



TIP SHEET 17

ALLERGEN MANAGEMENT

Food allergies affect a small but growing proportion of the population. They are most common in children, although some can be life-long, and can cause mild to severe and sometimes life-threatening reactions. Most food allergens are proteins and are not denatured in the food manufacturing process. Their recognition, management and communication to the consumer are therefore extremely important.

Allergens in food can be intentional (i.e. nuts in nut-based products, milk in milk-based products), or introduced via cross-contact, which is the term used when a residue or trace amount of an allergenic ingredient is unintentionally added to a food product. This can happen due to ingredient mixing, line change-overs, or insufficient cleaning and sanitation procedures.

LEARNING OBJECTIVES APPLICABLE CODE ELEMENT(S)

<ul style="list-style-type: none"> ○ CONTROL AND PREVENT THE SOURCES OF ALLERGENS ○ CREATE AN ALLERGEN MANAGEMENT PROGRAM ○ IMPLEMENT PROCEDURES FOR VALIDATING AND VERIFYING THE EFFECTIVENESS OF THE CLEANING AND SANITATION PROGRAM 	<ul style="list-style-type: none"> ○ 2.8.1
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KEY TERMS

- ALLERGEN
A substance that causes an allergic reaction.
- VALIDATION
Defined in the Food and Agriculture Organization’s CODEX Alimentarius Commission Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application – Annex to CAC/RCP 1 – 1969, Rev. 4-2003), as “A system, which identifies, evaluates and controls hazards which are significant for food safety.”

Validation as applied to control limits seeks to prove that the intended result was achieved and that it actually worked.



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○ VERIFICATION

Defined in the Food and Agriculture Organization's CODEX Alimentarius Commission Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application – Annex to CAC/RCP 1 – 1969, Rev. 4-2003) as “A system, which identifies, evaluates and controls hazards which are significant for food safety.”

Verification as applied to control measures seeks to prove that the control measure was done according to its design.

PROCESS STEPS

1. 2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented.
 - a. Document the responsibility and methods used to control allergens and prevent cross-contact with any dissimilar allergenic or non-allergen containing materials. Some food products contain ingredients that are known allergens and must be declared and labeled according to the regulatory labeling requirements in the country of origin and country of destination. However, cross-contact allergens are more difficult to control. These are trace or occasional allergens that are not intended to be in the product and will not appear on the ingredient listing. They occur through incorrect formulation, poor line scheduling, rework, processing aids, or unexpected presence in ingredients (e.g. lactose used as a carrier for flavors). Cross-contact allergens can only be controlled through thorough and effective management practices within the plant. (Note: Many retailers will not accept “may contain” labeling as a management control on retailer-branded products. Intentional inclusion of allergenic ingredients must be properly labeled. However cross-contact allergens must be prevented by means of proper management controls.)
 - i. 2.8.1.1.i. The allergen management program shall include a risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants that contain allergens.
 1. A documented risk (hazard) analysis of all the ingredients, raw materials and processing aids that are used within the site shall be conducted. Each site must know the intentional and cross-contact allergens that could occur, and the potential risk of occurrence. This includes ensuring suppliers of materials, ingredients, and processing aids (including food-grade lubricants) declare any allergenic substances in the materials they are supplying, including the potential for cross-contact allergens. This not only applies to ingredients used in a particular finished product, but those used throughout the site. The risk assessment must also apply to potential allergens in materials and products that are stored or produced on other lines within the same site, or at other times on the same line. For example, a confectionery manufacturer may produce a number of product lines, but only one contains peanuts.



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The risk assessment must include the potential for peanut allergens to contaminate non-peanut products.

- ii. 2.8.1.1.ii. The allergen management plan shall include an assessment of workplace-related food allergens from locker rooms, vending machines, lunch rooms, visitors.
 1. Irrespective of the site's considered allergen exposure, a risk analysis is required of all ingredients, materials, the workplace (canteens, locker rooms, vending machines) to determine the risk of cross-contact allergens so that action can be taken to minimize or eliminate the risk.
- iii. 2.8.1.1.iii. The allergen management program shall include a register of allergens which is applicable in the country of manufacturer and the country (ies) of destination.
 1. A list of allergens within the site that are of concern in the country of manufacture and the country of sale shall be developed. The list of regulatory allergens varies from country to country and food manufacturers must be familiar with the declarable allergens in the countries in which the products are sold, and ensure that the labeling laws in that country are met. They must also be aware of changes in legislation, as regulatory allergens change from time to time.
- iv. 2.8.1.1.iv The allergen management program shall include a list of allergens which is accessible by relevant staff
 1. A list of everything within the site that contains allergens that can be accessed by the staff involved in production operations shall be outlined. Staff awareness is critical to avoiding unintentional inclusion of trace amounts of allergenic material in products, and training must be provided that includes the consequences of unintentional consumption of allergens and the methods required to prevent contamination. Trace amounts of allergenic materials can be transferred to products from clothes, incorrect ingredient selection, spillages, and inadequate cleaning.
- v. 2.8.1.2. The allergen management program shall include instructions on how to identify, handle, store and segregate raw materials containing allergens provided to staff responsible for receiving those target raw materials and
- vi. 2.8.1.1.v. The allergen management program shall include the hazards associated with allergens and their control incorporated into the food safety plan.
 1. The food safety plan must show the hazards (potential problems) associated with storage, movement, and use of allergens in the plant and how those hazards are controlled. All identified intentional and cross-contact allergens must be included in the HACCP-based Food Safety Plan, and their controls identified. In some instances, allergen controls may be identified as CCPs due to the risk to public health, infringement of labeling regulations, and the potential for



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product recall. (Many recalls have occurred due to non-declaration of allergens.) Controls may include, but are not limited to:

- a. Specifications for ingredients and raw materials;
 - b. Receipt and separate storage of raw materials and ingredients;
 - c. Separate storage of work in progress and finished products;
 - d. Scheduling of allergen containing materials after non-allergen containing materials;
 - e. Equipment design to avoid build-ups, bottle necks, and to allow for separation of highly allergenic materials;
 - f. Control of rework;
 - g. Allergen cleaning and sanitation procedures;
 - h. Testing of products and equipment.
2. 2.8.1.3. Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.
- a. Instructions for the receiving and operational staff on how to identify, store, and keep separate non-allergenic materials and any materials known to contain allergens shall be documented. SQF sites must identify all allergenic ingredients at receipt, and store them separately from non-allergenic materials, and from materials containing other types of allergens. Staff involved in receiving and storage must be fully aware of the presence and risk of allergens and the storage procedure. All ingredients must be clearly labeled with the name of the allergenic substance and must be stored and transported to avoid spillage or leakage onto other non-allergenic materials.
3. 2.8.1.4. Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible, and
4. 2.8.1.6. Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.
- a. Where satisfactory cleaning cannot be implemented, separate handling and production equipment is required. Where the allergen risk is greater (e.g. peanut protein can cause serious allergic reactions in minute trace quantities), or the processing equipment design does not permit adequate cleaning, separate and isolated production equipment must be provided to avoid cross-contact. Care must also be taken to avoid cross-contact due to air flow, transfer on tools or equipment, or staff movement from one line to the other.



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5. 2.8.1.5. Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.
 - a. Cleaning and sanitation procedures on lines producing allergenic and non-allergenic products must be effective and validated. Effectively documented, implemented and validated cleaning procedures are essential to avoid cross-contact allergens transferring across products. See below.
6. 2.8.1.7 and 2.8.1.8
 - a. The site must ensure that all finished product is true to label with regard to allergens. This includes ensuring labels meet the allergen labelling regulations in the country of manufacture and the country of destination, and that product change-over procedures are controlled and supervised to ensure that the correct product is in the correct label.
 - b. See Tip Sheet 15 for further information.
7. Validation
 - a. The purpose of validation is to prove that the cleaning process employed is effective in removing the allergen of concern. This proof requires evidence that the specific allergen was in fact removed, or reduced to an acceptable level by the cleaning procedure. Therefore, only an allergen specific test will provide that evidence. The acceptable validation testing methods involve the use of a test specific to the allergen being removed. These generally require the use of a test method which uses an antigen (the allergen) and an antibody specific to the antigen. One example of the antigen and antibody test is the enzyme linked immuno-assay or ELISA method. The ELISA method can be either quantitative or qualitative and can be conducted in a laboratory or with test kits available for in plant use; either is acceptable. ELISA test kits are available from several manufacturers and are commonly used in the food processing industry. Lateral flow test devices also use an ELISA-based method and are also effective in detecting specific allergens. While lateral flow devices are qualitative only, most have sensitivities around 10 parts per million (ppm) and are available for most of the common allergens and are designed for use in a plant environment. Both the ELISA tests and lateral flow test kits have been accepted by recognized allergen research scientists and meet the requirements for sanitation validation of the SQF Code. It must be noted that there may be other 'acceptable' tests for validation methods that can be used but the test must meet the "allergen specific" criteria or provide some other evidence that the validation is effective. The SQF Institute does not endorse any particular technology or methodology and relies on the site to provide the evidence of a scientifically validated and effective cleaning method. Like any validation of any food safety control, periodic re-validation is required to account for any changes that may have occurred. Not all allergens have specific test kits available which includes some fin fish and allergens that have been modified by fermentation, heating or hydrolysis.



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- b. There are also sensitive ATP test swabs available; however the presence of ATP does not indicate the presence of protein which is the allergenic material. The use of these total protein swabs or the ATP sensitive swabs must be calibrated with the validated cleaning procedure by using them immediately after the validated method is used and recording the results of both the allergen specific test and the protein or ATP swab test. It is also to ensure surface swabbing is occurring at corners, joins, and crevices in the equipment as well as open surfaces, to check for protein held up in equipment.
- c. The purpose of a validated cleaning program is to confirm that the specifics of the cleaning process used are complete, effective, sufficient, and when implemented, will produce that same results every time.

RELEVANT RESOURCES

- Food Allergy Research & Education - Resources For Food Manufacturers
<https://www.foodallergy.org/education-awareness/community-resources/resources-food-manufacturers>
- Food Allergy Research and Resource Program
<https://farrp.unl.edu/allergen-control-food-industry>
- SQF Food Safety Code for Manufacturing Module 2 Guidance Document
<https://www.sqfi.com/wp-content/uploads/Module-2-Manufacturing-Guidance-with-cover.pdf>