



Food & Supplement Allergen Environmental Monitoring Guide

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A COMPREHENSIVE GUIDE TO UNDERSTANDING AND IMPLEMENTING A SUCCESSFUL FOOD ALLERGEN ENVIRONMENTAL MONITORING PLAN.

- Food Allergens Overview
- Goals for Environmental Control of Food Allergens
- Achieving Food Allergen Control
- Where to Test
- Tips on Food Allergen Test Methods
- Choosing Your Swab Type
- How to Sample
- Tracking Records
- Managing a Food Allergen Contamination Event
- Corrective Actions
- Routine Preventive Measures

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. Components in food that cause food allergy reactions are select, species specific proteins. Improper label declaration of the presence of allergenic foods and ingredients is the leading cause of product recalls and contributes to unnecessary consumer exposure to allergens.

In the United States, the law identifies nine major allergenic foods and ingredients made from such foods that must be properly declared on food labels. 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
- Sesame
- 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

Health Canada and the Canadian Food Inspection Agency (CFIA) identify the below as priority food allergens or key substances most frequently associated with food allergies and allergic-type reactions. These must be properly declared on labels.

- Eggs
- Mustard
- Crustaceans & Molluscs
- Fish
- Sulphites
- Wheat and Triticale
- Milk
- Peanut
- Sesame Seeds
- Soy
- Tree Nuts

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 incidental agriculture or processing 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 cross contact 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 unwanted 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 specific allergenic food proteins. Each assay targets a certain allergenic protein or class of proteins specific to an allergenic food, with limited cross reactivity to other food proteins. 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.

CHOOSING YOUR SWAB TYPE

Collecting environmental samples in an aseptic manner is critical to ensuring the quality of the testing results. If the person collecting the samples contaminates the specimen, the laboratory results will not accurately reflect the condition of your manufacturing environment. In addition, the type of swab you use, matters.

There are multiple commercial sampling tools available for use. Your best tool is to source sterile and dry swabs resembling a Q-tip stored in individual plastic coverings.

Swabs to not use:

- Sponges or sponge sticks
- Any swab soaked in a buffer solution
- Swabs used for microbiology environmental monitoring

If you prefer to source a pre-moistened swab for convenience, it should only be stored in distilled or HPLC-grade water.

HOW TO SAMPLE

1. Collect swabs needed. One swab is used per test. For example, if needing gluten and milk allergen tests, you will need 2 swabs per sampling area. If sending in for our tree nut or full allergen package, please note you will need a swab for each individual allergen screened.
2. Label each swab unit. If your swabs did not come in individual plastic containers, you may place swabs in sterile plastic bags after a sample is collected. One bag per swab. Make sure the sample number matches the sample number on your Sample or Order Form.
3. Wash, dry, and sanitize hands.
4. Aseptically glove hands.
5. Aseptically remove swab from its container.
6. Prepare your swab.
 - a. For dry surfaces: aseptically, moisten your swab before sampling with distilled or HPLC-grade water.
 - b. For wet surfaces: no distilled or HPLC-grade water is needed. Proceed with swabbing.
7. Thoroughly swab your designated area using a steady pressure.
8. Add swab back to individual container or plastic bag.
9. Sanitize sampling site.
10. Wash hands and replace gloves between sampling sites.
11. Within 24 hours, send samples to the laboratory in a clean container with ice packs such that sample temperature does not exceed 45°F.

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 CROSS CONTACT EVENT

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