



**Using Diagnostic Tools for Validation and Verification of an Allergen Control Program**

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## What You'll Learn From this Paper

This paper is the second in a series focused on testing. The first paper provided an overview of raw material, finished product, and environmental testing, with a focus on allergen testing. This paper will walk through how an allergen control program can play a role in assuring there are no undeclared allergens in food products. This paper is designed to:

- Provide the basic background information for
  - Raw material and finished product testing for undeclared allergens
  - Food contact surface testing to verify they are free of residual allergens
- Explain how the FDA final Preventive Controls Rule for Human Food addresses allergen controls
- Illustrate how FDA has updated the sanitation of food and non-food contact surfaces to emphasize allergen control
- Explain how allergens are addressed within GFSI schemes
- Describe the considerations when determining the best way to include testing in your food safety program

At the end of this paper, we trust you will have a better understanding of how allergen testing can be used in the food industry, the factors influencing testing both product and food contact surfaces, how the proposed regulations have focused on the need to control allergens, and the benefits allergen testing provides.

## The Role of Testing

The same variables that were discussed in the white paper [“Food Safety Testing and FSMA, GFSI, and Brand Protection”](#) should be considered for allergen testing as well. The specific reasons may be different but the importance of testing for verifying that controls are working and reducing the likelihood of undeclared allergens is the same. Similarly, when it comes to allergen testing the main types of testing that occur in a food environment are:

- Raw material testing
  - Verifies product specifications e.g., gluten-free
  - Ensures the supplier is executing its allergen control program
- Finished product testing
  - Confirms the formulation is accurate
  - Verifies cleaning and the controls to minimize cross-contact are effective
- Product contact
  - Provides verification of sanitation standard operating procedures using visual screening and rapid allergen screening tests.

## Allergen Preventive Control Measures

Every company has the goal of protecting its consumers and its reputation. To ensure they protect allergenic consumers, companies are required to label products to be truthful and not misleading, including representing all allergens present (FALCPA 2004). The ingredient declaration is the source for the consumer to review if the product contains any allergenic substances that could be harmful.

Increased vigilance for allergen control throughout the supply chain could benefit the food industry as a whole. One way to increase confidence in the supply chain is through allergen testing, both of food products and in the environment. Testing may help reduce the incidence of undeclared allergens. As reported in the FDA's report: *The Reportable Food Registry: A Five Year Overview of Targeting Inspection Resources and Identifying Patterns of Adulteration: September 8, 2009-September 7, 2014,* undeclared food allergens represent 47% of reportable incidences. This report is showing that, in Year 5, not only did undeclared food allergens trigger almost half of the RFR reports for the year, but also that most of the reports were associated with bakeries. Overall, dairy produced the greatest number of primary reports (24) – up by nearly 150% over Year 4 (10), with half of these concerning undeclared allergens. Bakery ran a close second with 23 primary reports. This report highlights the need to enact allergen control preventive measures. Testing can play a role in this.

## Methods

Allergen diagnostic tests can provide either a qualitative (pass/fail at a designated level) or quantitative result. Quantitative tests are most often used during the validation process and qualitative tests, often called screening tests, are used most often for verification and routine monitoring. The quantitative tests provide a numerical value to gauge cleaning and other intervention effectiveness during the validation process. The qualitative tests are often employed as a component of a preoperative inspection to determine whether to proceed with production or as a postoperative inspection to determine if sanitation efforts have been effective in removing allergens to targeted levels.

The most popular and accepted diagnostic methodology for allergen detection is an enzyme-linked, immunosorbent assay, or ELISA. This technology utilizes an antibody raised against the allergenic material, most often a protein and referred to as an antigen, to capture the material from a sample. The antibody is typically linked to a second, much larger particle, often colloidal gold that enables its detection either visually through the formation of a test line on a lateral flow device or a color change in a micro well. The advantage of the ELISA method lies with its ability to detect the specific allergen of concern (its specificity) in sufficiently low concentrations (its sensitivity) to prevent harmful reactions by allergic or intolerant consumers.

## Test and Hold

Most production facilities utilize allergen screening tests as either a post-operations check to verify cleaning efficacy or as a pre-operative check to determine that the production surfaces have been cleaned appropriately to begin production. Since these assays typically return a result in less than ten minutes, there is normally no test and hold issue. The exception can come from facilities that send out their allergen testing to commercial or corporate laboratories and then await the results before releasing product.

## Regulatory Requirements and Actions

### USDA

USDA's Food Safety and Inspection Service (FSIS) has recently issued Notice 29-13, "Targeted Verification of Product Formulation and Labeling for the Eight Most Common ("Big 8") Food Allergens". This is a notice to Inspection Plant Personnel to ensure that allergens are labeled accordingly. The IPP will accomplish the verification through review of the records and observations of the allergen control program.

### FDA

#### FALCPA

Currently, the Food Allergen Labeling and Consumer Protection Act (FALCPA 2004), requires food manufacturers to have risk mitigation steps in place to minimize the risk of accidental cross-contact between non-allergenic products and allergens (e.g., egg, fish and shell fish, milk, peanuts, soy, tree nuts and wheat). Food processors can voluntarily make use of allergen precautionary language such as, "manufactured in the same facility as peanuts." While this statement is informative to the consumer, this type of statement cannot be used in lieu of good manufacturing practices. Therefore it is important to have a system in place to make sure that labels accurately indicate if an allergen is present.

#### Labeling

The objective of any allergen control program is to ensure that the product label accurately represents the ingredients present in the product so that consumers can make an informed decision. A significant number of allergen related recalls occur when product is mislabeled and has the potential to be contaminated with allergenic ingredients not listed on the label. One of the most important elements of an allergen control plan, (ACP), therefore, is control and coordination of all elements of the manufacturing process including a check that the proper labels are applied. This labeling requirement is also important for ingredients received from suppliers. Care must be taken to ensure that suppliers follow the same rigorous ACP standards as are required internally. The final location where product labeling is critical is in the storage areas of the facility. Allergenic material should be labeled and stored in sealed containers in designated, segregated locations within the storage facility and a plan must be in place to handle spills or other environmental contamination events.

#### Preventive Controls

The Food Safety Modernization Act (FSMA) is maintaining the elements of the FALCPA and, within the context of the final preventive controls rule for human food, it is shifting the responsibility from the final finished packaging form and the labeling to prevention and proposing to require an allergen control program with specific elements that will address cleaning and sanitation, cross-contact, and labeling (section § 117.135(c) (2)). Specifically, it is proposing to require appropriate sanitation controls are in place and effective for undeclared allergens (section § 117.135(c) (3)).

The final Preventive Controls rule for Human Food identifies the major elements of an effective allergen control program. It also places strong ownership and accountability by the facility for an effective allergen

control program to eliminate the likelihood of an undeclared allergen.

The Preventive Controls rule does not explicitly require testing for allergens as a mandatory part of the allergen control program. It does however identify where testing may play a role in verification and validation. For example, if a company is manufacturing a cheese filled cracker and a peanut butter filled cracker on the same production line, it would be useful to perform allergen testing on the contact surfaces. This will provide confidence in the SSOPs, demonstrating that the cleaning processes are effective at removing the allergens. For example, if a new product is being formulated to contain eggs, and there are no eggs used on that line today, there are a number of steps that could be considered to ensure allergen control. But looking at this through the lenses of allergen cross-contact cleaning validation and verification, scheduling the line time and effective cleaning and sanitation are key. Since no other products contain egg, then this product should be run last (albeit considering other allergens on the line as well) and the cleaning and sanitation may easily be validated by performing allergen-specific quantitative testing on the different equipment surface types to ensure the procedures are effective. This can then be verified by qualitative allergen tests.

The FDA is not requiring validation for allergen controls in the way that validation is required for process controls. However, if there are ways to validate that cross-contact is avoided, for example, by doing a study where the amount of an allergen can be quantified after a specified sanitation process is employed, this is recommended.

### Current Good Manufacturing Practices

While most people equate “preventive controls” with the new requirements to control specific hazards, the FDA final rule also updates current good manufacturing practices, and one of the most notable updates of cGMPs relates to allergen control, with 23 changes to clearly distinguish requirements directed to allergen cross-contact. The basis for these is to prevent a failure to:

- properly clean and sanitize
- control movement of products, traffic and allergenic dust/aerosols
- properly store ingredients, works-in-process, and rework
- develop and maintain accurate and not misleading labels

This increased focus on GMPs for allergens sends a strong signal to the food industry that the FDA is serious. What’s more, the revisions are changing from recommendations to requirements.

Industry members can protect their brands by developing and maintaining an allergen control program to ensure there is a significantly reduced possibility of an undeclared allergen. So where do you start? The best place to start is to know the risk, performing a risk assessment of the ingredients. The risk assessment includes an evaluation of the inherent risk (e.g., is the product an allergen or contain an allergenic component?). Secondly, consider the supplier. Examples of some areas to review can be the history of specification compliance, third party audit performance, have they had any recalls/ withdrawals, do they manufacture other products with allergens, etc. Once the risk is assessed it is time to determine how to best mitigate that potential risk. Mitigation strategies can include auditing the suppliers, and requiring testing of the ingredient to be reported on the certificate of analysis. This can assist in understanding the risk coming into the facility.

The risk assessment and mitigation does not stop at receiving. Next, you must know the facility and production. There are a number of activities that can be controlled to reduce the risk of unintentional allergen cross-contact. For example if using an allergen or a product containing an allergen that generates dust or a liquid that can aerosolize, the air handling should be considered. This topic is addressed in the cGMP update on plant and grounds, section 117.20. Also consider if there are overlapping traffic patterns or movement of goods that could move these potential allergens around. Scheduling of production plays a role as well to minimize the potential for cross-contact by scheduling least to most allergens, (section 117.135(c)). Once these risks have been assessed they will need effective mitigation.

Cleaning and sanitation are key components of an allergen control program. There are a number of areas to consider for effective allergen cleaning. If the product scheduling is such that the most allergen contain products are produced last, cleaning must ensure that the potential for the start-up of the least allergen containing products are free from the risk of cross-contact. This is true of all the utensils that are used on that production line or in that area as well, as well as employees' hands (section 117.35(c (2))). In addition to visual inspection, testing the different product surfaces that are exposed to the allergens can initially validate the SSOPs. Testing can also be used at set frequencies to continue to verify the removal of all the target allergens from those surfaces. These set frequencies can be determined and included as a part of the Master Sanitation Schedule or as part of your food safety plan. Practices should be reconsidered, for example, when a formula changes, or when a new product is added to that production line. Other allergen cleaning considerations include how to effectively and demonstrably remove dust and aerosols near the production line processing allergens or from traffic moving this around the facility. One item that may be overlooked is cleaning the cleaning equipment.

As stated earlier, validated and verified sanitation as part of an overall allergen control program is key. And any testing information that is applicable to managing these hazards plays a strong role in the verification of the overall program. It can help provide the confidence that the allergen hazards are under control.

## **Industry Requirements: GFSI**

Increasingly, GFSI has become a major force within much of the food industry. GFSI set forth a guidance document outlining expectations of food safety management systems and different audit schemes have been benchmarked against the GFSI standard. Every GFSI scheme has a section that identifies the requirements for allergen management.

SQF has published an allergen guidance document to further define what their specific GFSI scheme requires for allergen control. This document goes into very specific details on validation and verification. The expectation is that a manufacturing facility must document that their procedures will significantly reduce the likelihood of an unintentional allergen being present in a finished product. This requirement for validation is more than just a finished product test revealing that the allergen of concern is not present. The sanitation validation must include

testing evidence, where a test is available, that the specific allergen of concern has been removed or reduced to an acceptable level from contact surfaces. SQF has listed accepted methods such as ELISA and lateral flow.

Another GFSI benchmarked scheme, BRC, also has detailed allergen control requirements. Similar to SQF the cleaning methods in a facility must be validated and verified to ensure they remove or reduce the allergen to acceptable levels. Another scheme, FSSC 22000, does not mention anything specifically about validation or verification but the allergen requirement states “products shall be protected from unintended allergens.”

SQF, BRC, and FSSC 22000 note testing as an option to verify the conformity of raw materials, and allergens could be considered as part of the specification. FSSC 22000 also mentions testing in the context of verification planning, noting that testing can be used to verify the overall effect of prerequisite programs, operational PRPs and elements within the HACCP plan, and generally to make sure that hazard levels are within identified acceptable levels.

## Summary

Because there is no “cure” for food allergies the food industry must protect its consumers and brands with an effective allergen control program. The ultimate goal of an allergen control program is to provide truthful and not misleading product labels with accurate allergen information for consumers. In order to do this, manufacturers must know if allergens are present in the products, including the possibility of inadvertent inclusion due to cross-contact. Many facilities handle both allergen containing and non-allergen containing products, and must be vigilant about practices within the facility to limit transfer. While finished product testing can verify that a system is under control, it is reactive and in some cases testing is impractical, either because of food production (workflow) issues, detection issues related processing effects on the allergen, or because it is difficult to gain statistically significant results. Preventing allergen cross-contact is preferred, and one mechanism to do this is through thorough cleaning and sanitation. Testing can be used as a tool to define and verify “thorough”. Today, both qualitative and quantitative tests are available for many of the major allergens. With FDA’s increased focus on cross-contact of allergens (both as part of preventive controls and cGMPs), and the detailed requirements of several GFSI schemes, facilities would be wise to carefully assess how they are currently controlling allergens.

### Our Recommendations:

The allergen control plan is intended to provide systematic structure to prevent cross-contact, develop and maintain accurate and truthful product labels, and provide safe products to consumers. The elements to build a strong allergen control plan include:

- assessing allergens in the facility when performing the hazard assessment
- assessing the adequacy of sanitation
  - Validation and verification through product contact testing including frequencies of such activities

What’s important is that the methods used and the frequency of implementation provide confidence the risks are mitigated. Additional elements to control allergens include good hygienic practices, product scheduling, traffic control, and labeling. In addition to all the preventive measures, finished product testing can provide further confidence in the effectiveness of the allergen control program.

## About Our Paper Sponsor – Neogen

Neogen is a leader in developing and marketing diagnostic test kits that provide food safety solutions. Its products are unsurpassed in terms of ease of use, convenience and speed. Neogen's comprehensive line of rapid food safety diagnostics includes:

### Food Allergens

Neogen offers food allergen test kits to detect almond, egg, gliadin (gluten), hazelnut, crustacea, total milk, mustard, peanut, sesame, shellfish, soy, and walnut residues. Neogen provides allergen test kits in multiple formats for validation, verification and finished product and environmental, (contact surface), testing.

### Foodborne Pathogens

Neogen provides multiple different pathogen detection systems. Neogen's revolutionary new ANSR™ system is the quickest and easiest testing method to definitively detect pathogen DNA in food and environmental samples — providing results in as little as 10 minutes. Reveal® 2.0 tests for pathogens are fast and easy immunological lateral flow devices, which can be used at nearly any facility.

### General Microbiology

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Neogen's new Reveal® Q+ fully quantitative lateral flow test for mycotoxins are quick and easy, with results in just minutes. Agri-Screen® and Veratox® mycotoxin tests kits provide screening and quantitative ELISA-based test for aflatoxin, DON, fumonisin, zearalenone, ochratoxin, and T-2/HT-2.

### Sanitation

Neogen's AccuPoint® Advanced sanitation monitoring system quickly and easily measures ATP collected from food contact surfaces or liquids as a verification of sanitation programs. DataManager software allows for complete data traceability and data analysis.

## About The Acheson Group, TAG

The Acheson Group (TAG) brings clients practical food safety solutions. Food companies today worry about operational efficiency and risk control, brand reputation and complying with current and new regulations. TAG brings a unique suite of services that provides deep industry expertise and a global perspective focused on assessing and managing operational risk, reputational risk and regulatory risk. Our team is comprised of noted industry leaders with global experience in food safety and defense. Our clients span farm to fork and include technology companies looking to assist all sectors of the food industry.