

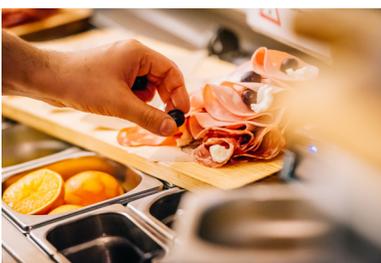


Identifying the Risks for Allergen Cross-contamination in Production and Shipping

As we highlighted in our previous whitepaper, food safety issues may arise at any stage in food handling, from food production to consumption. This includes the farm, the processing facility, the retailer, and in consumers' hands. It occurs when a contaminant enters the food process. This is especially true when it comes to allergens, as approximately 1-2% of adults and 5% of children in western countries have a true food allergy. This is a major concern for food business operators and processors. They must have a robust allergen risk management plan designed to ensure what is in the product matches what is on the label. This article will address how to prevent and detect allergen cross-contamination in production and shipping.

Where do allergens occur/appear?

Allergens can naturally occur in ingredients or products, posing a risk of cross-contaminating other components and products in any given facility. However, an allergen can be introduced inadvertently through other means, including inappropriate hygiene practices, incorrect formulations, changes to raw material, suppliers, or product scheduling, or improper contact with the product either during processing or after. No matter the source, it is vital to establish an allergen control plan as part of the food safety management process.



Both the USDA and FDA require that facilities manage allergens and prevent cross-contact and undeclared allergen issues. Both agencies have issued regulations and mandatory programs to assist in preventing this significant food safety risk. USDA has created several guidance documents to help prevent this hazard. Additionally, USDA asks facilities to address allergen control in HACCP food safety plans. FDA also has created numerous guidance documents for allergen control in food facilities. Per the newest Food Safety Modernization Act regulations, facilities must address allergen control in their food safety plans.

The first thing to do is establish allergen control points in the facility and throughout the manufacturing process. Areas to consider include:

- Ingredient sourcing
- Raw material storage
- Plant traffic flow
- Production lines - scheduling and segregation
- Food contact surfaces
- Non-food contact surfaces
- Sampling and testing
- Packaging labels
- Segregation during transport, storage, and handling

Each of these points should be evaluated for the risk of allergen introduction and/or risk of cross-contamination. Management of each of these points requires thorough cleaning and testing as part of GMP requirements and a strong HACCP plan. Since each point is controlled by these practices, they are considered critical control points (CCPs) as they are areas where proper control can reduce and eliminate any risk or hazard. Therefore, they require a proper validation, monitoring, and verification schedule (*see Prevention of allergen contamination section for more details*).



There are a number of specific ways to help eliminate the sources of allergen contamination. These include:

- **Supplier management**

Facilities should request an allergen statement from their suppliers, indicating what allergens are handled in the supplier's facility as well as if allergens are present in any materials being supplied by them. This includes a formal audit of the supplier on a regular basis – annually, or more often if an issue is found.

- **Raw material receiving & testing**

Tied very closely to supplier management, it is the facility's responsibility to test raw materials to ensure they meet minimum specifications and contain minimal, if any, allergens. In addition, any allergen-containing material must be segregated and labeled properly to minimize the risk of cross-contamination. This can include segregation into distinct warehouse areas, proper labeling, and written product identification to ensure anyone using this material understands that allergens are present, which could impact other products produced within the facility.

- **Color-coding systems**

Colored labeling can be used to indicate the presence of an allergen and warn the user not to use the material in specific production areas, on specific lines, or in specific pre-process formulations. Color coding can also indicate where an item should be stored– from segregation to something as simple as not storing on upper shelves due to the risk of spilling onto lower surfaces holding non-allergenic ingredients. Color coding can also be used for bulk tanks, as they are often difficult to decontaminate once an allergen has been stored in them and can be dedicated to storing the same allergen in future bulk holdings.

- **Dedicated lines or segregation and sequencing**

Since manufacturing companies often handle multiple products, some containing allergens, it is vital to have dedicated areas for manufacturing allergen-containing products or a scheduling plan that involves separating the allergen from other products and a validated sanitation plan. Separation is ideal, especially in facilities where wet cleaning is difficult. Segregation can also include heavy separation panels to prevent dust cross-over from a dedicated line to non-allergen lines. If dedicated or separated lines are not feasible, then allergenic products need to adhere to a rigid schedule, being manufactured on shared equipment after non-allergenic products. However, this requires thorough allergen cleanup – so it is best to run the allergenic materials at the end of a shift or just before a major cleanup in the facility.

- **Equipment and facility design**

First, it is best to introduce the allergen at the latest possible stage in processing to limit the amount of equipment subjected to allergen cleanup. Second, if in-process holding totes are used, then they must be clearly identified and dedicated to the allergen or effectively cleans between uses. Third, when introducing new products or processing into facilities, there must be a clear safety plan, including design flow and ways to reduce the risk of allergen cross-contamination.

- **Segregation during transport, storage, and handling**

Storage and distribution can introduce cross-contamination risks but not at the same level as the material is packaged, introducing a barrier to contamination. However, if the material spills during loading or unloading, if unclean containers or trucks are used to transport food, or if worker hygiene is poor, cross-contamination can occur. Therefore, it is vital to ensure transport occurs in clean tankers

or vehicles and care is taken when loading and unloading (and even segregating material) on a truck. Transport can even be scheduled separately for the allergen-containing product or adding an additional layer of protection such as a pallet cover for allergen-specific material can be implemented.

- **Employee education and movement**

Workers can be a source of allergen cross-contamination through clothing, hair, hands, and shoes. Therefore, they must be well trained in simple things like cleaning their hands and footwear, knowing what paths they should take when moving from room to room, and scheduling maintenance staff for specific areas of the processing facility at defined times. The best way to avoid human error is to provide regular training to reinforce GMP and sanitary procedures.

- **Cleaning operations/CCP**

Cleaning and cleaning validation are of the utmost importance when it comes to having a sound allergen management program. Proper cleaning must take place between production runs when allergen-containing material is processed. As there is zero tolerance for allergen presence, cleaning steps must remove all allergens from the production equipment. Equipment must be as easy to clean as possible, especially replacement parts. Any parts brought into the facility must be cleaned before installation and the processing area must be cleaned post-installation to ensure no allergens were introduced through the process.

An essential part of cleaning is the movement of waste residue through a facility. All paths must move from cleanrooms into dirty areas and material must either be disposed of or thoroughly cleaned before reuse.

Prevention of allergen contamination

As mentioned on page 2, an effective cleaning and sanitation program is essential to ensuring allergens are properly managed within a facility. The facility team is responsible for developing and validating robust sanitation procedures to ensure they can remove allergens. Quality assurance should be actively involved in this process along with facility management personnel.

- Validation of protocols – ideally, if equipment can be cleaned in place (CIP), the processes development must be designed and validated to prevent cross-contamination as well as to eliminate allergens present. In addition, utensils used in the allergen-containing processing area must be cleaned separately from other utensils. Environmental monitoring for air pressure, flow, and presence of allergens must be completed (and should be part of GMP procedures).
- SSOPs (Standard Sanitation Operating Procedures) are documented sanitation procedures that should be followed to ensure food contact surfaces are clean and free from the risk of contamination. A typical SSOP will include:
 - Identification and description of the equipment, surface or area to be cleaned
 - The Log Out - Tag Out (LOTO) procedure
 - Any personal protective equipment required to carry out the procedure
 - A list of tools and products needed for the process and where to find them
 - Instructions on preparing the equipment, surface or area for cleaning
 - Instructions on disassembling equipment (if required)

- The TACT (Time, Action, Chemical and Temperature) conditions for cleaning and sanitizing
 - The instructions for self-inspection
 - The pre-operational checks to verify that the procedure has been effective
 - Instructions on assembling and final disinfection (sanitation)
- The easiest and best way to prove that cleaning is truly effective is to take samples of the final rinse water (post-cleaning) and analyze for the presence of any relevant allergens by ELISA (enzyme-linked immunosorbent assay) testing. Other test areas include equipment surfaces, final products, and other non-food contact surfaces. Again, these samples should be analyzed by ELISA for the presence of allergens.
 - As an alternative to ELISAs, some facilities use more rapid tests to detect the presence of allergens. These tests utilize a lateral flow test device to detect if an allergen is present or not. Results can be semi-quantitative, depending on the device. The advantages of these tests are often time to results and ease of use.

Tests for detecting the presence of allergens

Hygiena™ offers a series of ELISA tests for the common allergens – almond, BLG, casein, cashew, coconut, crustacean, egg, fish, hazelnut, lupine, lysozyme, macadamia nut, milk, mustard, ovalbumin, peanut, pistachio, sesame, soy and walnut. Our AlerTox® ELISA kits are designed to provide both low levels of detection (LOD) and levels of quantification (LOQ). Hygiena also provides kits for the detection of gluten, GlutenTox® ELISAs.



KIT	LOD	LOQ	KIT	LOD	LOQ
AlerTox® ELISA Almond	0.2 ppm	5 ppm	AlerTox® ELISA Lysozyme	2 ppm	25 ppm
AlerTox® ELISA BLG	1.5 ppm	10 ppm	AlerTox® ELISA Macadmia	0.1 ppm	1 ppm
AlerTox® ELISA Casein	0.05 ppm	0.20 ppm	AlerTox® ELISA Milk	0.05 ppm	0.5 ppm
AlerTox® ELISA Cashew	0.2 ppm	2 ppm	AlerTox® ELISA Mustard	1.5 ppm	2 ppm
AlerTox® ELISA Coconut	0.4 ppm	2 ppm	AlerTox® ELISA Ovalbumin	5 ppm	25 ppm
AlerTox® ELISA Crustacean	1 ppm	20 ppm	AlerTox® ELISA Peanut	0.3 ppm	1 ppm
AlerTox® ELISA Egg	0.05 ppm	0.4 ppm	AlerTox® ELISA Pistachio	0.13 ppm	1 ppm
AlerTox® ELISA Fish	1.4 ppm	4 ppm	AlerTox® ELISA Sesame	0.2 ppm	2 ppm
AlerTox® ELISA Hazelnut	0.3 ppm	1 ppm	AlerTox® ELISA Soy (STI)	16. ppm	50 ppm
AlerTox® ELISA Lupine	0.2 ppm	2 ppm	AlerTox® ELISA Walnut	0.6 ppm	2 ppm

For routine monitoring for allergens, Hygiena also offers rapid lateral flow tests for allergen detection. Results can be obtained in 10 minutes using a simple lateral flow device with no need for additional equipment. Products include AlerTox® Sticks, GlutenTox® Sticks, AllerFlow Gluten, and GlutenTox® Pro. In addition, Hygiena offers the Cube Reader for GlutenTox® Sticks Plus for quantitative, semi-quantitative, and qualitative data on the amount of gluten present in samples. Learn more about our allergen detection solutions at <https://www.hygiena.com/food-safety-solutions/allergen-detection/>