Top 6 Best Practices for Your Allergen Control Program

The Food Safety Modernization Act’s (FSMA) Proposed Rule for Preventive Controls for Human Food has two major features—provisions requiring hazard analysis and risk-based preventive controls, and revisions to the existing Current Good Manufacturing Practice (CGMP) requirements found in 21 CFR part 110.

Included within these revisions is the requirement that each covered facility prepare and implement a written food safety plan, which includes a hazard analysis, preventive controls (e.g., process controls, food allergen controls, sanitation controls, and recall plan), monitoring procedures, corrective actions, verification activities, and recordkeeping.

How can you make the most of your Allergen Control Program?

Use the 6 Best Practices in this e-book!

Allergen Control Programs are multifaceted with elements ranging from ingredient supplier verification, storage, scheduling, formula and rework control, sanitation and changeovers, and label verification.

In essence, there are two main goals of an allergen control program, which appear simple on paper, but are very difficult to execute.

Goal #1: If you make a product with an allergen in it, you need to make sure that the allergen is declared on the label.

Goal #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-contact.
Best Practice #1: Confirm the correct label is put on the line for rolls of printed film at both the beginning and end of the roll

If you’re using rolls of film, with printed ingredient statements, for your packaging, confirm that you have the correct labeling at the beginning and end of the roll. Why? “The way the film is manufactured at the packaging manufacturing site often involves splicing multiple rolls together; and when those rolls get spliced, there is the opportunity for incorrect rolls to get spliced together,” Stephanie Lopez, President, AIB International—Certification Services, explained.

This could be the function of someone in the production department or quality department. Either one is acceptable. It’s up to the individual company to decide which is best for their culture.

Best Practice #2: When doing allergen cleaning validation, complete the validation process for each combination of allergen and surface type

Validation can be accomplished by either:

⇒ Swabbing the cleaned surface after cleaning has taken place, or
⇒ Taking a sample of the product made immediately after the allergen was run and the line was cleaned.

The 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 may not work for peanut paste on ultra-high molecular weight polyethylene (UHMW) plastic.

Cleaning may be done mechanically, with chemicals, and/or through purging the line with an ingredient.

Tip: The most difficult areas to clean should be swabbed. This includes hinges or similar potential harborage areas.
Best Practice #3: Create a transparency/acetate (i.e., clear sheet of film) with the correct ingredient statement to confirm ingredient statements on packaging for finished products AND raw materials upon receipt

After creating an acetate with just the ingredient statement, companies can then take the acetate and overlay it onto the ingredient statement coming in. “This helps minimizes the need to read every single word - you simply overlay the acetate and if all of the words align, you know it meets the requirement,” Lopez explained. If anything is out of alignment, then a word-by-word review needs to take place.

Ingredient suppliers, especially suppliers of blends, may change their ingredients without prior notice. These changes may involve the addition of new allergens. Their legal obligation is to ensure that the packaging has the correct ingredients declared and they may have overlooked sending an updated specification to you. Therefore, part of the receiving process should involve confirmation of ingredient statements for each lot.

While there is no legal requirement for suppliers to notify you when they change their ingredients, it is a related best practice to include as part of your contract that you be notified in writing anytime there are changes.

“If you’re exporting a product outside of the United States that requires packaging in a language other than English, the pre-printed 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 personnel.

Best Practice #4: When an allergen is added to a formula that did not previously contain it, the packaging or labels that were used for the old formula must be disposed of or otherwise made unusable

Although there may be reasons for not immediately discarding the packaging, such as recycling or keeping it for accounting purposes, the packaging and label must be rendered unusable.

One way to do this is to drill a hole (at least 1/2 inch) through discontinued film for packaging to avoid using it accidentally. Film can be used for recycle but not on the lines.
Best Practice #5: Be aware of and test for allergen cross contact radius

Cross contact is a unique type of cross contamination. Because many allergens come in powdered form and can become airborne easily, the air current in facilities may carry the allergens to areas that are not intended for that particular allergen, creating a hazardous situation for the products on the line. Air currents in the plant may also carry allergens to surfaces that are touched by personnel who have direct product handling, but are not handling that specific allergen.

How far does allergen dust spread?
Allergens are a concern in parts per million (ppm), so it is critical to look beyond just a visual inspection of the area.

⇒ Take sterile, empty petri dishes and place them in 5 foot intervals away from the source of the allergen dust or powder.
⇒ Remove the lids from the dishes and store the lids in an allergen free area.
⇒ Leave the open plate throughout the shift during and after running the dusty allergen.
⇒ Conduct allergen testing on the dishes to determine how far the allergen is spreading (Note: Allergen testing can be conducted in-house or sent to a lab).

Best Practice #6: Assign a number for each type of allergen to be placed on the bottom unit of each ingredient pallet via stickers

When packaged non-bulk ingredients are received at a facility, stickers are provided on the bottom unit of the pallet with allergen information. This should be as simple as possible. “The best I have seen is simply assigning numbers to each type of allergen. This allows the warehouse personnel and line workers to easily identify which allergens are present, per the number,” Lopez shared.

When looking at racking in the warehouse for “Like above Like,” personnel can see if the numbers match each other. “This eliminates color coding of tags, which is not effective for multiple allergens and can be a challenge for color blind personnel. This is also much simpler than listing the allergens by name, which may pose a challenge for a site where there are multiple languages spoken,” Lopez explained.