allergens. FALCPA has significantly increased the number of recalls due to allergens, causing manufacturers to scrutinize how they are addressing allergens.

- **FDA/FSMA.** Under the FDA, FSMA revised several provisions ([CFR Part 117](https://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol-3/content-detail.html)) that address allergen cross-contact, make it clear that Current Good Manufacturing Practices (cGMPs) require protection against such contact, and ensure that they continue to address health concerns related to allergens. Areas covered include cleanliness, plant construction and design, general maintenance procedures, and the sanitation of food contact surfaces.

Per the FSMA rules, companies must have a preventative controls qualified individual in place to oversee procedure development and implementation, as well as validation of the procedures. The rule requires that facilities that work with major food allergens shall develop and implement food allergen controls, which include:

- Providing protection against cross-contact during storage, handling and use.
- Labeling of finished food and ensuring no misbranding occurs.
- Instituting sanitation controls to prevent contamination and the cross-contact of food products, including developing procedures to ensure the cleanliness of food contact surfaces such as the cleaning steps required, type of chemicals to be used and which types of tools will be used to clean.
- Creating procedures designed to prevent allergen cross-contact and cross-contamination from unsanitary objects and personnel to food, packaging materials and product contact surfaces, as well as from raw to ready-to-eat product.
These directives, which apply to all sites and products under FDA jurisdiction (but not to USDA regulated products), are now required. The final rule was published in September 2015 and most businesses were expected to be compliant by mid-September 2016, with exceptions for smaller companies.

Compliance Guidelines

The Food Safety and Inspection Services (FSIS), a division of the USDA, addresses the use and labeling of “Ingredients of Public Health Concern.” This includes foods that can produce both immunological and non-immunological reactions. As such, FSIS encourages the use of allergen statements, consistent with FALCPA and other statements, which highlight the presence or absence of ingredients of public health concern. All ingredients must be declared by regulation.

FSIS also addresses policy on rework to prevent mis-branding of foods, prescribes in-plant controls for ingredients that can lead to food sensitivities, and establishes responsibilities for food manufacturers. Through this, only “like” products are permitted as rework and all ingredients must be declared, although they may be listed as “minor” if they are less than 2% of the formulation.

Industry Standards

The AIB, Global Food Safety Initiative (GFSI) and The Food Allergy Research and Resource Program (FARRP) are three industry-based organizations that have recently taken allergens into consideration within their recommended standards and practices.

• AIB. The AIB provides industry standards regarding best practices for allergen labeling, cleaning validation, and cross-contamination prevention. Confirmation must be performed to ascertain that the correct label is on the line for rolls of printed film at both the beginning and end of the roll. Allergen cleaning validation must be completed as well, either by swabbing the cleaned surface after cleaning (either with chemicals or by purging the line with an ingredient), or taking a sample of the product run immediately after the line has been cleaned.

To prevent cross-contamination, the AIB indicates that for formulas which did not previously contain allergens but now do, manufacturers must dispose of, or render useless, old packaging and labels that previously applied. In addition, manufacturers should take into account the airborne nature of powdered allergenic materials, and consider the potential impacts of those materials on other lines within the facility.

• GFSI. GFSI implicates allergens in the Technical Specification ISO 22002-1 (Part 1: Food Manufacturing), the Safe Quality Food (SQF) Institute code, and the International Featured Standards (IFS). The requirements include managing allergens to prevent cross-contact, including protecting products through cleaning and/or product sequencing, as well as adhering to policies regarding traceability and handling rework material with allergens. For example, the IFS asks manufacturers to identify the relationship of product lots to raw material batches as well as the relationship of final products and their labels.

• FARRP. A collaborative effort between the University of Nebraska and over 80 industry-related member companies, FARRP is designed to create and deliver reliable information on allergenic foods for the food industry. In cooperation with the Food Allergy Research and Education (FARE), FARRP developed recommendations to food processors for creating their own allergen control plans to help prevent allergenic food and ingredients from contaminating products. Written within the plans are guidelines that mandate the storage, handling, processing, packaging, and identification of allergenic foods and ingredients. These guidelines must be enforced by the company, and the plans themselves must be updated every time there is a change in the product or process.

Recommendations

In general, there are avoidable allergens and unavoidable allergens to consider when seeking to prevent cross-contamination. Facility layout and practices should be designed to minimize avoidable allergens, and package labeling should reflect this. Based on Hixson’s experience, and taking into account the regulations and guidelines from the standards and industry-based organizations, Hixson has the following recommendations pertaining to allergens:
• **Allergen production and processing.** The strategy should be to minimize allergen exposure of locations, material movement and transfers, processes, equipment, and personnel handling and operating these processes. Steps to take in order of priority include:
  1. Dedicate facilities within your organization that handle or process allergens.
  2. If dedicated facilities are not possible, segregate production lines and personnel into dedicated rooms with dedicated personnel and dedicated HVAC systems where possible.
  3. If dedicated rooms are not possible, design material and product flow to limit exposure within facilities by producing allergen-containing product on dedicated production lines.
     ○ Provide control measures to prevent cross-contamination between lines producing different allergens or allergen and non-allergen products.
     ○ Eliminate crossovers of open production lines, e.g. conveyor belts.
     ○ Use shielding, partitions, covers, and catch pans to protect exposed unpacked product while being staged or in production.
  4. If dedicated production lines are not possible, a robust production scheduling matrix strategy and sanitation regime can be beneficial to minimizing cross-contamination.
     ○ Allergens should be scheduled during the end of a product campaign.
     ○ Start with products with the fewest number of allergens and/or the smallest allergen load.
     ○ Schedule products in order of risk levels from lowest-to-highest incident rate. Current U.S. research shows the order of allergens posing the lowest-to-highest incident rate to be soy, shellfish, wheat, eggs, milk, seafood, tree nuts, peanuts.
     ○ Only “like” product is permitted as rework. Schedule production of materials containing allergens.

On production lines producing or handling allergens:
- Design product flow to limit equipment exposure by using the minimum number of processing steps, adding allergens at the last possible process step.
- Use dedicated tools and hoses.
- Require a change of work wear when moving from an allergen to a non-allergen area, particularly where dust is a concern.

When introducing allergenic ingredients into the product stream:
- Use adequate dust control/dust collection to prevent spreading powdered forms of allergens.
- Ensure HVAC systems cannot spread allergen-contaminated dust to other areas in the facility.

• **Allergic ingredient receiving.** The strategy to receive and store allergen ingredients is to isolate, segregate, and contain allergens to prevent inadvertent contamination of non-allergic ingredients. Facilities should:
  - Provide staging areas for the inspection and preparation of all incoming allergens within receiving areas which handle allergenic ingredients.
  - Label pallets holding allergens immediately upon arrival to alert facility personnel of the allergen and accommodate labeling prior to storage.
  - Reject any pallets with torn packages to reduce cross-contamination through spillage. In addition, manufacturers should consider stretch-wrapping pallets to “seal” each unit and prevent spillage during transit if containers on pallets could be subject to tears and spills.

• **Allergenic ingredient and product handling and storage.** Allergen types should be segregated from each other and from non-allergens as much as possible using the following prioritization:
  - Store non-allergens and different types of allergens in separate rooms or spaces if possible.
  - Separate racks or bays. Ideally store allergens in dedicated bays allocated for each type of allergen with all allergens in a separate area from non-allergens.
  - If it is necessary to store allergens with non-allergens, never stack allergens on top of non-allergens.
  - Tanks and silos containing product with allergens should be marked to indicate the presence of allergens.
  - Material movement should always follow the same path to the processing equipment and should be the shortest distance with the least number of cross-overs with non-allergen movement paths.

• **Allergen sanitation.** The following are sanitation recommendations for allergen processing equipment:
  - To sanitize lines, isolated Clean-in-Place (CIP) systems and rinse water is preferred.
  - Per the SQF, three product flushes may be required to assure removal of allergens.
  - For dry cleaning, the use of vacuum cleaning rather than compressed air is strongly recommended.
“Pushes” with non-allergens such as salt, flour or starch can be used to purge allergenic material.
- Use dedicated tools and hoses for cleaning equipment and surfaces with which allergens come into contact.
- Test the CIP rinse water, equipment surfaces, environmental surfaces, and in-process product to verify allergens are removed. The Enzyme-Linked ImmunoSorbent Assay (ELISA) has been used to test for allergens effectively.

Per the FDA, “…because adhering to GMP is essential for effective reduction of adverse reactions,” it is recommended that manufacturers follow the GMP principles of sanitary design in production design, equipment selection and installation, such that:
• Equipment is cleanable to a microbiological level.
• Equipment is completely accessible for inspection, maintenance and cleaning / sanitation.
• Equipment is constructed to prevent pooling of product or liquid collection on any surface.
• Any hollow areas in equipment are hermetically sealed or eliminated where possible.
• No niches exist where bacteria can grow.
• Maintenance enclosures are of hygienic design.
• Cleaning and sanitizing protocols are validated.

Facility Design to Prevent Allergen Risk

The purpose of this paper was to present regulation, industry standards, and recommendations for facility design in regards to managing allergens. In general, while the USDA and FDA do not provide specific construction requirements, these agencies do require that companies put plans and programs into place that manage allergens to prevent unwanted contamination and risk to consumers.

References

www.foodallergy.org/facts-and-stats

FDA Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)


FARRP & University of Nebraska Lincoln, “Components of an Effective Allergen Control Plan”

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