Allergens

Validating Label Claims via Allergen Limits Testing

Some of the most discussed food safety topics within the industry involve cleaning validation and allergen control, the latter being quite difficult to tackle.

Undeclared food allergens are well-recognized as a public health concern due to the potential for severe and life-threatening reactions in allergen sensitive consumers. Confusing the issue is that allergen thresholds are not established for many allergens, as individual consumers can react differently based on the severity of their specific allergy. Nevertheless, the food industry has a legal obligation to protect consumer health and produce safe foods for all consumers.

Since food manufacturing is a complex process, it is easy for low levels of allergens to find their way into manufacturing facilities at any step from farm to table. Unintended allergens can make it into food ingredients, equipment, and processed products in several ways but fall under two primary sources – intentionally added allergenic ingredients and their derivatives, or unintentional cross-contamination with allergenic components.

The most common method is cross-contamination during manufacturing either the product or one of its components, including raw materials. This can arise at any time throughout the whole supply chain - from the fields in which the food components are grown, to the containers in which the ingredients are transported, to storage at the manufacturing locations and even during manufacture and final product packaging. Unintended allergens can also enter in several ways depending on the production process, the source of the allergen (ingredient, airflow or other), and the physical form of the allergen (dispersible/liquid, particulate/powder or solid, or oily). Examples include the presence of low levels of allergen throughout the whole product (raw ingredient) or the presence of the allergen in a portion of units only (from carryover at changeover).

There is also uncertainty about the exact nature of the risk to which allergic consumers may be exposed because currently, no quantitative limits have been agreed upon which are generally accepted by authorities, including the FDA, regulatory agencies in Canada and Japan, and national and union authorities in the EU and the UK, among others. To overcome this limitation, many food manufacturers have added precautionary allergen labeling such as “may contain” for products produced on the same line as an allergen-containing product. However, regulations state that this type of precautionary labeling is not an appropriate strategy to manage lack of Hazard Analysis and Critical Control Points (HACCP) during manufacturing, or lack of adherence to generally recognized Good Manufacturing Practices (GMP).

Manufacturers of allergen-free products must ensure that their claims are not only backed by documentation from suppliers of ingredients but also confirmed by their own analysis. Testing for food allergens is a valuable tool when used as part of a risk-based approach to allergen management. Test results can provide assurance and verification of critical controls within a comprehensive risk management program.

For all these reasons, an effective allergen control plan must be in place for any food processing facility. This Allergen Control Plan is a company's written document regarding the storage, handling, processing, packaging, and identification of allergenic foods and ingredients. This plan must start with conducting a thorough risk assessment of each step in the process to determine where procedures and controls need to be implemented. This can be visually laid out as a flow diagram to help understand where allergenic ingredients and foods exist in the plant and where they are introduced into the process. Before any raw materials enter the facility, control measures must be in place.

It starts with the raw material – all potential allergens must be identified and documented, including any introduced through maintenance or cleaning. This process must be applied to the whole facility to identify any potential allergens that could become introduced into the final product and involves close inspection of supplier ingredient specification. Next, these allergenic foods or ingredients need to be segregated from other ingredients at every step in the process, from receiving to shipping the finished product. They must also be inspected upon receipt to verify no changes have been made at the supplier level.

While physical segregation minimizes allergen risk, it is not always possible. In this case, dedicated production lines and equipment is the best practice, along with staggering scheduling of production runs, always running non-allergenic foods first. It can even come down to using dedicated employees on specific production lines.

Other possible issues include maintenance plans and equipment planning/mapping. Equipment should be fully washable to ensure proper sanitation and positioned to minimize cross-contact via airflow or air-borne dust. Maintenance should be scheduled by requiring processes that prevent cross-contamination – this can include separate cleaning tools, clean work apparel (changed after working on other lines), and processes for repairing equipment, including bringing in and changing out parts.

Most importantly, the allergen control plan must include a thorough, verified cleaning method that has been validated to remove allergens from surfaces (and remove possible other contaminants, including pathogens). Cleaning practices must be considered a CCP (critical control point) as they are the sole action in place to reduce and eliminate any hazards. Therefore, cleaning requires proper validation, monitoring and verification schedules. When deciding on a cleaning method, many variables must be considered, including soil type (liquid, powder, or oil), surface texture (stainless steel is smooth and easy to clean while plastics, rubber, and mesh belts are not), and type of equipment.

As no one method for cleaning works for every facility, validation work must be done to demonstrate that the cleaning is effective and removes/reduces the allergen to an acceptable level, working to get to a non-detectable level (visual inspection is not sufficient). There are several considerations when planning a cleaning validation study – what allergen to use as the target for the study, which test method to use, and which samples to take.

When choosing a target "allergen", choose something that is present at high levels with a high protein content and is hard to clean away from the line (mimicking the most challenging situation). There must also be a good laboratory test to detect the chosen target antigen (preferably a quantitative method, such as an ELISA). If no test exists for the allergen, you will need to rely on results from similar allergens that are run on the line in combination with visual examination and/or ATP testing results.

The validation process involves running a positive control, clean samples (swabs, water, purge materials), and a sample of the next off-line product (not containing the same allergen). Tests must verify the positive control at a range of concentrations, including at the detection level expected. Clean samples should be taken from areas that are challenging to clean along the manufacturing system/line. Testing the next off-line product verifies the equipment is clean internally too. These tests are repeated three times and over different shifts to demonstrate the cleaning works consistently and with all personnel.

Once the validation program has been implemented, it should be reevaluated at least annually or whenever there are any significant changes, such as soil type, surface type (new equipment), cleaning method, or if a more sensitive testing method becomes available. After each allergen changeover, the following should be completed: visual examination, ATP swabs (a general indicator of cleanliness), allergen surface swabs and allergen testing of the product.

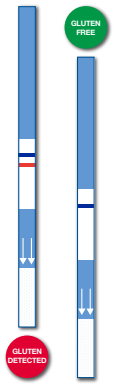
The most routinely used analytical method for detecting the presence of food allergens is the **Enzyme-Linked Immunosorbent Assay (ELISA)** technique. The sensitivity of ELISA kits currently available is in the low parts per millions (ppm) reporting range. However, there are limitations to the ELISA method. It often requires protein extraction, unknown specificity due to the effects of food processing on the allergen of interest or the matrix in which the allergen could be found, and potential cross-reaction with other proteins (low specificity).

Other allergen testing methods include lateral flow devices, DNA-based techniques, such as Polymerase Chain Reaction (PCR), Mass spectrometry (MS), and other non-specific methods such as protein tests, ATP and visual inspection to verify cleaning. The choice of test method is critical and depends on the purpose of the test, the type of sample, food matrix, processing effects, desired turn-around time, availability of equipment, the skill level of the person doing the analysis and the cost.

ELISA and lateral flow devices are often used on-site at the production facility because results can be obtained quickly, costs are relatively low, and personnel can be easily trained to use these tests. Other methods are costly and require specialized equipment and skilled personnel, so they are not often used.

When evaluating allergen testing methods, evaluate multiple parameters including – ease of use, sensitivity needed, whether quantitation is required, are interfering substances present, has the sample been exposed to extremes that could possibly modify the allergen (high temperature, pressure, fermentation or hydrolysis). Other important variables to consider are cost, time to results, test specificity, portfolio of options, and testing location (manufacturing site vs. lab).

A group of products meeting these requirements are available commercially from Hygiena™. Easy-to-use **AlerTox™ Sticks** can provide results in less than 10 minutes with no need for special equipment. Detection levels range from 1 – 20 ppm, depending on the allergen. Currently, tests are available for peanut, walnut, almond, soy, egg, fish, crustacean, hazelnut, beta-lactoglobulin, mustard seed, casein, and total milk. A related product, **GlutenTox® Sticks**, rapidly identifies gluten in food, beverages, or on surfaces with a detection limit of 3 ppm (<20 ppm is considered “gluten-free”). When combined with the **Hygiena Cube Reader**, quantitative gluten levels (from 1 – 40 ppm) can be obtained in <50 minutes. **GlutenTox™ Pro**, another rapid gluten detection system, requires no lab equipment and can be used on food, beverages, and surfaces to detect residual gluten (5 – 40 ppm) with a 10-minute assay.



GlutenTox® Sticks

AlerTox™ Sticks

Hygiena Cube Reader

GlutenTox™ Pro kit

If further quantitation is needed, Hygiena's **GlutenTox® ELISA** kits can be used. They can quantify the gluten levels present in food samples from 0.6 ppm to 200 ppm in 90 minutes. **AlerTox® ELISA** kits are also available for a variety of other allergens, including peanut, walnut, soy, and sesame. If food processing surfaces need analysis, Hygiena's **AllerFlow Gluten** can rapidly determine if gluten is present at 5 ppm or more in 10 minutes. For a more general analysis of any area, Hygiena offers **AllerSnap™** swab devices that can detect the presence of protein residue (potential allergens) left behind after cleaning, providing results in 15-30 minutes.

When paired with ATP monitoring solutions for cleaning validation, also from Hygiena, cleaning validation can be easily documented and facilities can be classified as 'clean'. As an added bonus, data can be stored and analyzed in supporting cloud software, SureTrend™ Cloud, for tracking trouble areas and trending test results across multiple lines and facilities.

No matter the type of food, it is essential to ensure proper allergen control at all levels and in all areas involved in the manufacturing and packaging processes. By implementing a detailed allergen control plan using products such as those mentioned above, food manufacturers can feel confident that their finished products are free of potential allergens and that their facilities are clean for the next production run. Having confidence in accurate, low-level detection levels will ensure consumers that the food products are safe. In addition, this will strengthen the brand overall and save significant costs (such as reduced recalls, reduced re-cleanings and less discarded product).

GlutenTox® ELISA kits

AllerSnap™ swab
AllerFlow Gluten swab

AlerTox® ELISA kits