

DRAFT CIAA

Guidance on Food Allergen Management for food manufacturers

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Foreword

This document aims to provide sound, evidence-based and consistent guidance on good practice in allergen risk management for food producers. By harmonising and disseminating good practice across the European food industry at all levels, this guidance will ensure a consistent understanding of, and approach to, managing allergens to a high standard throughout the European food industry. This will help minimise the risk to allergic consumers and enable them to make informed product choices.

This **guidance sets out** general principles that can be used to manage specific allergenic substances in different situations. The focus of this guidance is the production of prepacked foods. However, the general principles also apply to non-prepacked foods. Actions that may be appropriate in each specific situation need to be determined by each individual food business. Different sectors of the food industry may have specific requirements that build on the approach set out here.

This guidance was prepared by the Allergens Ad hoc Working Group of CIAA.

The Group wishes to express its special thanks and acknowledgment to the **Food Standards Agency** (FSA, UK) for agreeing to the use of its “Guidance on Allergen Management and Consumer Information” (July 2006) as the basis for this paper.

Additionally, the following documents were considered in the drafting of this guidance:

- **CIAA** Guidance document on the practical application of the Directive 2003/89/EC on ingredient and allergen labelling (Version 08/2005);
- The **FDI** Dried Foods Industry Guidance on Allergen Control and Risk Management (Version 1.02, August 2008);
- The **Swedish Food Sector Guidelines** for management and labelling of food products with reference to Allergy and Intolerance (Version August 2005);
- The **Federalimentare** Guidelines on the Labelling of Allergens (Version 2, 6 November 2009)
- Research results from projects such as: “The Basis, Prevalence and Cost of Food Allergies across Europe” (**EuroPrevall** FOOD-CT-2005-514000).
- Recommendations re analytical testing **from the MoniQA EU Network of Excellence**,

The Group wishes to express its special thanks and acknowledgment to all organisations which supported this work.

1 Introduction

Scientific understanding of the risk from food allergens has grown over the last 20 years and continues to develop. Food allergy and intolerance are now well recognised as a food safety issue, which must be managed. Understanding of the risk from allergenic foods remains very inconsistent across industry. Managing the risk to allergic consumers would benefit from an improved consistency of allergen management, methods and practices.

The food industry has made significant efforts in implementing allergen risk management. Whilst reducing unintended exposure of allergic consumers to allergens, this has also led to the spread of advisory labelling. This can reduce the choices available to allergic people, resulting in frustration and risk-taking behaviour, which negates its purpose. Advisory labelling on possible cross-contact with allergens is justifiable only on the basis of a risk analysis applied to a responsibly managed operation.

In order to manage their condition, consumers with food allergies and food intolerances must be fully informed about the nature and composition of the foods they are buying. Changes in food labelling legislation have led to significant improvements in the labelling of allergenic ingredients in foods. However, unintended allergenic constituents can be present in foods as a result of manufacturing and other operations.

Allergenic foods possess some unique characteristics as a food safety hazard, which need to be considered in assessing and managing the risk:

- Allergens are unlike many other food safety hazards (e.g. chemical residues, pathogenic microorganisms) inasmuch as they are generally extensively used and valuable foods, harmless to the majority of consumers.
- Consumers intolerant or allergic to different foodstuffs can react to a wide range of amounts of allergenic foods. These amounts can vary considerably (from micrograms to grams.) depending on the individual's personal tolerance, their health and their current medication. A few acutely sensitive consumers can react to very low levels (low micrograms), albeit mildly.
- Although much work has been done to determine thresholds/no adverse effect levels and use them in food safety risk assessment, agreement between stakeholders has not yet been reached on how to interpret this information in public health terms.

Scope

This guidance has been drafted for the **management** - in any food-manufacturing environment - **of allergenic foods and substances** ("allergens") identified in EU legislation.

Food companies have a responsibility to establish a food safety management system to comply with legal requirements. Allergen Management should be **an integrated part of food safety assurance** strategies and should consider the risk from food allergens together with other food safety risks. It should be built into operational standards for a company's own manufacturing, for 3rd party manufacturing performed on behalf of the company and be incorporated into all raw material supply standards.

This Guidance recognises that small and medium sized enterprises (SMEs) may not be in possession of the same capabilities and resources as larger food companies. However, this

Guidance goes no further than the relevant legislation prescribes and therefore seeks to embody good practice in allergen risk management in addition to providing practical recommendations to guide SMEs, amongst others, through different situations relating to specific allergenic substances.

Objectives

This document aims to:

- provide general guiding principles to all food operators regarding food allergen risk management, which can be readily adapted to different product process and production facility designs.
- provide information about food allergy and food allergens to indicate their importance as food safety hazards,

2 Risk Management Processes

2.1 Overview

The need to **manage potential risks from allergenic foods** in a food production environment is universally accepted by all stakeholders in the food supply chain. This responsibility may be met in several different ways, for instance, via a Prerequisite Programme and then via integration in a business's HACCP Programme.

Allergen management in food businesses should be seen as an integral part of existing food safety management rather than a completely new system. An effective allergen management system must consider all operations from sourcing of raw materials through manufacturing and packaging to the finished product, including new product development.

Food businesses should operate in line with Good Manufacturing Practice (GMP) principles. This requires a commitment to ensuring that products meet food safety, quality and legal requirements, using appropriate manufacturing operations controls, including effective food safety and quality assurance systems. Adherence to existing GMP controls will be essential for allergen management, for example avoiding cross-contact by segregation using cleaning, separate utensils, line dedication, equipment and storage dedication etc.

Risk management starts with **risk assessment**, which, for allergens, requires consideration of, at a minimum, the likelihood that they are present, their physical form (powder, liquid, pieces etc), as well as the amount of any allergen present. Risk management must encompass every component of the supply chain, from raw materials supply specifications to the sale of the finished product and including product design and development. This evaluation should be carried out by personnel appropriately trained in allergen management.

Documented procedures for the control and prevention of contamination must be in place and visible or readily available to all employees in the work area. The procedures should contain information about:

- Product development guidelines in terms of allergens.
- Good hygiene, for example, rules regarding clothing, hand-washing and hand contact with foods.
- Cleaning of premises, equipment and tools.
- Handling of rework materials, for example, the conditions under which such product may be used.
- Waste management, for example, how waste should be labelled and kept separate from rework.
- Situations where potential cross-contamination can occur between raw materials, products, production lines or equipment, and each employee's responsibility for preventing this.
- Production scheduling;
- Labelling of raw materials, semi-finished goods and finished products.

Change control. Changes to any process within a food production facility, or introduction of a new raw material or product, can affect allergen cross-contact risks for other products manufactured at the same site. Moving production of a product to another site may also alter the allergenic risk associated with it. Any such changes will therefore require a re-assessment of the original risk for all potentially affected products and, if required, application of new risk management measures. Any new risk identified, which cannot be reduced further, will need to be communicated to consumers, for instance through advisory labelling.

Figure 1 below illustrates the critical elements that must be considered in assessing allergen risks in a food manufacturing environment (numbers refer to sections in the document).

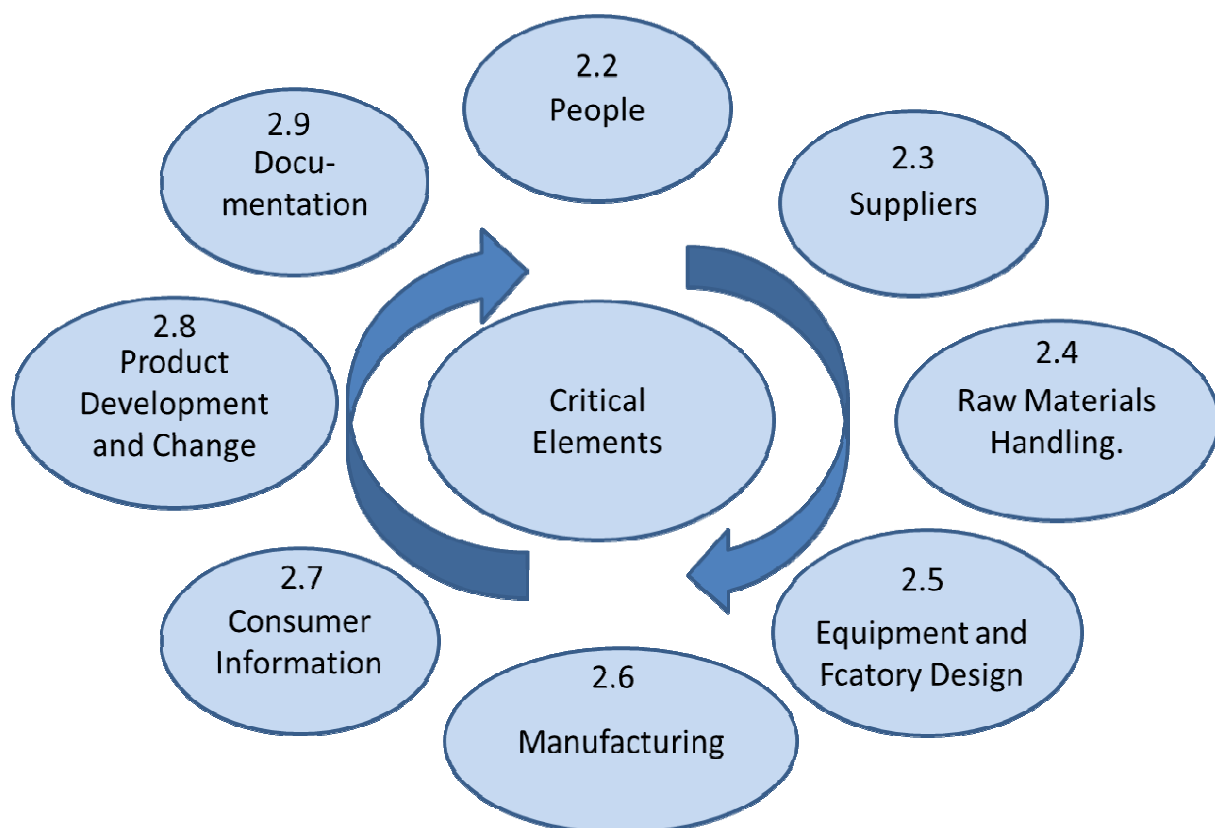


Fig. 1: Critical elements in allergen risk management

2.2 People

2.2.1 Training

All involved in the commercialisation, production and distribution of foods should understand the implications of the presence of food allergens and the need to manage the ensuing risk. Thus individuals (e.g. marketing, internal auditors, product developers, design engineers, plant personnel and contractors, employees handling consumer complaints) should receive training specific to their job responsibilities in this area. They should become aware of measures needed to minimize the risk of allergen cross-contact. All appropriate personnel should be encouraged to take immediate action, if any risk of contamination is suspected.

Allergen training should be provided to all new employees during orientation and should be repeated on a regular basis (annual refresher courses recommended). Any visitors to site should receive appropriate induction according to site GMP rules.

Training and awareness programs should include:

- General allergen awareness including the nature and possible consequences of their unintended or undeclared presence in products and specifics from a consumer perspective.
- Awareness of allergen presence in raw materials and ingredients.
- Awareness of the hazards and allergen risks identified at each stage of the food supply chain, including production, storage, transport and/or distribution process and the corrective measures, the preventive measures and documentation procedures applicable in the individual's business.
- Hygienic design of facilities and equipment in relation to allergens.
- Procedures for storage of raw materials and products, verified and validated cleaning regimes, re-work, label controls and waste management.
- GMPs covering procedures to minimise cross-contact, including hand washing, use of protective clothing including laundering.
- Procedures for people traffic patterns around the site, for example, people changing production line or site, movement to the canteen and of visitors.
- Equipment movement around the site, for example, maintenance tools, food trays, etc.
- Sources of allergen information, e.g. supplier specifications, supplier audit reports.
- Human resources procedures to manage the risk to allergic employees who may come into contact with ingredients.

Details and recommendations for training sessions are listed in Annex 5

2.2.2 Personal Hygiene

Cross-contact of products with allergenic materials may occur due to poor personal hygiene within a manufacturing facility. The application of existing GMP rules should be sufficient to minimize the risk of such cross-contamination. However, in relation to allergen controls the following aspects should be emphasised:

- The risk arising from the likelihood of cross contact happening with people being the vector of the contamination needs to be assessed. For instance, allergens present as

dry products (powders) are much more likely transferred by people than non – volatile liquids containing allergens.

- Provision of dedicated work wear and laundry facilities for use in areas handling specific allergens or where a high risk of cross-contact through clothing exists.
- Employees should not be permitted to bring food or drink into areas where products, ingredients or primary packaging is exposed.

Contractors and visitors must comply with all GMP rules. Copies of the rules should be provided. A dedicated host should be designated when employing contractors or welcoming visitors, and the host should be responsible for assuring that they know and comply with GMP rules. Visitors should always be accompanied the host.

2.3 Supplier Management

A food operator at any point in the supply chain can only perform his own risk assessment effectively if he is in possession of correct information about the complete allergen status of the raw materials and ingredients used. This requires knowledge of each supplier's understanding and application of allergen management. When it comes to allergens and other risks, a good relationship between raw material suppliers and manufacturers promotes good product safety.

In practice, a food operator will need to:

- Ascertain that allergen status is fully described in raw material, packaging, labelling and specifications declarations. For instance, generic terms such as 'flavouring, spices' are not appropriate where these substances originate from allergenic sources according to European legislation.
- Assess each supplier and the application of allergen management practices in their operations and document that assessment. For instance, this can be achieved by means of a questionnaire and, where appropriate, audit.
- Understand the allergen risk analysis from each supplier in order to apply the analysis appropriately and consistently to their products.
- Ensure that information from suppliers is correctly recorded (it is good practice to document this information in a material and recipe management database), including complete allergen status i.e. intentionally present allergenic derivatives as well as potential cross contact.
- Lay down procedures on how information received from the supplier is handled/processed/acted upon.
- Make sure a change notification process is in place with the supplier, so that newly identified allergen risks for ingredients that are already being supplied, are properly notified and can be acted upon.

Where several alternative ingredients can be substituted in a product, e.g. alternative seasonings and raising agents with carriers or a particular ingredient may need to be purchased from different suppliers, the food operator needs to ascertain the impact on the allergen status of the resulting product(s).

2.4 Raw Materials Handling

2.4.1 Incoming Raw Materials Handling

Focus at this step should be clear identification of incoming raw materials and ingredients and minimising the possibility of cross-contact. Thus:

- Allergenic raw materials, semi-finished products, etc., should be identified upon receipt and, if possible, kept in sealed packaging or separate from each other and from other foods. Clear labelling reduces the risk of mix-ups and cross-contact.
- All deliveries should be checked before unloading commences. For all deliveries (including allergenic materials) consideration should be given to the need for a special “allergen spillage” procedure, analogous to glass breakage procedures.
- Where allergenic materials are sampled on delivery, measures should be in place to make sure that the sample and the sampling tools do not create a cross-contact risk, e.g. by using colour coded and/or disposable sampling equipment. Bulk delivery points should be locked when not in use to prevent unauthorised off-loading prior to the completion of necessary checks.

2.4.2 Handling of raw materials and intermediate semi-finished products

The main risks that arise from raw material storage are cross-contamination of other raw materials and inadvertent selection for a recipe of an allergenic material not present in the product. Thus, the key principles that must be applied are clear identification and segregation of each allergenic material from other materials and each other.

Typically;

- Assure/check that allergenic materials are delivered clearly labelled, and securely packed to prevent accidental misuse, cross-contact or damage prior to receipt.
- Store allergenic raw materials in clearly identified areas, for example, using colour-coded boxes and/or demarcation of storage areas using painted lines on the floor.
- All allergenic materials should be stored in clearly marked packaging until required
- Where allergenic raw materials are de-bagged or de-boxed, they should be placed in dedicated closed and clearly labelled containers. Such containers must only be used for storage of other raw materials after appropriate cleaning using validated procedures.
- Ingredients, in dry, powder form can present a particular danger of cross contamination during handling. Special care should be taken with these types of ingredients.
- Ascertain segregation and management of allergenic materials at all stages of the manufacturing process, including picking and transfer. In cases where allergenic materials are stored in non-segregated areas, appropriate means of preventing cross contact should be used, for example utilisation of bottom level racking.

- Ensure information on the identity of raw materials is readily accessible and available at all times.
- Considerations for raw material storage also apply to semi-finished products.

2.5 Equipment and Factory Design

Production includes ingredient dispensing, recipe make up, mixing the raw materials and ingredients, processing them and then packaging the finished product. Critical allergen risks related to equipment and factory design include incorrect equipment selection, cross-contact between materials as well as between products produced on the same line. Good manufacturing practices (GMP) form the basis for minimising these risks.

Specific considerations to minimise allergen risks include:

Equipment and Layout Design: Avoid the crossover of open production lines (for example conveyor belts) to prevent cross-contamination through spillage; Allow adequate space between production lines and around equipment to permit effective cleaning thus helping to minimise the risk of allergen cross-contact

Dedicated lines, areas and equipment: where practically possible, areas and equipment should be dedicated to a specific allergen profile within a production facility. This includes weighing equipment, scoops and utensils, containers, etc. These tools and aids should be colour coded or appropriately labelled.

Movement control: Limit movement between physically separated areas or dedicated equipment, to avoid allergen cross-contact between these and other operations, and manage the movement of equipment, personnel, vehicles and maintenance tools.

Cleaning: Where there is a significant risk of cross contact from shared equipment then the equipment must be capable of being cleaned effectively. Appropriate protocols and verification procedures must be in place to validate the cleaning regime.

Air: Implications of potential airborne contamination should be assessed. Dedicated air handling units with controlled pressure between areas or dust extraction systems might be required for very dusty production areas (for example, where nut products and nut free products are produced in the same production areas).

Accumulations of settled allergenic material on flat surfaces (e.g. machine guards, window sills, shelves) should be cleaned up.

Non-Food Material Specifications: Care should be taken to avoid the use in processing areas of other sources of allergenic materials, for example lubricants, glue for direct packaging materials and anti-caking fats.

2.6 Production Process and Manufacturing Controls

2.6.1 Recipe verification

The first requirement to avoid allergen risks is to ensure the correct materials are used in the recipe. Systems therefore need to be designed to avoid recipe mistakes. These systems will

depend on the actual production facility, and can include not only verification of the recipe at the time of addition of materials, but also software and engineering design features to avoid use of the wrong ingredient(s). An example would be a system which checks barcodes in the recipe against those of the raw materials or ingredients when these are weighed out for a pre-mix and prevents the operator from continuing if they do not match. Rework represents a special case of an “ingredient” which these systems also need to consider.

2.6.2 Separation

There are a number of ways of separating the production of allergen-containing products from those that do not contain the allergen or contain a different allergen. These can include separation:

- By use of dedicated facilities;
- By use of designated areas (zones) for specific allergens
- By using physical barriers between the production lines.
- By minimising unnecessary movement of materials and personnel
- By scheduling of production runs (production planning), i.e. Where possible, production runs should be scheduled such that products without allergenic materials are produced first (after the last full cleaning).
- By appropriate cleaning of equipment between production runs, including flushing with inert materials (e.g. salt).
- By managing re-work, to ensure that residual material containing an allergen is not re-worked into a product not containing the allergen.
- By separating the air supply, where this is appropriate and practicable.
- Combinations of the above

2.6.3 Internal Labelling for handling and production

There must be control procedures to ensure proper labelling of raw materials, semi-finished goods and products. When finished packing materials are of the same or similar appearance, e.g. for different flavour variants, it is especially important to ensure that the correct packaging is used. In this context, a checklist to be signed by the person responsible is recommended.

Co-products, misshapes and broken products, which for quality reasons are not acceptable as finished product but could still be consumed by employees or sold through factory shops- must be subject to the normal allergen labelling controls.

2.6.4 Packaging and post-production controls

Incorrect packaging and/or labelling is a major cause of allergen-related product recalls. Procedures for checking that the correct labels are applied to products should be implemented and audited regularly, so that accurate information is provided to allergic consumers. Checks should be in place between processing and packing to ensure the correct packaging is used, for example with the use of automated label verification systems.

If packaging materials are stored (even for short periods) in processing areas, there is the potential for cross-contact with allergenic material. Production planning should include the order in which different products are manufactured and packaged. Special attention must be paid when the production of bulk volumes takes place at one location and the packaging of the finished product at another. In such cases, the order of packaging must be designed to reduce the risk of cross-contact by allergens and must include effective cleaning routines

It is important that, following recipe changes or the introduction of a new allergen cross-contact risk etc, the old packaging is not only withdrawn from use but is physically destroyed, so that it cannot be used in error. It is also essential to ensure that the product is packed in the appropriate correct packaging. If packaging variants are of similar appearance, such as different flavour variants, additional controls are recommended, for example by installing an inline scanner.

There should be systems to ensure packaging is removed at the end of a run, including any packaging that may be within the wrapping machine. This will help to avoid packaging mix-ups when the product to be packed is changed and, therefore, reduce the number of instances in which misleading information is passed to the consumer.

Finished products containing allergens should be securely packaged so that they cannot contaminate other products. It is important to ensure that the correct outer packaging is used for multi-pack products and that allergen information appears on, or is visible through, both the inner and outer wrappers.

2.6.5 Rework – Internally recycled product

Defined procedures for the handling of rework in production must be in place. Ideally, the principle should be “identical into identical” i.e. rework should go into another batch or run of the same product. Where this is not practicable, allergen containing rework should only be used in product where that specific allergen is already present (for example, reworking chocolate that contains hazelnuts or hazelnut fillings into other hazelnut-containing chocolate products). Oils used for cooking allergenic foods (for example, shellfish, fish and breaded or battered products) should not be used subsequently for cooking products not containing that allergen without undergoing a validated filtration step.

The use of re-work material containing allergens must be properly managed and documented. Storage, processing, identification and labelling procedures must all be the same as those for the original allergens. Responsibility for the management of re-work must be clearly defined.

2.7 Consumer Information

2.7.1 Ingredient labelling

Labelling is a very important risk management and risk communication tool. The allergen labelling requirement applies to all of the ingredients which are specified in the food labelling legislation since they are known to cause hypersensitivity in a significant proportion of the population, together with all substances derived from those ingredients, unless specifically exempted by the legislation. This declaration applies when the ingredients or their derivatives are present as:

- an ingredient including constituents of food additives, enzymes or flavourings, or a component including carriers, diluents and solvents
- an ingredient of a compound ingredient
- a processing aid or a component (including carriers, diluents and solvents) of a processing aid.

Details and recommendations for labelling, the allergen list and exemptions from labelling are listed in Annex 1 and 2. Note – **under revision to reflect new food info regulation x x x. INCO**

2.7.2 Use of advisory (“may contain”) labelling

As with ingredient labelling, advisory labelling performs an important role in reducing the risk from inadvertent allergen exposure. By communicating to the allergic consumer the potential unavoidable presence of one or more unintended allergenic constituents due to cross-contamination, highly sensitive and reactive consumers can avoid the product in question. However, to achieve this aim it is imperative that advisory labelling is applied consistently, and only following a thorough risk assessment which establishes that the residual risk is too high.

Any decision to use an advisory warning should only take place after good manufacturing practices and controls have been put in place to minimise cross-contamination, and a thorough assessment of the remaining risk. Advisory warnings are not an excuse for poor manufacturing controls and do not exonerate manufacturers from their responsibility for safety.

Advisory warning wording should be meaningful for the individual market (e.g. “may contain traces of...” “may contain”, etc.), and strive to be as consistent across industry as possible, taking into account guidance and recommendations from relevant national stakeholders e.g. patient groups, health ministries.

Advisory descriptors for allergenic ingredients should be designed where practicable such that each specific allergen is clearly described, and group names are avoided. For example, specific varieties of nuts should be detailed rather than use “may contain nuts”.

The following flow chart shows the decision steps in assessing how a product’s label should be designed. A decision to use advisory warnings in the labelling should always be based on a documented risk assessment.

(Documented risk assessment should come under Annex with examples which are in public domain – completed when the work of the ILSI Expert Group is finished)

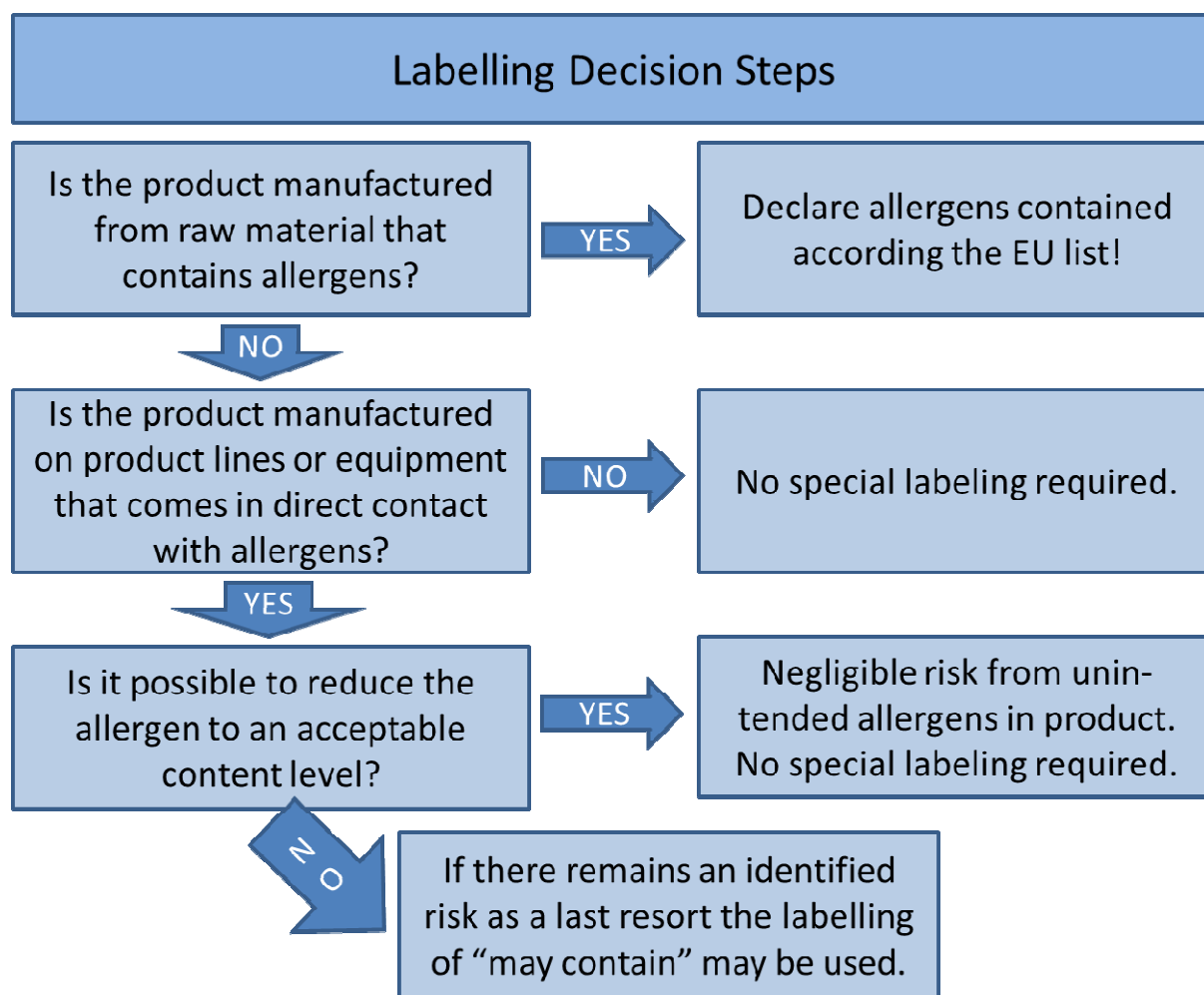


Figure 2: Simplified approach to finished product labelling. “Acceptable content level” means the remaining allergen cross-contact after all preventive measures. Advisory warning labelling indicates unavoidable cross-contact with allergens.

2.7.3 Non-commercial samples (e.g. for taste sessions, exhibitions)

Complete allergen information should be available to consumers for non-commercial samples (i.e. products not for resale) namely ingredients and any unintended allergenic constituents. In particular, where products are presented at taste sessions, sent to customers or presented at exhibitions may contain directly or indirectly unexpected allergens, appropriate communication tools – verbal or written – the prospective consumer should be clearly informed of its content

2.8 Product Development and Change:

2.8.1 Reformulating Products

Consumers do not always become aware of product recipe change unless some clear indication is given. This is particularly so for allergic consumers, who will often remain loyal to a product they trust. This is particularly important when the allergen profile changes. Therefore, when an existing recipe is changed or one ingredient is substituted for another

one containing allergens, the consumer should be clearly informed about the change in product composition. This can be done, for example, by using prominent labelling flashes, preferably on the front of the pack, in addition to the amended ingredients list. Suitable warnings might be, for example, “New Recipe” and “Now Contains”.

It may also be possible to use other methods such as websites and patient group updates, to inform consumers of recipe changes. In addition, food operators and retailers are strongly advised to provide updated information to consumer support/allergic patient organisations as they have systems in place for informing their members about changes and this approach helps to target the information at those who are most at risk.

2.8.2 New Product Development

The starting point for all food production is ensuring that complete product specifications are available. In product development, the ingredients and manufacturing procedures should be looked at from an allergy perspective. The people responsible for development of products and recipes must have sound knowledge of the risks to people with food allergies and other food intolerance. By definition, most food allergens are common and valuable components of the diet and it is neither practicable nor even desirable to exclude them from new products. However, in order not to add complexity to existing allergen risk management practices, new product development technologists should be mindful of the following when developing new products:

- Using an allergenic ingredient in a product;
- Introducing new allergens into new formulations of existing products/ brands.

Successful implementation of new products into existing manufacturing facilities will require attention to the following principles prior to starting production or running trials:

- Ensure all documentation is updated accurately and completely.
- Inform relevant personnel in good time when new allergenic ingredients are to be used, so that they can perform an ingredient assessment and as required design a plan to manage them.
- Ensure conduct of factory trials of allergen-containing products includes measures to avoid allergen cross-contact with existing products.
- Ensure information on the presence, or potential presence, of allergens is made available to those involved in factory trials and in taste testing;
- Ensure information is clearly conveyed with products presented for wider test and marketing purposes.

2.9 Documentation and record-keeping

Efficient and accurate record keeping is critical to the application of allergen management within the food safety programme. A simple record-keeping system can be effective and

easily communicated to employees. It should be integrated into existing operations using existing paperwork, such as delivery invoices and checklists to record allergen status.

A record of the risk management programme should be retained with the risk assessment to demonstrate due diligence. This may be shared, as appropriate, with enforcement agencies and customers to demonstrate how risks have been managed and reduced. This should include details of how the program is validated, and ongoing verification. Internal compliance with instructions and procedures for control of allergen risks should be verified regularly by trained internal auditors.

3 Cleaning and cleaning validation

3.1 General

Effective cleaning is one of the most important aspects of any allergen management strategy. A “visually and physically clean” standard is not just a casual visual inspection of the production line or area, it also requires that all of the trouble spots are identified and inspected (key inspection points should be highlighted on cleaning schedules)

Cleaning considerations should be built into the design of equipment. For instance, dismantling should be made easy so that hidden areas of the equipment can be adequately accessed and cleaned as failure to clean properly can lead to a build-up of raw material- or product residue inside the equipment. Avoiding the crossover of production lines and allowing adequate space for effective cleaning will also help minimise the risk of allergen cross-contact.

Documented and validated cleaning procedures using proper cleaning equipment are essential to ensure that effective and proper cleaning is performed. Adequate time must be allocated for cleaning.

Cleaning practices that are satisfactory for microbiological safety may not be adequate for removing some allergens and their validity for such a purpose should be assessed. Equipment may need to be dismantled and manually cleaned to ensure hard to clean areas are free from allergen residues. Particular food materials (for example, powders, seeds, pastes and particulates) may present significant cleaning problems and any relevant industry guidance, where this has been developed, should be followed. Adequate procedures should be in place for cleaning both production and packaging machinery. Where adequate cleaning cannot be assured (e.g. because of inaccessibility), the residual risk from allergen cross-contact should be assessed and advisory labelling used, if deemed appropriate.

The actual cleaning procedure must not contaminate other areas (for example, by use of compressed air), or an area which has already been cleaned (for example, clean dry mix areas from the top down). Any spillage that occurs during production, storage and transportation should be cleaned up immediately to ensure that there is no subsequent allergen cross-contact. Where known allergen cross-contact has occurred, the contaminated material should be labelled and physically moved away from the non-contaminated ingredients and work-in-progress.

Consideration should be given to maintenance activities, such as the use of dedicated tools or adequate cleaning procedures where tools are not dedicated. Where adherence to a cleaning regime is part of a separation system, it should be validated as “fit for purpose” and compliance should be monitored.

Investment in developing and following appropriate cleaning regimes will help to minimise food allergen cross-contact and can reduce the likelihood of needing costly product recalls.

Key Cleaning Principles for Allergen Control:

- Ensure that cleaning equipment itself is dedicated (if possible) and cleaned after use to minimise the risk that it may carry and transfer allergen traces.
- Establish appropriate cleaning regime
- Validate cleaning regimes.
- Monitor that cleaning is being done properly.

- Keep records of cleaning.

3.2 Cleaning Methods

3.2.1 Wet cleaning

Wet cleaning systems can be very effective and are the best cleaning option, where usable without introducing microbial risk. They are particularly effective where allergens are in a form that may be difficult to remove using dry cleaning only. The cleaning stage and cleaning chemicals must be capable of removing all contaminants and the rinsing stage must be sufficient to flush the system.

In dry food manufacturing environments a separate risk assessment should be undertaken to ensure that no microbiological hazards are introduced as a result of any wet cleaning procedures.

3.2.2 Dry cleaning

Where dry cleaning is undertaken, the use of brushes, dustpans etc. is acceptable, but suitably filtered/protected vacuum systems are often preferred. Compressed air blow lines for allergen cleaning are strongly discouraged, as the airstream could re-contaminate adjacent equipment or carry allergens into clean areas. Cleaning equipment should be well maintained.

It is essential that cleaning equipment is itself cleaned to prevent the transfer of allergens. Dedicated cleaning equipment which is identified by colour can be used to minimize cross-contamination.

3.2.3 Dry flushing

The use of flushing materials as a mechanism for removing and/or reducing levels of allergenic materials can be beneficial and can be more effective when used in combination with other cleaning methods. Flushes should pass through all parts of the plant with which the allergen may have been in contact, including raw material addition points, internal hoppers and packing machinery. It is unlikely to be sufficient to flush only the primary process (main mixer etc.).

Consideration should be given to quantity and nature of the flushing material. Flushing agents should be inert non-allergenic materials such as salt. Where the chosen flushing agent is not a significant ingredient in the next production batch, an additional dry-clean may be appropriate.

Used flushing materials should be identified, handled and stored using the same controls as for the original allergen which the flush now potentially contains. Subject to an individual company's risk assessment, it may be appropriate for used flush material to be used as an ingredient in a production batch containing a similar allergen profile. (e.g. salt used for flushing after the production of an egg-containing batter, could be used as ingredient for subsequent production of the same or a similar egg batter.) Otherwise, the flush material should be carefully disposed of in a manner which will not lead to cross-contact.

The most effective and cost efficient methods for prevention of allergen cross-contact may be based on a combination approach, for example scheduling, cleaning and flushing. The nature and extent of any cleaning program will be determined by the risk assessment.

3.2.4 Validation and verification of cleaning

In addition to routine cleaning verification (the process line is inspected and signed back into normal use after cleaning to confirm that all detailed measures, cleans, flushes etc have been completed), it is necessary to regularly demonstrate that allergen protocols remain effective.

It is recommended that the validation be carried by a multi-skilled team. In addition to production staff, the team could include (as appropriate) engineers, quality specialists, hygiene specialists, and people with knowledge of allergens. It is important to include people with detailed knowledge of the process, the equipment and the relevant cleaning procedure. It is also important that the related cleaning procedures are developed and thoroughly documented in advance of any validation activity.

The first step of a good 'cleaning validation' is to define a 'worst case'. For example:

- Which allergenic derivative is the most complicated / challenging to clean e.g. sticky materials, particulates?
- Which one is used in a higher quantity?

A validation study requires the physical validation of the cleaning (post cleaning and/or pre-operational inspection process) combined with quantitative analytical evidence by using validated analytical methods . When no test for the analytical validation is available, allergen line validations should follow the physical validation protocol only and then comply with the visibly clean standard (no product residue) or test for a marker allergen (a labelled allergen with the highest percentage by formula).

Documented validation should be considered part of the plants' HACCP program, and be done in addition, if changes in formula, the process, equipment or cleaning procedures are identified to present an unavoidable likelihood of cross-contamination.

4 Analytical Methods and their Application

Allergen management depends on a number of factors outlined in this guidance document. Analysis can help and support understanding of allergen management capability and control but should never be regarded as the sole tool sufficient for allergen management.

Analytical testing is inappropriate for quality control purposes but supports upstream quality assurance, validating cross-contamination control capability.

The typical applications of analytical testing are;

- Provision of quantitative data for the purposes of risk assessment;
- Confirmation of raw materials composition;
- Validation of allergen control measures such as cleaning practices, scheduling, segregation barriers;
- Monitoring suppliers' control capability
- Confirming "free from" status

Allergen analysis is divided into different methods for different purposes. Most commonly used are lateral flow devices or dipsticks and ELISA (Enzyme linked immunosorbent assays), which are protein based. Some mass spectrometry methods are also emerging. PCR (polymerase chain reaction) assays, since they are typically indirect tests (detecting non-allergenic DNA but not protein) are only useful where protein detection assays are not available (e.g. celery). Lateral flow devices can be used by trained factory workers on site while ELISA, mass spectrometry and PCR have to be performed in specially equipped accredited laboratories.

ATP (adenosine tri-phosphate) and protein assays are also on site assays but not specific for allergens. These detect general contamination with biological material / proteins which are not necessarily the allergens of concern, but can indicate level of cleaning capability.

Analytical results can be misleading unless critical considerations are built in along with competent technical advice. These considerations include:

- Choice of appropriate method (Sensitivity, Selectivity, Specificity and Reproducibility)
- Confirmation that analytical test has been validated for the food matrix to be tested;
- Risk-based sampling programme is relevant to the site, production equipment and process, product;

Analytical results are very useful when the efficiency of cleaning procedures (cleaning validation) needs to be assessed. Here, quantitative values give an insight whether the procedure is appropriate to remove allergens from the production line. On site swabbing test and dipstick tests can indicate that the tested part of the production line remains free from allergens (to its limit of detection). However, a single test result does not provide sufficient information about the allergen presence/absence. A single test as part of a holistic allergen

management review to verify absence of allergens is very good supporting evidence of the success of the risk management control measure.

I. More details in Annex 6 – Methods for allergen detection.

5 KEY PRINCIPLES OF ALLERGEN RISK MANAGEMENT

In summary, the allergen status of all raw materials (including intentionally present flavourings, additives, carriers, rework and processing aids and assessment of probable cross-contact), should be known. Food operators must be able to demonstrate their responsibilities as follows:

- Policy and guidance
 - manage potential risks from allergenic foods
 - operate in line with Good Manufacturing Practice
 - integrate allergen risk management in existing food safety management
 - document specific allergen risk management procedures
- People
 - With respect to people food businesses are responsible for identifying allergen management-related training needs of all personnel
 - deliver training on allergen risk to personnel according to the needs of their role
 - implement rules for personal hygiene
- Supply management
 - Implement a specific supplier management review related to allergen risk.
 - Check the allergen status of all raw materials with suppliers and review regularly.
 - Ask suppliers to notify the allergen status (intentional and cross-contact) of the materials they supply and any changes to the status.
- Manufacturing
 - Handle incoming raw materials and ingredients according to the Allergen Management Plan.
 - Clearly identify allergenic raw materials and segregate as appropriate.
 - Ensure that stored raw materials and ingredients with allergens will not pose a risk of cross-contact to non-allergenic goods.
 - Ensure the handling of allergenic ingredients does not create a risk of cross-contact with other raw materials.
 - Check implications of any change of raw material supplier.
 - If applicable, understand the rationale for suppliers using advisory labelling.
 - Implement validated cleaning procedures
- Communication
 - Ensure that recipes, manufacturing, packaging and consumer information is produced with a high awareness of allergen risks,
 - Use "may contain" labelling only after thorough risk assessment and if the risk cannot be sufficiently reduced after all practicable measures are undertaken.

6 Glossary of terms

allergen status

cross contact

cross contamination

Hazard

ingredient specifications

operating procedure

raw material

Rework

Risk

senior management (in the meaning of ISO 22.000)

validation

verification

Food Operator

HACCP

GMP