

Food Allergen Environmental Monitoring Guide

October 2012

A comprehensive guide to understanding and implementing a successful Food Allergen Environmental Monitoring Plan

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Food Allergens Overview:

Each year millions of consumers can have an adverse allergic reaction to foods. Food allergies can be mild or severe; in some instances, exposure can cause extremely serious reactions and even death. Because there is no permanent cure for food allergies, avoidance and early treatment of symptoms are the only management strategies available to affected individuals. There are over 160 different types of food known to trigger an allergic reaction in people with food allergies. The reaction causing Food Allergens are select, species-specific proteins present in certain foods. Improper label declaration of the presence of food allergens is a leading cause of product recalls and contributes to many instances of consumer allergen exposure.

In the United States, the law identifies eight major allergenic foods. These foods and ingredients derived from these foods account for 90 percent of food allergic reactions:

- Milk
- Eggs
- Fish (e.g., bass, flounder, cod)
- Crustacean shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, walnuts, pecans)
- Peanuts
- Wheat
- Soybeans

According to European Union (EU) regulations, the following foods and ingredients derived from these foods are identified:

- Cereals containing gluten, (e.g., wheat, rye, barley, oats, spelt, kamut or their hybridized strains)
- Crustaceans
- Eggs
- Fish
- Peanuts
- Soy
- Milk (including lactose)
- Nuts (e.g., almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts and Queensland nuts)
- Celery
- Mustard
- Sesame seeds
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as SO₂.
- Lupine
- Molluscs

It is important to conduct regular ingredient testing to ensure that cross contamination from common food allergens is not occurring. For example, oats can be contaminated with wheat residues due to common use of harvesting and processing equipment. Other common pairs include corn with soybean and tree nuts with peanuts.

Goals for Environmental Control of Food Allergens:

- Primary Goal:** Finding allergens in the food-processing environment before they contaminate products
- Secondary Goal:** Assess the effectiveness of current cleaning, sanitation, and employee hygiene practices

Achieving Food Allergen Control:

- Ingredient control – know what you are buying and don't inherit your supplier's problems, test to make sure you are not bringing allergens into the processing environment
- Facility mapping – know where allergens are likely to occur
- Dedicated equipment
- Production scheduling – allergen-free products before allergen-containing products
- Thorough cleaning
- Traffic control – personnel and equipment
- Segregation of allergen-containing and allergen-free ingredients and products
- Rework control
- Air and dust control
- Water control – to prevent wash water contamination

Where to Test:

A well designed Allergen Environmental Monitoring Program will include samples from various areas throughout your production process. It is important to consider equipment that is used for both allergen-free products and allergen-containing products. Consideration of employee traffic patterns and behaviors also is important to identify areas that are easily contaminated. Equipment that can carry dust, such as vacuum cleaners, brooms, and compressed air are also potential sources for food allergens in the processing environment.

The simplest way to organize your sampling program is to map the processing environment and identify multiple sampling sites based on your specific facility design and processes. The number of samples to collect will depend on line complexity. If the final number of sampling sites is substantial, you can rotate sites at each sampling interval to increase coverage. For example, if you have identified 60 potential sampling sites, you can randomly select 10 to 15 sites each week, making sure that each site is sampled at least once per month. This system will help you stretch your testing budget while making sure you sample all sites needed to maintain program effectiveness. Keep a detailed sampling site log and facility

map that details locations of sampling sites. The log should contain written detail on how to collect samples from difficult to access areas such as within processing equipment.

When considering sites to sample, those sites that are direct product contact surfaces – those surfaces where product is exposed to the environment before final package closure – are considered most important. Suggested sampling locations include tables, conveyor belts, buckets, fillers, hoppers, utensils, employee hands, and gloves. It is important to note that all product produced on the line tested should be held until final results are received when testing any direct food contact surface sites for allergens.

Items and surfaces directly over or in close proximity to direct food contact surfaces such as areas within enclosed equipment, brooms, vacuums, and compressed air lines are also important areas for testing consideration. Product holds may not be required for testing these sites.

Tips on Food Allergen Test Methods:

ATP quick tests may be useful in assessing the cleanliness of surfaces; however, these kits do not directly measure allergenic proteins or pathogens. ELISA -based methods are developed specifically to determine the presence of allergens. Each assay targets a certain allergenic protein or class of proteins, with limited cross-reactivity. For example, an ELISA that targets the milk protein, Casein (milk solids), will not detect another milk allergen, such as Beta-lacto-globulin (whey protein). Additionally, when target proteins (such as egg or gluten) are denatured due to heat treatment (baking, frying, or pasteurization) or fermentation, ELISA -based methods may not detect them properly, so it is necessary to select kits that are appropriate for the matrix at hand. Likewise, certain sample types may give false negative results when using ELISA -based methods. In such cases, DNA-based methods may be appropriate. Finally, ELISA methods do not exist for some allergenic proteins, but PCR can provide an alternate, source-specific detection method in these situations.

How to Test:

1. Label sample bags using a separate code for each sampling site
2. Wash, dry, and sanitize hands
3. Aseptically glove hands
4. Aseptically remove swab or sampling tool. Use a sampling device that does not contain allergenic protein. Some swabs used for microbial testing contain allergens.
5. Sample area using steady pressure
6. Aseptically replace swab in bag and seal
7. Sanitize sampling site
8. Wash hands and replace gloves between sampling sites
9. Include a negative control for each allergenic target by aseptically removing a swab and then placing it back into the sleeve. Code this bag similar to other samples
10. Within 24 hours, send samples to the laboratory in a clean container with ice packs such that sample temperature does not exceed 45°

Tracking Records:

Keeping accurate up-to-date records is important for the success of any environmental monitoring plan. Good record keeping can help provide the necessary information on which decisions regarding future allergen monitoring can be based. A log book or spreadsheet could be used to track these key areas.

- Date and Time of Sampling
- Name of Person Collecting Sample
- Sample Locations
- Date Submitted to Laboratory
- Results
- Corrective Actions if Needed

Managing a Food Allergen Contamination Event:

In the event that a food allergen contamination has occurred, it is very important to determine the cause of the contamination, so that improved control strategies can be established. Here is a list of steps to take when a contamination occurs.

1. Examine ingredient control program, increase ingredient testing frequency to ensure control
2. Break down and inspect equipment
3. Thoroughly clean and sanitize all equipment, surfaces, and tools in area
4. Resample areas where allergens are found
5. Re-clean, re-sanitize, and resample as needed
6. If allergens persist implement corrective actions

Corrective Actions:

- Limit access to area
- Break down and inspect equipment in area
- Resample positive area and surroundings to determine if contamination is localized or spread
- Clean and sanitize all equipment, surfaces, and tools in area
- Conduct pre-operational inspection and resample
- Do not restart operations until all tests are negative
- Document corrective actions and consider SOP to prevent reoccurrence
- Increase frequency of sampling from weekly to daily
- After 3 consecutive days of negative results normal sampling may resume
- If problem persists, consider removal of contaminated equipment and replace or redesign

Routine Preventive Measures:

- Control sources of ingredients, water, and air with robust testing programs
- Repair structural damage and eliminate cracks and crevices that can harbor allergens
- Review and monitor GMPs
- Review and monitor SSOPs
- Audit production and maintenance practices
- Reinforce proper employee hygiene practices

Please contact us to learn more about how we can help you with your Food Allergen Environmental Monitoring Plan. To help you ensure regulatory compliance and eliminate product recalls, we provide customized strategic environmental monitoring plans, certification programs, audits, nutritional labeling expertise, and testing services that will help you protect your brands.



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