

SQFI Guidance

RE: 2.8.3 Allergen Cleaning and Sanitation Practices

1. INTRODUCTION

The SQF Institute provides updates to expand on the meaning of the SQF Code, and provide further guidance on the important issues addressed in the SQF Code. The management of allergens is covered in the 7th Edition of the SQF Code in Module 2, section 2.8.2. In this update, SQFI addresses allergen management, with particular emphasis on cleaning and sanitation practices for allergen control.

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 '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.

2.8.2.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented.

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 (eg 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)

2.8.2.1.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

A documented risk (hazard) analysis of all the ingredients, raw materials and processing aids that are used in the facility shall be conducted.

Each facility 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 facility. The risk assessment must also apply to potential allergens in materials and products that are stored or produced on other lines in the same facility, or at other times on

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the same line. For example a confectionery manufacturer may produce a number of product lines, but only one contains peanuts. The risk assessment must include the potential for peanut allergens to contaminate non-peanut products.

2.8.2.1.ii. The allergen management program shall include a register of allergens which is applicable in the country of manufacturer and the country(ies) of destination

A register (list) of allergens in the facility 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.

2.8.2.1.iii The allergen management program shall include a list of allergens which is accessible by relevant staff

A list of everything in the processing facility 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

2.8.2.1.iv. The allergen management program shall include the hazards associated with allergens and their control incorporated into the food safety plan.

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 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 product recall. (Many recalls have occurred due to non-declaration of allergens)

Controls may include, but are not limited to:

- Specifications for ingredients and raw materials;
- Receipt and separate storage of raw materials and ingredients;
- Separate storage of work-in-progress, and finished products;
- Scheduling of allergen containing materials after non-allergen containing materials
- Equipment design to avoid build-ups, bottle necks, and to allow for separation of highly allergenic materials
- Control of rework;
- Allergen cleaning and sanitation procedures (refer below)
- Testing of products and equipment

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2.8.2.iv. 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.

2.8.2.1.vi. The allergen management program shall include provision to clearly identify and segregate foods that contain allergens

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 suppliers 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.

2.8.2.1.vii. 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.

2.8.2.1.viii. 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.

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. This is discussed in greater detail in section 2.

2.8.2.1.ix. Separate handling and production equipment where satisfactory line hygiene and clean-up or segregation is not possible.

Where satisfactory cleaning cannot be implemented, separate handling and production equipment is required.

Where the allergen risk is greater (eg 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.

2. CLEANING VALIDATION AND VERIFICATION

One of the areas of possible confusion is the requirements for allergen cleaning validation and verification.

Section 2.8.2.1.vii states; "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.

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Section 2.8.2.1.viii states “Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitizing of areas and equipment in which allergens are used shall be effectively implemented.

Interpretation:

The SQF Code requires validation and verification of cleaning and sanitizing procedures for the product contact equipment, and therefore the use of finished product testing for validation of cleaning is not considered adequate. A program of verification needs to be built on an initial validation study that identifies the target allergen(s), threshold levels, and the severity of contamination, and shows the cleaning process and testing used are effective to give the desired results consistently. Once the cleaning process has been validated as effective, a verification/monitoring/inspection program shall be established to assure that the validated cleaning process is being used, is maintained and effective.

Validation

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 facility 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.

Verification

Once a validated cleaning method has been shown to remove the allergenic material of concern, the facility must verify that the validated procedures were used each time. This verification must be documented by a responsible person from the facility who has been trained in the validated cleaning method. The most common method used is direct observation of the validated cleaning procedure during the sanitation process. Another acceptable verification method is the use of highly sensitive swabs that test for proteins. These recently developed swabs will detect total protein at approximately 20 ppm. Since these devices only test for total protein and not specific allergens, they are not acceptable for validation but will serve to verify that equipment has been thoroughly cleaned. There are

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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.

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.

- When there is a mixture of different allergens in use, the acceptable method for confirming the thoroughness of cleaning is to test for the highest risk allergens, the highest concentration allergens, or the ones that are most difficult to remove. Examples of difficult to remove allergens include milk proteins, such as in chocolates or caramels or cooked eggs. In some cases, a supplier may choose to test for an allergen protein which is lower in concentration. Such is the case with low fat peanut butters where the soy flour is used at a much lower concentration in the 'mixture' with peanuts.
- Nearly all of the allergens of concern do have specific test kits available however, there are a few allergens that do not have a test kit. The supplier must record, in a detailed risk assessment, the procedures they are utilizing and use due diligence in confirming their procedures are appropriate for their application and products. There are currently no acceptable test kits for certain fish species, all tree nuts and some other allergens. In specific cases, the use of the highly sensitive protein swabs may prove to be an acceptable alternative. These tests are usually sensitive to 5-10 ppm of total protein. The supplier must be aware of the threshold levels (LOAEL or Lowest Observed Adverse Effect Levels) for each target allergen. They vary widely across all the allergens of concern.
- Suppliers using whole or partial nuts on their products, such as a muffin topping, may have to verify removal of all the nuts fragments from the equipment based on visual inspection. Ground nuts and nut butters do require the use of a validated cleaning procedures and a recognized allergen specific cleaning test on equipment such as conveyors, augers, and other product transfer devices. This due to the presence small nuts particles and oil/protein residues.
- The SQF Codes require that facilities validate their cleaning methods against the allergens of concern in the country of manufacture and the country of destination. New allergens are emerging all the time so both the supplier and the auditor need to ensure they address the most current list.
- Finished product testing is not sufficient by itself to validate cleaning methods since any allergen present is diluted by the product and can become nearly undetectable thus rendering a questionable result. However, finished product testing can be useful when an allergenic ingredient might be mistakenly added to a product during the manufacturing process. Extensive finished product testing conducted in conjunction with visual inspections of operating equipment may provide the evidence that the allergen removal verification method is working. Further evaluation on a case by case basis may be needed in some of these situations.
- For those processors producing dry products, an inert product flush may be the most effective method to remove allergens. In this case, three product flushes may be required to assure removal of the material of concern.

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3. CONCLUSION

It is the responsibility of the SQF certified facility to validate their cleaning procedure to ensure it removes allergenic material of concern to prevent cross contact with non-allergen or dis-similar allergenic foods. This must be accomplished to meet the regulatory requirements in the country of origin and the country of destination, as well as all customer requirements. The methods for validation and verification of the cleaning procedures as well as the other allergen safety procedures used in the facility must be documented as part of the food safety manual. The procedures must be scientifically valid and any exclusions or exemptions must be thoroughly documented with a detailed risk assessment. There must be a documented re-assessment of the allergen control program performed at least annually.