



# 9 Things Your Allergen Control Program is Missing

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## The Impact of Food Allergies

Every year in the United States, 200,000 people require emergency medical care for allergic reactions to foods. Researchers estimate that 32 million Americans have food allergies, including 5.6 million children under the age of 18. That's one in 13 children, or roughly two in every classroom. And allergies are on the rise: The U.S. Centers for Disease Control and Prevention (CDC) reports that the prevalence of food allergies in children increased by 50% between 1997 and 2011.

Those with food allergies rely on food manufacturers to identify, process, and market foods that are correctly handled and labeled. To ensure allergenic ingredients don't end up in the wrong products and to keep the population safe, it's crucial to create and implement an Allergen Control Program. An Allergen Control Program outlines the storage, handling, processing, packaging, and identification of allergenic ingredients, and is made up of documentation specific to each company.

### Key Goals of an Allergen Control Program

Allergen Control Programs are multifaceted, with elements ranging from ingredient supplier verification to storage, rework control, sanitation, and changeovers, among others.

There are two main goals of any Allergen Control Program, which appear simple on paper but can be tough to execute:

- **Goal No. 1:** If you make a product with an allergen in it, you need to make sure the allergen is declared on the label by its common name.
- **Goal No. 2:** If you make a product that is NOT supposed to have a specific allergen in it, you need to do everything possible to prevent cross contamination.

If you're like most food businesses, you have an allergen program in place. But what if you're missing a few pieces that would make your program more complete?

**This guide walks you through nine recommendations that can improve your Allergen Control Program.**

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## **Recommendation No. 1**

### **Expand your color-coding program to include pallets and stretch wrap**

Color coding is a useful tool for facilitating allergen control at your plant or distribution center. Most sites have uniquely colored containers and scoops for allergen-containing materials. The best Allergen Control Programs expand that color coding to include color-coded pallets and stretch wrap for stored materials.

Not only does expanding color coding help prevent cross contamination from pathogens, allergens, and foreign contaminants, it has a variety of other benefits. For example, warehouse operators eliminate the need for additional labeling, saving valuable time, money, and energy. Stretch wrapping also acts as a deterrent for product tampering, making intentional product damage more easily recognizable and adds a degree of privacy to pallet contents.

#### **Benefits of incorporating color-coded pallets and stretch wrap into your Allergen Control Program include:**

- Prevents cross contamination in food processing facilities.
- Distinguishes critical zones and control points.
- Color-coding programs are viewed favorably by auditors and customers.

#### **Auditors Appreciate the Effort**

Even though color coding isn't a standard rule or requirement, it's a practice that regulatory authorities commonly favor. It shows your business is committed to food safety.



## Recommendation No. 2

### **Establish and implement an Allergen Cleaning Validation Program**

When doing allergen cleaning validation, complete the process for each combination of allergen and surface type.

The same variables must be considered for allergen cleaning validation as with any type of cleaning confirmation. The difference, however, is what's at stake. Undeclared allergens are a life-threatening contaminant, and incomplete or inaccurate validation data puts lives at risk.

Establishing and implementing an Allergen Cleaning Validation Program is a terrific way to reduce risk. Two testing methods exist: One is to test the cleaned surface, and the other is to test the product after the surface is cleaned. Both testing methods have limitations, primarily from the nature of sampling. Conducting both types of testing ensures the greatest number of variables are addressed.

The allergen cleaning validation process should be completed for each combination of allergen and surface type. For example, a cleaning method that works for liquid eggs on stainless steel might not work for peanut paste on ultra-high molecular weight polyethylene plastic. Cleaning can be done mechanically, chemically, or by purging the line with another ingredient.

**TIP:** The most difficult areas to clean should be swabbed. This includes hinges or similar potential harborage areas.

## Recommendation No. 3

### Evaluate non-ingredients for allergens

Although Allergen Control Programs have always included an assessment of raw materials for the presence of allergens, additional allergen-containing materials could be brought into the facility. For example, some pumice-like soaps contain walnut shells, which provide abrasion to facilitate the removal of heavy-duty soil, such as inks used in printing or greases used by maintenance personnel.

The best way to address this is through an existing Chemical Approval Program. Ensure that one of the criteria evaluated is the presence or absence of allergens.

### Create a master list of approved chemicals

Develop a master list of all approved chemicals, identifying the name, manufacturer, intended use, locations of use, and departments authorized for use. Divide the list into categories, such as boiler and water treatment, pesticides, herbicides, laboratory, janitorial, sanitation, and maintenance. This master list serves as a reference for departments to learn which chemicals are approved for regular purchase.

### Assess packaging materials for allergens

Packaging and production aides may also contain allergens and must be assessed. For example, sulfites are used in the production of some food packaging materials, such as cellophane. Protective edible coatings and waxes, such as those used by the fresh produce industry, also must be assessed for allergens.



## Recommendation No. 4

### **Create an acetate with the correct ingredient statement to confirm ingredient statements on incoming finished products and raw materials.**

After creating an acetate with the ingredient statement, companies can overlay it onto the incoming ingredient statement.

“This helps minimize the need to read every single word – you simply overlay the acetate and if all the words align, you know it meets the requirements,” explained Stephanie Lopez, VP of Food Safety Services Americas, AIB International.

If something doesn't align, a word-by-word review needs to happen. Ingredient suppliers, especially blend suppliers, often change their ingredients without notice. These changes can involve the addition of new allergens. Their legal obligation is to ensure that packaging declares the correct ingredients and to ship out updated specifications.

Therefore, part of the receiving process should involve confirmation of ingredient statements for each lot. While there's no legal requirement for suppliers to notify manufacturers when they change ingredients, it's best practice to include a section in your contract that you be notified in writing any time there are changes.

“If you're exporting a product outside of the United States that requires packaging in a language other than English, the preprinted acetate will allow you to confirm that the specifications and packaging have the same declaration, even if you're not familiar with that language,” Lopez added. Depending on how the product is received, this process can be performed by either the receiving personnel or quality control department.



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## Recommendation No. 5

### Establish an Allergen Cleaning Validation Program for spillage.

When dealing with spillage, it's important to gauge the situation while keeping in mind the allergen's physical form, correct procedure to clean and contain, and steps toward future prevention.

All routes of contamination must be considered when cleaning a spillage. The allergen's form – powder, liquid, or solid – will determine the routes of contamination and how to deal with the spillage itself.

A sound Allergen Control Program will always include the sanitation of food contact surfaces. However, responding correctly to an allergen spillage is also part of an effective Allergen Control Program.

#### Spillage procedures should include:

- Identification of any affected surfaces or products.
- Disposal of affected materials.
- Removal of allergen debris in a manner that prevents further spread.

#### Testing for contamination is important

General cleaning practices aren't always enough to remove all allergen traces. Assessing the contaminated area with residue or environmental swab testing will detect all elements not otherwise cleaned. If machinery is found to have allergen traces, it might need to be dismantled and cleaned manually. This will ensure all areas are allergen free.

Teaching workers how to handle an allergen spillage greatly reduces the risk of cross contamination.





## Recommendation No. 6

### Be savvy about FDA food labeling

When an allergen is added to a formula that didn't previously contain it, packaging and labels used for the old formula must be discarded.

The Food and Drug Administration (FDA) issued a final rule establishing Jan. 1, 2022, as the uniform compliance date for all FDA food labeling regulations issued between Jan. 1, 2019, and Dec. 31, 2020, that require changes to the labeling of food products.

The changes include modifying the list of required nutrients that must be declared on the label, updating serving size requirements, and providing a refreshed design. The new labels will make it easier for consumers to make informed decisions about the food they eat.

While complying with the new FDA regulations requires all companies in the food business to update their labels, other forces also drive the need to update labels more regularly, such as when an allergen is added to an existing formula.

One way to do this is to drill a hole (at least half an inch) through discontinued packaging film to avoid accidentally using it. Film can be recycled but not used on the lines.

Over 60% of FDA recalls are due to labeling issues. Most of these errors relate to allergens. For example, processors might inadvertently put the wrong label on products, fail to include changes in ingredients (undeclared allergens) on labels, or create labels that don't include a complete allergen list.

## Recommendation No. 7

### **Be aware of, and test for, allergen cross-contact radius.**

Cross contact is a unique type of cross contamination. Many allergenic food products (e.g., milk powder, sesame seeds, flour) easily enter the air supply and are then deposited onto allergen-free products. This can happen even if the allergenic foods aren't produced in the same area or production room.

It's important to determine whether a facility's common air supply could cause such problems. The air currents in facilities can carry allergens, creating a hazard for products on the line. Air currents can also carry allergens to surfaces touched by personnel who directly handle product but who don't come into contact with those specific allergens.

Preventing cross contamination requires effectively cleaning equipment and processing suites, being sure to collect and remove all contaminants before they become widely dispersed. Collecting, controlling, and filtering pathogens and allergens minimizes the spread of harmful contaminants and keeps them from returning to the processing environment.

### **How far does allergen dust spread?**

1. Allergens are a concern in parts per million (ppm), so it's critical to investigate beyond a mere visual inspection of the area.
2. Take sterile, empty petri dishes and place them in five-foot intervals away from the source of the allergen dust.
3. Remove the lids from the petri dishes and store them in an allergen-free area.
4. Leave the open petri dishes throughout the shift and during and after running the dusty allergen.
5. Conduct allergen testing on the petri dishes to determine how far the allergen has spread. Remember that any allergen testing can be conducted in-house or sent to a lab.

### **Controlling exposure to allergen dust**

The best way to reduce hazardous allergen dust exposure and cross contamination is to install dust collection systems with high-efficiency primary and secondary cartridge-style filters. Primary filter media should be selected for each application based on the dust particle size, flow characteristics, quantity, and distribution. If the primary filtration system doesn't use a HEPA filter, it's recommended that a secondary HEPA filter be used downstream. Secondary filters prevent hazardous allergen dust from discharging into the atmosphere and can be configured to prevent return-air ducting contamination and the associated costs of cleaning hazardous allergen dust leakage.

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### Recommendation No. 8

**Assign a number for each type of allergen and place it on the bottom unit of each ingredient pallet via stickers.**

When packaged, non-bulk ingredients are received at a facility, stickers with allergen information should be added to the bottom unit of each pallet. Keep the stickers as simple as possible.

“The best I’ve seen is simply assigning numbers to each type of allergen. This allows warehouse personnel and line workers to easily identify which allergens are present, per the number,” Lopez shared. When looking at tracking in the warehouse for “like above like,” personnel can see if the numbers match.

“This eliminates color coding of tags, which isn’t effective for multiple allergens and can be a challenge for colorblind personnel. This is also much simpler than listing the allergens by name, which can pose a challenge for a site where there are multiple languages spoken,” Lopez explained.

Placing stickers on non-bulk ingredients in receiving is a fast and low-cost way to highlight which allergens are present.



## Recommendation No. 9

### **Confirm the correct label is put on the line for rolls of printed film at the beginning and end of the roll.**

Rolls of film can contain mixed SKUs due to splicing. This increases the potential for unlabeled allergens after the food is packaged.

“The way the film is manufactured at the packaging manufacturing site often involves splicing multiple rolls together; and when those rolls get spliced, there's an opportunity for incorrect rolls to get spliced together,” Lopez explained.

If you're using rolls of film with printed ingredient statements for your packaging, confirm you have the correct labeling at the beginning and end of the roll. This task can be assigned to someone in the production or quality departments; either one is acceptable. It's up to the individual company to decide which best suits their environment.



## Maintaining an Allergen Control Program with TraceGains

The need for food, beverage, and supplement manufacturers to have a clearly defined allergen control program in place has never been more essential. Today, food allergies are a growing global health threat for both children and adults, strict measures to prevent potentially dangerous allergic reactions must be established and rigorously enforced. TraceGains offers a comprehensive set of solutions to manage this risk and keep your customers safe.

### Market Hub

Market Hub is a comprehensive ingredient, raw material, and packaging sourcing directory that allows you to search based on specific allergen profiles. The system provides industry-standard allergen statements to ensure the accuracy of information requests allowing you to sufficiently determine the presence of an allergen.

For companies looking to expand the distribution to a new geography, allergen considerations can be reviewed as they differ from one country to another. For example, Canada defines mustard seeds as an allergen, but the United States doesn't. With Market Hub, companies can easily navigate conflicting policies by identifying foreign suppliers who hold geographically appropriate allergen statements for ingredients and materials in their region.

### Supplier Management

Supplier Management digitizes documentation and information exchange, extracting allergen data from online forms that can be used to power dynamic dashboards and reports. Companies can quickly access allergen data representing incoming raw material shipments or drill down to the impact of a specific allergen across a subset of applicable products. Supplier Management helps food, beverage, and supplement manufacturers maintain FSMA compliance by ensuring required supply chain documents are up to date and easily accessed for an audit. The system can inform safety procedures by highlighting when an allergen has changed making it easier to maintain your allergen control program.

### Audit Management

Whether you are conducting an internal audit, or you're being audited by a third party, proving how your business activity prevents allergen contamination is an important part of the process. Audit Management helps companies validate conformance to the Allergen Control Program.

### Quality Management

With Quality Management, companies can draft and maintain allergen control policies and carry out routine spot checks and validations to confirm adherence with the program.

### Specification Management

TraceGains offers companies the ability to co-author raw material and product specifications with suppliers in real time. All correspondence and agreements are tracked digitally, for a complete audit trail to ensure mutual agreement on the allergen profile for all supplier-provided materials.

