

# Guidance on Food Allergen Management for Food Manufacturers

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# Index

<b>Foreword</b> .....	<b>p. 03</b>
<b>1. Introduction</b> .....	<b>p. 04</b>
<b>2. Risk Management Processes</b> .....	<b>p. 06</b>
2.1. Overview .....	p. 06
2.2. People .....	p. 08
2.3. Supplier Management .....	p. 10
2.4. Raw Materials Handling .....	p. 11
2.5. Equipment and Factory Design .....	p. 12
2.6. Production Process and Manufacturing Controls .....	p. 13
2.7. Consumer Information .....	p. 15
2.8. Product Development and Change .....	p. 16
2.9. Documentation and Record-Keeping .....	p. 17
<b>3. Cleaning and Cleaning Validation</b> .....	<b>p. 18</b>
3.1. General .....	p. 18
3.2. Cleaning Methods .....	p. 20
<b>4. Analytical Methods and their Application</b> .....	<b>p. 22</b>
<b>5. Key Principles of Allergen Risk Management</b> .....	<b>p. 24</b>
<b>6. Glossary</b> .....	<b>p. 26</b>

<b>Annex 1: Background on Food Allergies and Intolerances</b> .....	<b>p. 32</b>
<b>Annex 2: Allergen Risk Analysis and Management</b> .....	<b>p. 38</b>
<b>Annex 3: Allergen Labelling</b> .....	<b>p. 56</b>
<b>Annex 4: Allergen Change Over (Cleaning/Flushing) Validation</b> .....	<b>p. 64</b>
<b>Annex 5: Allergen Analysis</b> .....	<b>p. 70</b>
<b>Annex 6: Gluten-free Products</b> .....	<b>p. 80</b>
<b>Annex 7: Precautionary Allergen Labelling</b> .....	<b>p. 86</b>

# Foreword



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Scientific understanding of the risk from food allergens has grown over the last 20 years and continues to develop. Food allergies and intolerances are now well recognised as a food safety issue, which must be managed. Understanding of the risk from allergenic foods remains inconsistent across the 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 practices. 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. Approaches for the application of advisory labelling need to be developed.

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:



- **Allergenic foods are 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.**

# 1

# Introduction

This Guidance document was prepared by FoodDrinkEurope to provide sound, evidence-based and consistent information on good practice in risk management of allergenic foods and certain food intolerances (hereafter referred to as 'allergen management') for food producers of foodstuffs intended for sale to the general population. 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 and certain food causing intolerances 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 foodstuffs causing allergy or certain intolerances in different situations. The focus of this Guidance is the production of prepacked foods intended for sale to the general population. 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 herein.

It is **not the intention of this document** to describe risk management requirements that deliver food products which make a claim that they are intended for allergic consumers.

Special thanks and acknowledgment go 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 document. Furthermore, express acknowledgment and appreciation must be given to Sylvia Pfaff, Food Information Service Europe (FIS), who oversaw the drafting of this Guidance from its inception and did much in compiling the information referenced in this section.

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

- **FoodDrinkEurope** 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**.
- **International Life Sciences Institute**, ILSI Europe Concise Monograph Series - Food Allergy.





## 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 third 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. It must be stressed that whilst this Guidance goes no further than the relevant legislation prescribes, it 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. It is ultimately for each and every food company to decide on the application of the Guidance.

## 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' 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 products 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.

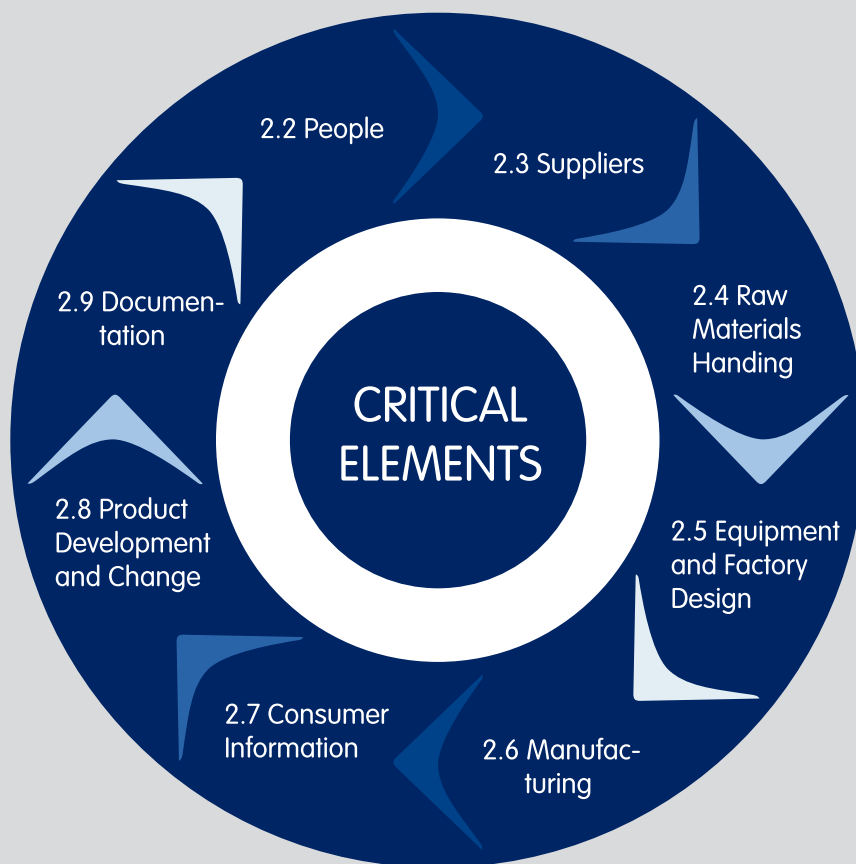


Changes to any process within a food production facility, or introduction of a new raw material or product, can affect allergen cross-contact risks for other products manufactured at the same site. Moving production of a product to another site may also alter the allergenic risk associated with it. Any 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 relevant 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. top management, 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 are recommended). Any visitors to site should receive appropriate induction according to site GMP rules.

Training and awareness programmes should include as appropriate:



- 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.



## 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 for use in areas handling specific allergens or where a high risk of cross-contact through clothing exists. Such work wear should be restricted to working areas (i.e. not in canteen area, etc.).
- 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 by 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 the 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, an 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, 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

The focus at this step should be the 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, for example, 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 should be applied are clear identification and segregation of each allergenic material from other materials and each other.

As appropriate:

- 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.
- 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 and inspection 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, or a validated cleaning programme should be in place.

### Movement Control:

Limit movement between physically separated areas or dedicated equipment, to avoid allergen cross-contact between these and other operations. 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 must be in place to verify and 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. Accumulations of settled allergenic material on flat surfaces (e.g. machine guards, window sills, shelves) should be cleaned up.

### Non-Food Material Specifications:

Implications of the use in processing areas of other sources of allergenic materials and foods causing intolerances should be risk-assessed. Some examples include peanut oil in lubricants, wheat flour in cardboard packaging release agents.





## 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 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 separating the air supply, where this is appropriate and practicable.
- Or
- 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 products but could still be consumed by employees or sold through factory shops, must be subject to the normal risk assessment and risk communication 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 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.

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.

### **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 rework must be clearly defined.

## 2.7 Consumer Information

### 2.7.1 Ingredient Labelling

Labelling is a very important risk management and risk communication tool. Food information legislation in the EU lists foods known to cause allergic hypersensitivity in a significant proportion of the European population, and several foods known to provoke intolerance reactions in sensitive individuals such as sulphites, lactose and gluten. Substances or products causing allergies or intolerances, as well as ingredients and processing aids originating from a substance or product causing allergies or intolerances are required to be declared for pre-packed and for non-pre-packed foods, unless the derivatives are specifically exempted by the legislation.

As regards prepacked foods, this information must be provided on the package or on a label attached thereto. For non-prepacked foods, Member States may adopt national measures concerning the means through which the allergen information is to be made available and, where appropriate, their form of expression and presentation.

Labelling of these ingredients, processing aids, substances or products causing allergies or intolerances is obligatory when they are deliberately used in the manufacture or preparation of a food and are still present in the finished product, even if in an altered form.

The allergen list and exemptions from labelling as well as details and recommendations for labelling are outlined in Annex 3 accompanying this document.

### 2.7.2 Non-commercial Samples (e.g. for taste sessions, exhibitions)

Complete allergen information for those allergens identified in EU labelling legislation should be available to European consumers prior to consumption for non-commercial samples (i.e. products not for resale presented at taste sessions, sent to customers or presented at exhibitions). Alternatively consumers could be pre-screened and rejected from taking part in consuming such commercial samples should they have any food allergies or intolerances.



## 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 and 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 (or different 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” or “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 recommended 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; and
- 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:**

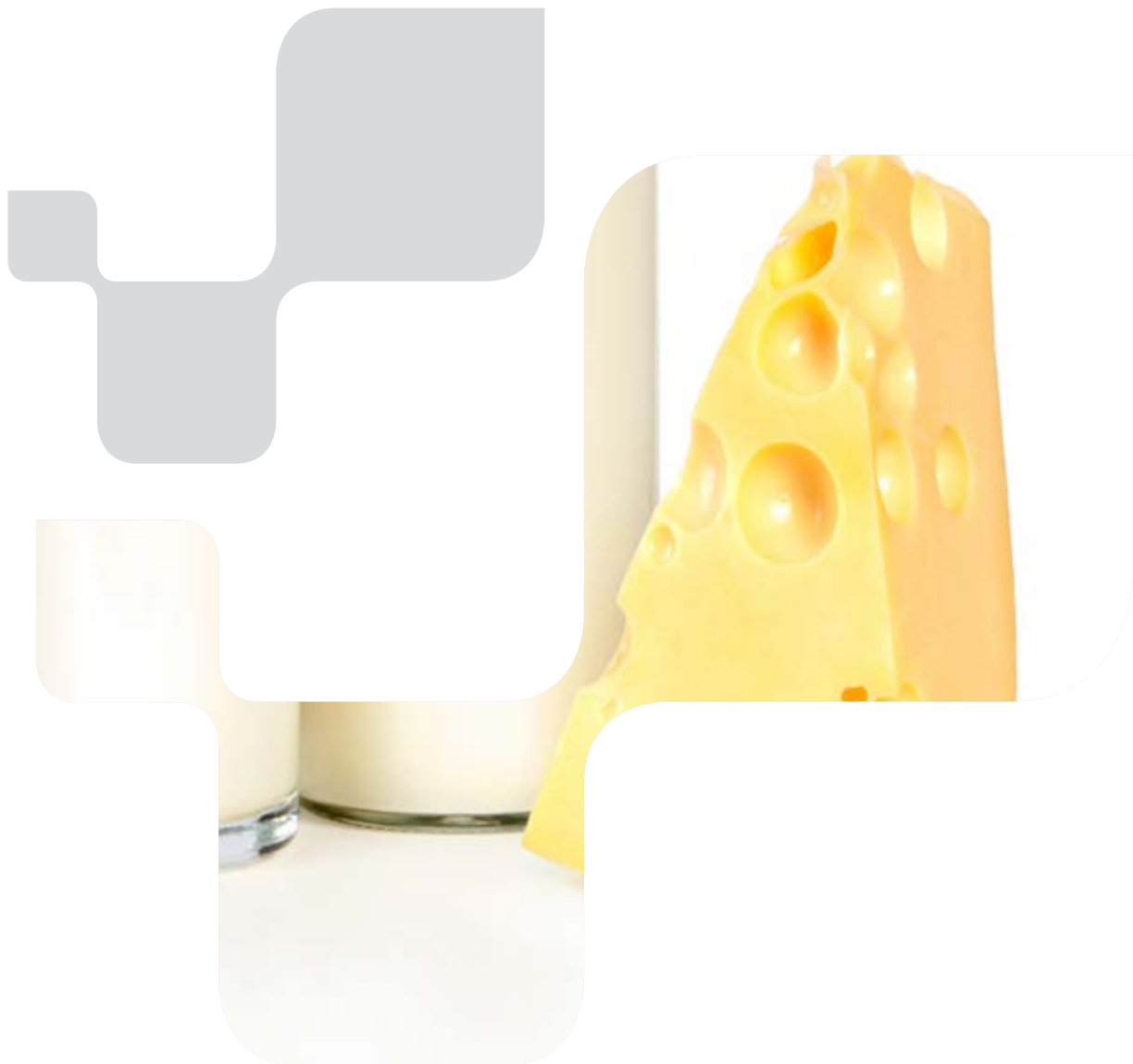
- **Ensure all documentation is updated accurately and completely.**
- **Inform relevant personnel in good time when new allergenic ingredients are to be used, so that they can perform an ingredient assessment and as required design a plan to manage them.**
- **Ensure conduct of factory trials of allergen-containing 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 a 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 programme 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.

Line cleaning must be evaluated for its ability to control the hazard; i.e. issues with heterogeneously distributed common allergen traces due to cross-contact and effectiveness of (controlled) wet or dry cleaning need to be assessed. Line cleaning of heterogeneously distributed allergenic material will be considered as effective only if

the whole production line may be visually assessed and complies with the visibly clean Standard (no product residue visible).

Documented and validated cleaning procedures using proper cleaning equipment are essential to ensure that effective 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 regimes.
- Validate cleaning regimes.
- Verify that cleaning is being done effectively.
- 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 practicable and 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. The use of compressed air is 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 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 the 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 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 an 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 programme 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.

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).

**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?
- Which one is used in the highest proportion in a recipe?

Documented validation should be considered part of the plants' HACCP programme, 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 and segregation barriers;
- Monitoring suppliers' control capability; and
- Confirming the status of any allergen claims.

Allergen analysis is divided into different methods for different purposes. The most commonly used are lateral flow devices or dipsticks and ELISA (Enzyme linked immuno-sorbent 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 an analytical test has been validated for each of the food matrices to be tested.**
- **Risk-based sampling programme is relevant to the site, production equipment and process, and product.**



Analytical results are very useful when the effectiveness 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 5 – 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 (GMP).
- Integrate allergen risk management in existing food safety management.
- Document specific allergen risk management procedures.

### • 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.

### • People

- Identify 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.





#### • 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.
- Approaches for the application of advisory labelling need to be developed.



# 6

## Glossary of Terms

### Allergen

Allergens are antigens which cause allergy. Most allergens reacting with IgE or IgG antibodies are proteins, often with carbohydrate side chains, a foreign substance or protein (antigen) that stimulates an allergic reaction.

### Allergy

Allergy is a hypersensitivity reaction initiated by immunological mechanisms. Food allergy is an IgE-mediated hypersensitivity reaction, which can lead to anaphylaxis. A state in which objectively reproducible symptoms or signs can be initiated by immunologic mechanisms after exposure to a defined stimulus at a dose tolerated by normal subjects.

### Allergen status

In this Guidance, the term “allergen status” refers to the presence, or not, of any allergenic foods or their derivatives in a raw material, by-products, rework or processed food product. This status includes allergen presence whether intentionally present, or potentially present as a result of unintended cross-contact. Accurate knowledge

of the “allergen status” of materials is necessary to allow assessment of any risk they may present, and subsequent effective allergen risk management.

### Allergenic constituents or allergenic derivatives

Products, by-products or their components which have the potential to provoke an allergic reaction in sensitised individuals.

### Anaphylaxis

A generalised inflammatory immunologic reaction to a foreign protein in a sensitised individual, which may be severe enough to be life-threatening. A severe, life-threatening, generalized or systemic hypersensitivity reaction.

### Antibody

A protein molecule (immunoglobulin) produced and secreted by B lymphocytes in response to an antigen, which is capable of binding to that specific antigen.

### Automated label verification systems

Production systems, usually in-line, which can automatically verify

whether the correct packaging has been used for the product scheduled to be manufactured, and stop the line if incorrect packaging has been used in error.

### Coeliac disease

A disease in which the mucosa of the small intestine is damaged by exposure to gluten (also known as gluten sensitive enteropathy).

### Cross contact

In the context of food allergens, “cross-contact” occurs when a residue or other trace amount of an allergenic food is unintentionally transferred into another food, despite good manufacturing practices (GMP).

### Cross-contamination

An alternative expression for cross-contact.

### Enzyme

Proteins that catalyse the reactions of metabolism, speeding them up without themselves being used up in the reaction. Each enzyme is specific for a given substrate or reaction.



### **Food additive**

Any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

### **Food allergy**

An IgE-mediated hypersensitivity reaction.

Food allergy occurs when the immune system becomes sensitised to specific food antigens, usually proteins. Subsequent exposure to the specific allergenic protein when ingested can produce adverse reactions in the sensitised person, which can include potentially fatal anaphylaxis.

### **Food business**

Any undertaking, whether for profit or not and whether public or private,

carrying out any of the activities related to any stage of production, processing and distribution of food.

### **Food Business Operator (FBO)**

The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

### **Food Hygiene**

The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use.

### **Food information**

Information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication.

### **Food intolerance**

A hypersensitive reaction which is non-allergic, where immunological mechanisms have not been proven or are not responsible for the reaction. For example,

lactose intolerance is caused by a deficiency of the digestive enzyme, lactase.

### **Food safety hazard analysis**

A food safety hazard analysis is done in order to determine which potential hazards need to be controlled, how much control is needed, and which combination of control measures should be used in order to make sure that food is safe.

### **Food Safety Management System (FSMS)**

A network of interrelated elements that combine to ensure that food does not cause adverse human health effects. These elements include programmes, plans, policies, procedures, practices, processes, goals, objectives, methods, controls, roles, responsibilities, relationships, documents, records and resources. A FSMS is often one part of a larger management system.

## Good Manufacturing Practice (GMP)

A production and testing practice that helps to ensure a quality product. Basic preventive guidelines for plant and facility operations. Guidelines aimed at food processors aim to include all HACCP methods and procedures and typically address (1) plant design and construction material, (2) water supply, (3) plumbing and toilet facilities, (4) equipment and utensils, (4) raw food handling and testing practices, (5) personal hygiene, (6) pest control, and (7) waste disposal.

## HACCP (Hazard Analysis Critical Control Point)

HACCP is a methodology and a management system. It is used to identify, prevent, and control food safety hazards. HACCP management systems use the following methodology:

1. Conduct a hazard analysis.
2. Identify critical control points (CCPs).
3. Establish critical limits for each critical control point.
4. Develop procedures to monitor critical control points.
5. Design corrective actions to handle critical limit violations.
6. Create a food safety record keeping system.
7. Validate and verify your safety system.

HACCP was developed by the Codex Alimentarius Commission.

## Hazard

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

## Hypersensitivity

A state in which objectively reproducible symptoms or signs can be initiated by exposure to a defined stimulus at a dose tolerated by normal subjects. Hypersensitivity causes objectively reproducible symptoms or signs, initiated by exposure to a defined stimulus that is tolerated by normal subjects. Food allergy is an IgE-mediated hypersensitivity reaction to allergenic foods and their derivatives in sensitised individuals.

## IgA, IgD, IgE, IgG, IgM/IgE

Classes of immunoglobulin. Immunoglobulin E is a type of antibody which may cause an allergic reactions found in the immune system. We produce IgE molecules to fight infections caused by parasites, like worms; or those that cause malaria. We do not understand why, but the immune system of some people mistakenly produces IgE to harmless things like pollen or dust mites, giving rise to hay fever and asthma, and to some foods, giving rise to food allergies.

## Immunoglobulin

A protein molecule produced and secreted by B lymphocytes in response to an antigen, which

is capable of binding to that specific antigen (also known as an antibody).

## Inflammation

General term for the reaction of tissues to injury, infection or a localised immune (allergic) response; characterised by the infiltration of inflammatory cells and clinically by heat, redness, swelling and pain.

## Ingredient specifications

Technical document used to define the critical parameters of raw materials, processes and finished products which are necessary to manufacture the quality, composition and characteristics intended, including allergen presence.

## Ingredient

Any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'.

## Label

Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food.



## Labelling

Any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food.

## Lactose intolerance

A state in which an individual is unable to digest significant amounts of lactose, the predominant sugar in cow's milk. This results from a deficiency of the enzyme lactase, normally produced by the mucosal cells of the small intestine.

## Management

All the activities that are used to coordinate, direct, and control an organization. The term management does not refer to people. It refers to activities. (See top management below for reference to people).

## Management Review

The purpose of a management review is to evaluate the overall performance of an organisation's food safety management system and to identify improvement opportunities. These reviews are carried out by the organisation's top managers and are done on a regular basis. The overall purpose of a management review is to evaluate the suitability, adequacy, and effectiveness of an organisation's quality management system, and to look for improvement opportunities.

Management reviews are also used to identify and assess opportunities to change an organisation's quality policy and quality objectives, to address resource needs, and to look for opportunities to improve its products.

## Manufacturing process

Manufacturing processes are the steps through which raw materials are transformed into a final product.

## Microbiological safety

A 'microbiological criterion' means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch (Regulation (EC) No. 2073/2005).

## Operating procedure

A document which describes the regularly recurring operations relevant to the quality of the investigation. The purpose of an operating procedure is to carry out the operations correctly and always in the same manner. An operating procedure should be available at the place where the work is done.

## Operational standards

Qualitative or quantitative technical requirements which must be met to achieve intended targets and characteristics of a process, part-product or finished product.

## Packaging

The placing of one or more foodstuffs in primary wrapping, in a secondary container, and any subsequent containers.

## Pre-packed food

Any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; 'pre-packed food' does not cover foods packed on the sales premises at the consumer's request or pre-packed for direct sale.

## Prerequisite Programme (PRP)

The conditions that must be established throughout the food chain and the activities and practices that must be performed in order to establish and maintain a hygienic environment. PRPs must be suitable and be capable of producing safe end products and providing food that is safe for human consumption. PRPs support HACCP plans.

## Processing

Any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes.

## Processing aid

Any substance which (i) is not consumed as a food by itself; (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product.

## Raw material

Material before being processed or manufactured into final form.

## Retail

The handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.

## Rework

Taking by-products from a specific food manufacturing process and either re-processing to ensure a product meets specification, or recycling by-products back into the process for efficiency purposes.

## Risk

A function of the probability of an adverse health effect occurring upon exposure to an identified hazard.

## Risk analysis

A process consisting of three interconnected components: risk assessment, risk management and risk communication.

## Risk assessment

A scientifically based process consisting of four steps (i) hazard identification (ii) hazard characterisation, exposure assessment (iii) and (iv) risk characterisation.

## Risk management

The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

## Risk communication

The interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

## Senior / Top management

A person or a group of people at the highest level within an organisation. It refers to the people who coordinate, direct and control organisations.

## Small and Medium-sized Enterprise (SME)

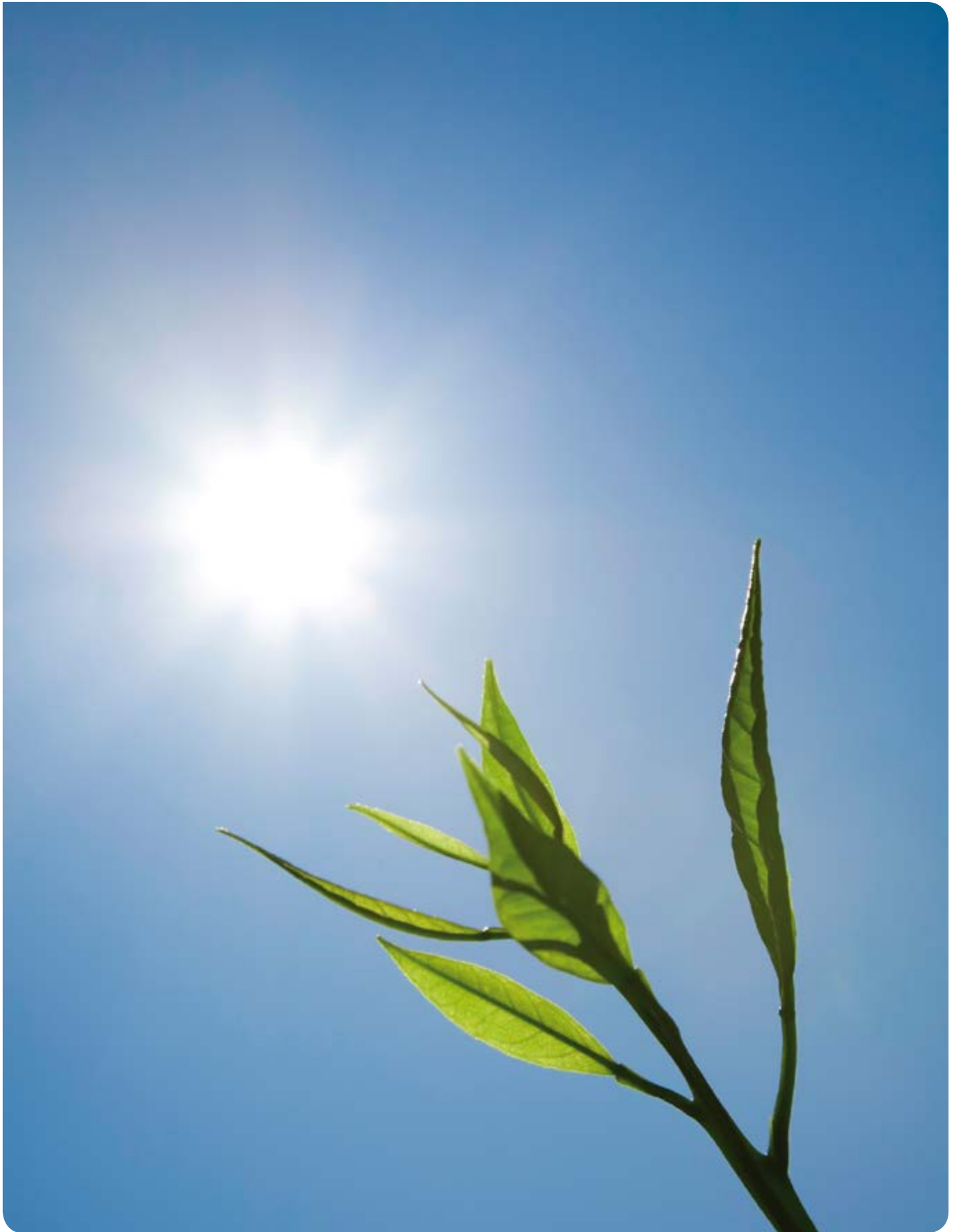
The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.

## Validation

A process that is used to ensure that food safety control measures are capable of being effective. The validation process uses evidence to determine whether control measures are capable of controlling or managing identified food safety hazards and ensuring that end-products are safe.

## Verification

Act or process of establishing (confirming) the accuracy or existence of something; in the quality field, verification is a systematic, objective, and documented process of confirming that a product or service conforms to various requirements (customer, regulatory, etc.). A process that uses objective evidence to confirm that specified requirements have been met.



# Annex 1

## Background on Food Allergies and Intolerances

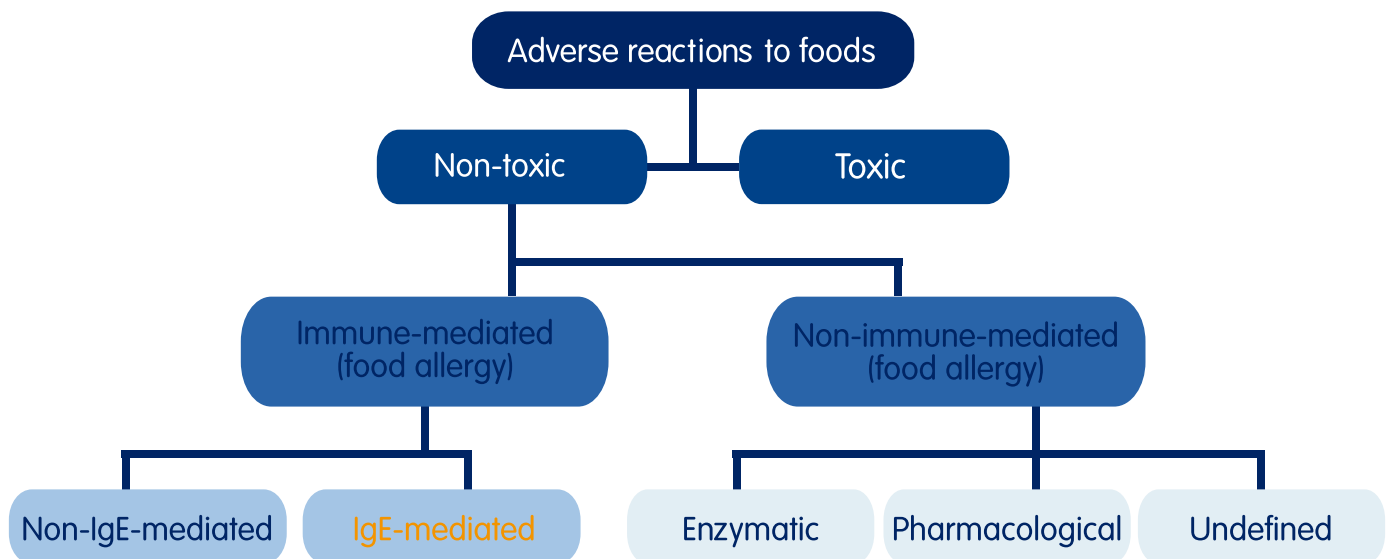


## Introduction

Food allergies affect around 2 to 4% of the population (1, 2) in Europe and an estimated 5-8% of children. Allergic reactions to foods also account for a high proportion of admissions to hospitals for acute allergic reactions (3). This means that in the 500 million population of the 27 EU Member States, an estimated 10-20 million people suffer from a food allergies. However, the number who believe they have a food allergy is considerably higher at around 20% of the population (4). Many children outgrow their allergies, such as those to milk and eggs by the age of 5-7 years. Other allergies, such as to fish and peanuts, tend to persist. For practical purposes, no cure exists for food allergy and allergic consumers must avoid foods which contain the ingredient(s) to which they are allergic.

## What is a food allergy?

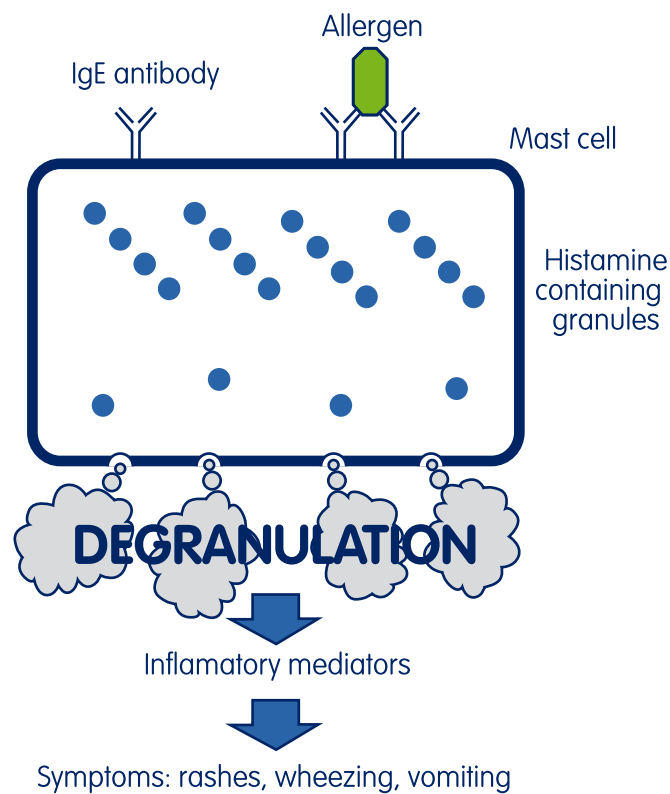
Food allergy refers to an inappropriate immune response to a food constituent (almost always a protein), causing the food to provoke an allergic reaction when it is eaten again. Foods can produce many different types of allergic responses, but from a public health and food safety perspective, those with the greatest impact are those in which the immune system produces IgE antibodies to proteins in the food and those reactions are the primary concern of this guidance. Care needs to be taken to differentiate food allergy from food intolerance, such as lactose intolerance, which does not involve the immune system (see below).



*Classification of Food Allergy and Food Intolerance by European Academy of Allergy and Clinical Immunology (EAACI), 2004.*

Allergic reactions to food can vary from very slight to severe and occasionally fatal, depending on the dose, the individual and other factors. Food allergy affects a greater proportion of children than adults (5) and reactivity to some allergenic foods, such as milk and egg, tends to be largely outgrown, while allergy to others, such as peanuts, generally persists.

During an IgE-mediated reaction to a food, rapid release of chemicals in the body (e.g. histamine) occurs, resulting in symptoms sometimes within minutes but occasionally up to 2 or more hours after ingestion of the offending food.



Main elements of an IgE-mediated reaction

**These symptoms can include one or more of the following.**

- **Skin problems (hives, itching, dermatitis, eczema, conjunctivitis, swelling of the lips, mouth).**
- **Respiratory problems (rhinitis, asthma, breathing difficulties, swelling of the throat).**
- **Gastrointestinal problems (nausea, stomach pain, vomiting, diarrhoea).**

In rare cases, a severe systemic reaction may occur, leading to a sudden drop in blood pressure, severe constriction of the airways, a generalised shock reaction and multiple organ failure. This is known as anaphylactic shock and can lead to death within minutes if not treated with adrenaline. Only a small number of people with food allergies are at risk of such serious reactions, but there are nevertheless many documented cases of death resulting from accidental ingestion of an offending food.

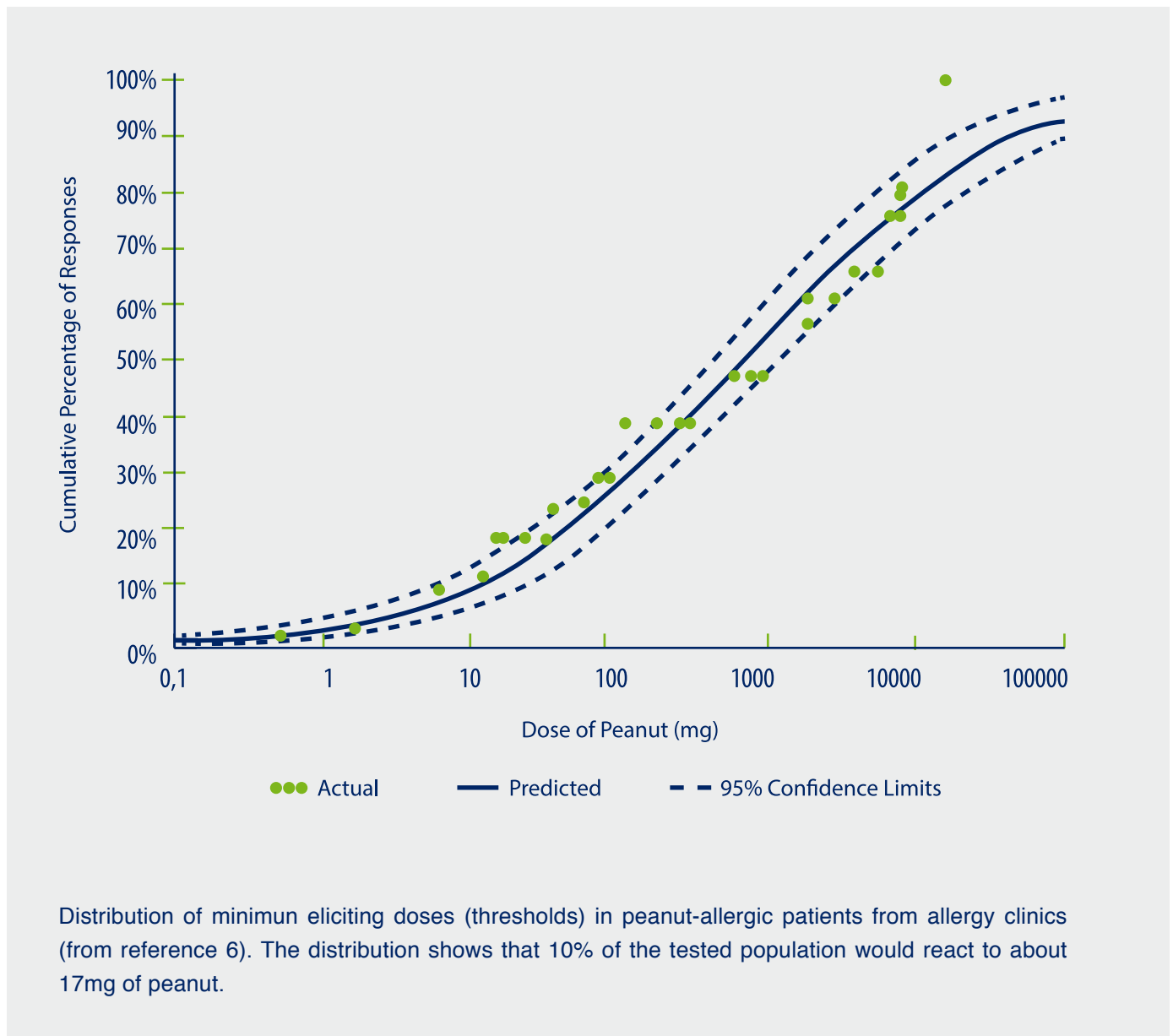
Oral allergy syndrome (OAS) is a form of food allergy in which people become allergic through inhaling pollen proteins and then react to similar proteins in foods. Generally, the symptoms can only be felt by the allergic person (itching) severe reactions are extremely rare. Typically OAS occurs with fruits and vegetables.

Whether a person develops a food allergy (or indeed any allergy) depends on complex interactions between individual susceptibility and factors related to exposure and the circumstances in which it occurs (e.g. concurrent viral infection, etc). Children born to allergic parents are more likely to become allergic themselves. Most food allergies begin in childhood, but onset can also take place later in life.

## How Much is Too Much?

The range of minimum doses required to provoke a reaction in allergic people (thresholds) spans a very wide range, from micrograms to grams. Recent work has helped to characterise the distribution of these

doses in the allergic population for some allergens (6), making it possible to assess allergen risks quantitatively (7).



## Other Adverse Reactions to Foods Involving the Immune System

Celiac disease manifests itself as an immunologically mediated, non-IgE reaction to gliadin, a prolamin (gluten protein) found in wheat, and similar proteins found in the crops of the tribe Triticeae (which includes other cultivars such as barley and rye). It is an autoimmune disorder of the small intestine that occurs in genetically predisposed people of all ages from middle infancy onward. Symptoms include chronic diarrhoea, failure to thrive (in children), and fatigue, but these may be absent, and symptoms in other organ systems have been described. Over the longer-term, osteoporosis and other severe health effects have been reported.

## What is food Intolerance?

Food intolerance refers to adverse reactions to foods, which do not involve the immune system and are not usually the result of inherent toxicity, but of some characteristic of the food (pharmacological activity), the affected individual (enzyme deficiency) or where the cause is unknown. Although not usually immediately life-threatening, such reactions can make the sufferer feel extremely unwell and can have a major impact on working and social life.

Because of the nature of food intolerance, symptoms cannot be precisely defined. They may occur very rapidly and mimic an allergic reaction (e.g. biogenic amines), but can also develop over many hours until the offending substance has been removed (e.g. lactose intolerance). Often the symptoms are vague and not always easily diagnosed.

People with food intolerance have to adapt their food consumption to their individual intolerance. It is often not necessary to avoid the food completely, e.g. in the case of lactose intolerance (8).

## Food Processing and Allergenicity

Because allergic reactions start with the recognition of the allergen (protein), any process that modifies the structure of a protein will have the potential to affect allergenicity. Food processing induces several physical, chemical and biochemical changes that are known to potentially impact the allergenic potential of proteins. Certain methods of food processing may enhance, reduce, or eliminate the allergenic potential of a food (9).

Removal of the protein fraction of the food can reduce exposure to allergens sufficiently to prevent allergic reactions (e.g. highly refined seed oils). This is recognised by the exemptions granted in the labelling legislation. However, there are no general rules regarding how different allergenic foods respond to physical (i.e., thermal, mechanical), chemical, or biochemical processing methods. Consequently, unless sound evidence exists that a specific processing method reduces allergenicity, it should be assumed that the allergenic potential of a processed food is identical to that of the food in its unprocessed form.

### To find out more:

Jackson WF (2003) food allergy. ILSI Concise Monograph Series. ILSI Press, Brussels.

[www.foodallergens.info](http://www.foodallergens.info)

a website developed by the Integrated Project Europrevall for the food industry



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# Annex 2

## Allergen Risk Analysis and Management

# Allergen Risk Analysis and Management

Effective risk management of food allergens requires careful consideration of allergen presence, both intentional from the recipe, and unintended through cross-contamination across all stages of food production from farm to fork.

Allergen HACCP risk assessments will help to identify where allergen hazards occur and whether the existing systems can manage the potential risk under normal operating conditions and good manufacturing practice. Such risk analysis should be undertaken by

appropriately trained experts, such as members of HACCP teams, as an integral part of the manufacturer's quality and food safety system.

The allergenic foodstuffs and their derivatives which should be considered are those which have been identified as of public health importance and require mandatory labelling, as outlined in EU legislation. The same approach could be utilised generically for other allergenic foodstuffs.

## 1. Characterisation of the Risk from Allergens

Characterisation of potential risk from the presence of allergens in the finished manufactured product is a fundamental activity within any food operation HACCP and should be done for each individual food handling site.

There are several recommended steps for allergen risk characterisation to ensure the necessary information is available, and the necessary assessment considerations have been covered. Completion of these stages will allow a food operator to determine whether allergen labelling is required for the finished product, identify the specific allergen-derived foodstuffs which need to be declared, and whether, despite good manufacturing practices and allergen risk management controls, any additional advisory warning might be required to provide further risk communication to allergic consumers.

Advisory labelling for the unintentional presence of allergens should only be used when following a thorough risk assessment, there is a significant probability of allergen cross-contamination occurring at a level which poses an unacceptable risk to allergic consumers.

Where practical and feasible, manufacturing processes should be modified to minimise the probability and extent of cross-contamination. Approaches for application of advisory labelling need to be developed.

These stages of characterisation require information as to allergen presence in the recipe and in potential cross-contamination scenarios for all the allergens of concern to a significant level of detail. They also require a thorough understanding of the likelihood of cross-contamination, and demand evidence of the capability of manufacturing controls to remove/avoid cross-contaminating allergen presence.

The assessment described can also be used for internal audits of allergen controls as a formal validation form to support site specific HACCP programmes, for evaluations of current manufacturing practices and changes to them, for risk assessments when new allergen containing products are being introduced, and for evaluation of the impact of changes to existing products (e.g. changes in the allergen list) and changes to processes.

## 2. Stages of an Allergen HACCP Risk Analysis

### 2.1. Identify all allergens present on site

Aim: To identify allergen hazards that may be introduced by food or non-food materials, or by food contact, and to determine the control mechanisms for the identified hazards.

**2.1.1. Identify allergen presence from materials intentionally added to the finished product recipe (either ingredients, additives, processing aids, rework and holdover, etc.). Fully describe the name or type of material, for example, flour is wheat flour. List carriers for flavours, for example: lactose.**

- Do the allergenic derivatives contain allergenic protein?
- Are the allergenic derivatives particulates / pieces, or difficult to manage, e.g. sticky, oily?
- If so, assess whether procedures are capable of managing the risk of cross-contact.
- Do the identified allergens / allergenic derivatives require labelling on pack?
- Will the consumer expect the allergen presence in this product type i.e. is it "hidden"? If so, consider whether additional emphasis of allergen presence is required in risk communication.

**2.1.2. Identify potential opportunities for cross-contact within suppliers' operations (growing, harvesting, processing, storage, transportation)**

- Does your supplier risk assessment show likelihood of cross-contact and can it be quantified?
- Can your supplier's procedures manage out this risk (cleaning, scheduling, dedication)?

**2.1.3. Repeat the above for any allergenic derivatives that may be introduced via non-food/packaging materials (either packaging materials for raw materials, rework, holdover, finished product, or other materials which become contact materials during production or during consumer use).**

**2.1.4. Do this for every food and non-food material present on site, including raw materials and semi-finished ingredients.**

**2.2. Identify potential opportunities for cross-contact within own operations (handling, storage, production processes, packing).**

Aim: To identify the key areas in manufacturing where cross-contact between allergen-containing and non-allergen ingredients and products can occur, and identify likelihood of undeclared allergen presence in the finished product.

**2.2.1. List all the concerned products / processes / lines and their respective allergen profiles, all potential carry-overs, cross-contamination allergens and rework added to the processes / lines.**

- Assess and reference all relevant raw materials, semi-finished product and finished product specifications.
- A separate assessment is required for each allergen to ensure cross-contact between different allergenic ingredients is also addressed, not only that between allergenic and non-allergenic foodstuffs.

**2.2.2. Identify the areas where potential cross-contact may occur.**

- Shared storage, handling, mixing, transportation.
- Cross-over / spillage points.
- Shared cleaning equipment.
- Shared production / packaging equipment and lines.
- Airborne cross-contamination.

### 2.2.3. Construct an allergen cross-contact map for site.

- Relevant HACCP documents or forms may be used to assist.
- When constructing a map all ingredients, materials, rework, work in progress, processes and flow of people through manufacturing which may present a risk of allergen cross-contact should be considered.

### 2.3. Assess each potential issue identified in 2.2 against critical elements per the table in section 3 of this appendix for compliance with the best practice considerations and evaluate the probability for cross-contact as 'likely' or 'unlikely'.

Aim: To determine the probability that allergen cross-contact will occur and ensure the control measures used for the minimisation of the potential for cross-contact are practical and sufficiently robust to be effective. The rationale for the evaluation should be documented.

#### 2.3.1. Are best practice considerations in place? Are there opportunities to improve risk management practices?

#### 2.3.2. What is the probability of cross-contact occurring under normal operating conditions?

● Likely: likely under normal operating conditions.

● Unlikely: unlikely to arise but still possible.

### 2.4. Determine the allergen hazard rating of any identified allergen cross-contact presence.

Aim: To evaluate the severity of the risk identified. Taken together the amount of hazardous allergenic food potentially present, and the probability that they are present in the final product describe the overall level of risk requiring control.

When assessing risk associated with allergens there are several key parameters which will influence judgment regarding the severity: amount of allergen (in practice amount of allergenic protein) allergen potency and prevalence, and physical form of allergenic ingredients.

#### 2.4.1. Allergen potency and prevalence

Potency refers to the amount of allergenic food needed to provoke a reaction.

Prevalence relates to the number of individuals in the population who react to a specific allergen. Allergens which are known to provoke severe adverse reactions

upon consumption of very low amounts, and to which a significant number of consumers in Europe are allergic; have been identified by the European Food Safety Authority (EFSA) and the European Commission as requiring risk management through mandatory on-pack declarations. These are listed in EU labelling legislation and present a recognised risk of severe allergic reactions to European consumers which requires risk management.

Other countries outside the EU have different patterns of food allergy and therefore other / additional food allergens should be considered for those markets.

#### 2.4.2. Allergen Protein Presence

The protein component of the allergenic food is responsible for causing the reaction. Lower protein content = lower allergenic potential. Materials with levels of protein below analytical detection would therefore generally present low or very low risk potential.

Some allergenic derivatives have been exempted from mandatory allergen labelling on-pack on the basis of dossiers demonstrating the lack of allergic reactions upon food challenge with these derivatives. These are listed in EU labelling legislation.



Examples include highly refined oils derived from allergens such as refined soya bean oil, or highly processed allergen derivatives such as wheat maltodextrin. These all have extremely low protein concentrations, and therefore have low allergenic potential as demonstrated in clinical studies.

### 2.4.3. Physical Form of Allergenic Ingredients

Particulates and fragments (nuts, seeds, chunks, solid agglomerates etc.) will usually remain intact and could potentially appear as non-homogeneous (hot-spot) contamination. This will potentially deliver higher doses of contaminating allergenic material to the consumer. Readily dispersible contamination includes powders or liquids in homogeneous form e.g. milk powder, soya flour. These are likely to appear evenly distributed throughout a product. Therefore consideration needs to be given to the form of the cross-contaminating material and the form of the product e.g. powder into powder, powder into liquid or particulates into powder.

Therefore, the following risk potential ranking for the cross-contaminating material is suggested:



Determination of the possibility of particulate contamination should not automatically lead to a precautionary label. Assessment of the probability of such contamination, combined with the factors described in earlier sections, should be used to identify risk from the final product.

### 2.5. Determine whether appropriate control measures are currently in place or can be implemented to minimize the risk of allergen cross-contact.

This is referred to as risk management and determined through a process of monitoring, validation and verification.

Validation work should be carried out and documented for each control measure/combination of control measures. Cleaning is a commonly applied control measure as it usually provides the break between allergen-containing and non-allergen-containing products. If the control measure has been implemented previously, the results from this historical work can be used as an input into the validation study. Guidance on undertaking a cleaning validation study is set out in appendix 6.

It should be recognised that ongoing verification of control measures will still need to be undertaken, after allergen risk assessment has been completed and the requirements implemented, using a variety of methods to ensure it is working effectively in practice. This may include audit, data analysis and review, or additional sampling and testing.

**2.5.1. Identify control measures in place to manage allergen cross-contamination using critical elements in Table 2 as a best practice guide.**

**2.5.2. Confirm effectiveness of control measures assigned for minimising risk of cross-contamination through robust scientific validation.**

**2.5.3. Confirm ongoing verification procedures in place to assure allergen risk management practices are carried out and remain effective.**



## 2.6. Determine risk communication requirements to identify any intentionally present and unintentionally present allergens for the consumer.

Aim: To provide the necessary information to consumers to allow avoidance of products containing allergens.

2.6.1. What should be mandatorily labelled in the ingredients declaration on finished product pack?

2.6.2. Are any additional advisory warnings of unintended presence needed? If so, for which allergens?

For further details on labelling requirements see Annex 3 and 6.



# 3. Allergen Risk Analysis

In table 2A below the critical elements are described that should be addressed during an allergen HACCP risk analysis and that should be included in allergen risk management programmes. Best practice considerations are detailed, based on common causes of allergen risk management failures, and thus the table may serve as the basis for a checklist, which can be used by food operators to verify the capability of their allergen risk management programme.

It should be noted that the use of the table is not a substitute for expert judgement based on sound information and experience, but rather a guide for structuring risk assessments. The table should not be used alone as an exhaustive list. Unique criteria will also exist relevant to each product, production process, line, and site and these must also be considered.

### Example of a risk assessment (Critical Element: Manufacturing)

Best Practice Consideration	Cross-contact Probability		Rationale for Cross-contact Probability	Allergen Hazard Rating	Control Measures
	Likely	Unlikely			
Contamination of adjacent lines by cleaning regime	X		Compressed air used for cleaning	Peanut pieces - High Refined soya oil - Low	Cleaning regime changed, no compressed air used. Advisory labelling not required

**Table 2A Critical elements for HACCP Risk Analysis and Risk Management**

BEST PRACTICE CONSIDERATION	Cross-contact Probability Likely   Unlikely	Rationale for Cross-contact Probability	Allergen Hazard Rating	Control Measures
<b>1. Critical Element: People</b>				
<p><b>All employees are trained to understand the site program(s) concerning allergen controls:</b></p> <ul style="list-style-type: none"> <li>• New hires receive allergen training</li> <li>• Employees receive job specific allergen training annually at minimum</li> <li>• Training program includes, but is not limited to</li> <li>• Employees allergen knowledge / skills is evaluated and verified</li> <li>• Training records are documented; all records are up to date</li> </ul> <p>Those employees are identified who missed required training. Follow-up is in place to assure training will be completed</p>				
<p><b>Project and site engineers, maintenance, and Quality representatives have been trained in hygienic design for designing equipment capable of effective allergen management &amp; cleaning (incl. equipment modification and controls). Training is documented</b></p>				
<p><b>Visitors and contractors receive allergen training related to traffic patterns, controls, and restrictions (as appropriate)</b></p>				
<p><b>Capable, accountable people to check accuracy and context of in-coming materials documentation</b></p>				
<p><b>Capable, accountable people to manage start and end-run line checks and recording</b></p>				
<p><b>Minimized people traffic between segregated areas/ zones</b></p>				
<p><b>Independent supervision of compliance to segregation and cleaning procedures</b></p>				
<p><b>Sampling Equipment for Quality Checks is dedicated or a validated cleaning program is in place</b></p>				
<p><b>Understanding of impact of all critical elements to manage allergens</b></p>				
<b>2. Critical Element: Suppliers (including 3rd Party Contract Manufacturing)</b>				
<p><b>Vendor assurance / audit specifically for allergen controls</b></p>				
<p><b>Allergen risk assessment based on all critical elements for each supplier's line and site available</b></p>				

BEST PRACTICE CONSIDERATION	Cross-contact Probability Likely   Unlikely		Rationale for Cross-contact Probability	Allergen Hazard Rating	Control Measures
<b>Audit approval process includes allergen management capability</b>					
<b>Effective communication business to business such a contracting, material specifications / bill of materials &amp; change management includes information for allergens</b>					
<b>Allergen awareness of impact on consumer safety, specifically including regulatory allergen list</b>					
<b>Supplier specifications includes</b> <ul style="list-style-type: none"> <li>• Correct information from supplier for intentionally present allergenic derivatives and cross contamination risks</li> <li>• Transparency of allergenic ingredients in compound ingredients</li> <li>• Declaration of processing aids containing allergens</li> <li>• Declaration of regulatory list of allergens if coming from outside the country or region</li> <li>• Effective version control (e.g. out of date supplier specification in use)</li> <li>• Good understanding of the meaning of the supplier information (e.g. whey protein / milk)</li> </ul>					
<b>Packaging suppliers using accurate information for printing</b>					
<b>Printing legible with good colour control</b>					
<b>Version control is in place in case multiple suppliers are used for same materials</b>					
<b>Bulk delivery and container handling: transport units are dedicated or validated cleaning protocol is in place</b>					
<b>3. Critical Element: Raw Material Handling</b>					
<b>Upon receipt, allergenic ingredients are identified and labelled for identification (e.g. coloured labels)</b>					
<b>Allergens are segregated from non-allergens and from each other in receiving warehouse facilities:</b> <ul style="list-style-type: none"> <li>• Area is visibly designated</li> <li>• Allergens are stored below non-allergens</li> <li>• No open allergen ingredient storage</li> </ul>					
<b>Allergen identification and traceability is in place from receipt to labelled finished product, incl. ingredients, part-finished product, work-in-progress &amp; hold over</b>					

BEST PRACTICE CONSIDERATION	Cross-contact Probability Likely   Unlikely	Rationale for Cross-contact Probability	Allergen Hazard Rating	Control Measures
<p><b>Bulk materials</b></p> <ul style="list-style-type: none"> <li>• Are contained and tracked</li> <li>• Have isolated weighing, transfer systems and tools</li> <li>• Appropriate controls are in place, if shared systems exist, e.g. validated cleaning protocols</li> </ul> <hr/> <p><b>Allergens packaged in single containers (pails, drums, bags/sacks):</b></p> <ul style="list-style-type: none"> <li>• Containers are not reused in other production areas or validated cleaning procedures are in place</li> <li>• Containers for recycling /waste are transported and stored properly</li> </ul>				

**4. Critical Element: Equipment and Factory Design**

<p><b>The plant layout allows for sufficient physical separation between lines and areas ("zoning")</b></p>				
<p><b>Good hygienic design of equipment to ensure capable of effective allergen management and cleaning</b></p>				
<p><b>Adequate barriers in place to prevent cross-contact through spillage, cross-over or dusting</b></p>				
<p><b>Airflow control</b></p> <ul style="list-style-type: none"> <li>• Air flow is appropriate to prevent airborne contamination (dust) from allergen zones to non/other allergen areas</li> <li>• Fans are not directed from allergen zones to non/other allergen areas</li> </ul>				
<p><b>Disposable parts, such as cloth belts and sleeves, are used for food contact material that is not cleanable. These parts are changed as a part of the allergen changeover procedure</b></p>				
<p><b>Conveyors, like open vibrators or conveyors crossing over other conveyors, will not pose any risk for cross contamination</b></p>				
<p><b>An engineering design review process relative to allergen controls is in place for new/modified equipment and equipment maintenance</b></p> <ul style="list-style-type: none"> <li>• Cleanability and accessibility of the line for cleaning and inspection is assessed as a part of the review</li> <li>• Line &amp; factory layout &amp; usage assessed for allergen management</li> </ul>				



**BEST PRACTICE  
CONSIDERATION**

Cross-contact  
Probability  
Likely | Unlikely

Rationale for  
Cross-contact  
Probability

Allergen  
Hazard  
Rating

Control  
Measures

**5. Critical Element: Manufacturing**

**Risk assessment and subsequent risk management to control introduction of new allergens into plant considering different approaches for discrete "hot-spot" (particulates) and homogeneous sources of allergens**

**Risk assessment and subsequent risk management to control introduction of new engineering / equipment into plant**

**Where possible, separation in preparation areas, and for work-in-progress**

**If equipment is shared an effective and validated cleaning/product flush regime is in place (including totes, tanks, containers, rework handling equipment, equipment for cleaning etc.):**

- Written procedures, effective cleaning standards to be achieved inclusively
- Individuals accountable for each cleaning activity and task are identified
- Appropriate CCP's/PP's validated on a regular basis (e.g. every 2 years)
- Finished product is put on hold until CCP verification or validation is completed
- Documented post-clean / pre-operational inspections, signed off
- Inspections completed by a person other than the person responsible for cleaning (independent inspection)
- Cleaning equipment and utensils are not a source of contamination
- Cleaning regime will not contaminate adjacent lines (e.g. no compressed air)
- Effective waste / cleaning equipment removal procedures
- Utensils and cleaning tools are effective and controlled (cleaned or dedicated)
- Sufficient cleaning equipment and time for cleaning

**Scheduling**

- Documented production matrix to assure appropriate production order (sequencing) to minimise opportunities for carry over
- Appropriate change management process for the production matrix

**Work In Process (WIP), Locally Manufactured Ingredient (LMI), Rework**

- Each unit (pallet, drum, tote, etc.) identified (product description, declared allergen and date of manufacture or other lot identification) for full traceability

BEST PRACTICE CONSIDERATION	Cross-contact Probability Likely   Unlikely	Rationale for Cross-contact Probability	Allergen Hazard Rating	Control Measures
<ul style="list-style-type: none"> <li>• Tracked, inventoried and reconciled</li> <li>• WIP / Rework is handled as only like into like (rework matrix)</li> <li>• Only brought back to the line when scheduled</li> <li>• All processes are included in the allergen cleaning/-flushing program (including the line, storage containers, mobile equipment, utensils, cleaning tools, etc.)</li> <li>• Containers/totes used for packaged finished product for re-packing are labelled with the product description describing the allergens and lot code/date</li> <li>• Old labels used for containers/totes are taken off prior to filling</li> </ul> <p>-----</p> <p><b>Animal feed and waste containers with allergens are handled and stored appropriately</b></p> <p>-----</p> <p><b>Unpackaged, exposed product is handled in a way that it is protected against allergen cross contact</b></p> <p>-----</p> <p><b>If there is allergen and non-allergen product mixed, there is a written procedure for disposal as:</b></p> <ul style="list-style-type: none"> <li>• Waste</li> <li>• Animal feed</li> <li>• Rework</li> </ul> <p>-----</p> <p><b>Procedures to control re-packing are in place</b></p> <p>-----</p> <p><b>Packaging Management</b></p> <ul style="list-style-type: none"> <li>• Measures are in place (e.g. scanners) To detect mixed packaging or labels received from suppliers and to assure finished products are appropriately labelled</li> <li>• Adequate job aids at the line to allow interpretation of foreign language packaging</li> <li>• Documented procedures are in place to assure packaging material mismatch is avoided after change over and during storage (e.g. no mixing of material on a pallet, no storing of multiple packaging types on the line, operators completely remove packaging and labels from the line during changeover)</li> </ul>				
<b>6. Critical Element: Consumer Information</b>				
<p><b>Packages which contain allergens are easily identifiable on site from those which:</b></p> <ul style="list-style-type: none"> <li>• do NOT contain allergens</li> <li>• contain OTHER allergens</li> </ul> <p>-----</p> <p><b>Labelling identifies each allergen individually i.e. hazelnut, cashew nut, soya, milk, wheat, barley</b></p>				

BEST PRACTICE CONSIDERATION	Cross-contact Probability Likely   Unlikely	Rationale for Cross-contact Probability	Allergen Hazard Rating	Control Measures
Allergen label reflects 'worst-case' allergen labelling, if same product is produced in multiple manufacturing sites, and/or if sold in multiple markets due to consumer brand recognition				
Appropriate allergen reference list is used (in the EU per Directive 2000/13/EC and its most recent amendments)				
Appropriate processes linking specification and artwork systems ensuring correct information is transferred from the recipe and/or outcome of a risk assessment to the artwork				
Inner wrap is consistent with outer wrap (where inner wrap contains allergen information)				
Consistency between languages, if multi-lingual packs are produced				
If an "allergen box" is used, consistently between ingredient list and allergen box				
<b>7. Critical Element: Product Development &amp; Change</b>				
Risk management upon introduction of new allergens into plant (new product or factory trial)				
Risk management upon introduction of new process / equipment into plant (new production platform or line)				
Minimising allergens through product recipe design				
Understanding of 'hidden allergens' (e.g. Tahini / sesame, barley malt extract / gluten)				
Risk assessed use of shared lines, utensils and packaging materials for trials				
<b>Critical Element: Documentation</b>				
Allergens are listed on the HACCP forms and correctly described				
Allergens listed on the HACCP plans are listed on <ul style="list-style-type: none"> <li>• Specifications (ingredients, finished product, product label) and product formulations</li> <li>• Batch cards/sheets</li> </ul>				
HACCP plans are available for <ul style="list-style-type: none"> <li>• Plant trials</li> <li>• Sales samples</li> <li>• Commercial runs</li> </ul>				

## 4. Considerations for Risk Prevention

Following an analysis of food allergy incidents, the most common causes of allergen risk management failure are considered to be (i) intended product in intended pack that is wrongly labelled (ii) mismatch of product to packaging, and (iii) unintentional presence of allergen in product.

The checklists below in Table 2B are provided to act as a guide for food operators to verify that the likely causes of these failures are considered and controlled within their allergen risk management programme. They can also be used to support root cause analysis in the event of a food allergy incident.



Potential Issue	Critical Preventative Element	BEST PRACTICE CONSIDERATIONS
<p><b>Intended product in intended pack that is wrongly labelled</b></p>	<p><b>Information in the product specification</b></p>	<p>Correct information from supplier for intentionally present allergenic derivatives and cross contamination risks</p> <p>-----</p> <p>Good understanding of the meaning of the supplier information (e.g. whey protein / milk)</p> <p>-----</p> <p>Effective version control (e.g. out of date supplier specification in use)</p> <p>-----</p> <p>Correct information transfer to recipe information / bill of materials (BOM)</p> <p>-----</p> <p>Transparency of allergenic ingredients in compound ingredients</p> <p>-----</p> <p>Declaration of processing aids containing allergens</p> <p>-----</p> <p>Risk assessment for every manufacturing line regarding allergen cross-contamination</p> <p>-----</p> <p>Allergen change management for products made on different lines</p> <p>-----</p> <p>Allergen label reflects 'worst-case' allergen labelling across manufacturing sites if sold in multiple markets due to consumer brand recognition</p> <p>-----</p> <p>Risk assessment of the need to carry-over of allergen warning from supplier to product</p> <p>-----</p> <p>Allergen change management for recipe, ingredients or product procedure</p> <p>-----</p> <p>Check ingredient substitution for impact on allergen profile</p> <p>-----</p> <p>EU allergen reference list used</p> <p>-----</p> <p>Supplier or finished product specification complete and available</p> <p>-----</p> <p>Accountable person to sense check and approve BOM, recipe &amp; specification</p>
	<p><b>Allergen information transfer to artwork / websites or other media</b></p>	<p>Capable, accountable person to sense check accuracy and context</p> <p>-----</p> <p>Specification changes drive artwork changes</p> <p>-----</p> <p>Specification and artwork systems linked and sense checked</p> <p>-----</p> <p>Correct information transferred from the recipe to the artwork</p> <p>-----</p> <p>Multi-lingual packs - accuracy of allergen name, right word used, consistency between languages</p> <p>-----</p> <p>Allergen information in ingredients list correctly highlighted or replicated in any 'Contains' box if used</p> <p>-----</p> <p>Inner wrap consistent with outer wrap</p> <p>-----</p> <p>Market pack / multiple variants consistent with web site</p>
	<p><b>Supplier printing</b></p>	<p>Use of up- to -date drums / cylinders or plates</p> <p>-----</p> <p>Accurate plate generation</p> <p>-----</p> <p>Good plate maintenance</p>



Potential Issue	Critical Preventative Element	BEST PRACTICE CONSIDERATIONS
<p><b>Intended product in intended pack that is wrongly labelled</b></p>	<p><b>Supplier printing</b></p> <hr/> <p><b>Consumer access to information</b></p>	<p>Printing colour control for pack and text  -----  Version control between multiple suppliers for same materials  -----</p> <p>Good legibility, taking into account colour contrast, format &amp; size of font  -----  Good registration (cutter guides)  -----  Good print &amp; packaging quality  -----  Emphasised allergen information  -----  Consistency of labelling between pack, website, media  -----</p>
<p><b>Mismatch of product to packaging</b></p>	<p><b>Packaging management</b></p>	<p>Right packaging brought to the line  -----  No wrong packaging remaining after change over  -----  Named person accountable for record keeping &amp; documentation  -----  Clearly distinct packaging for different products to avoid confusion  -----  Avoid mixing of packaging on a pallet  -----  Specific job aids on the line to allow interpretation of foreign language packaging  -----  Avoid storing multiple packaging types on the line  -----  Consistency in allergen colour coding packs during manufacture  -----  Clear and accurate pallet labelling &amp; warehouse control for allergens  -----  Adequate lighting in work area  -----  Segregation of packaging types as received from suppliers  -----  Management of partially used packaging  -----  Capable repacking control to manage allergens  -----  Adequate control of multi-component product packaging  -----  Adequate control of multi-pack inner and outer wraps  -----  Risk assessed use of existing packaging for trials  -----  Awareness of colour blindness impacting correct packaging selection  -----  Capable start and end-run line checks and recording  -----  Change-over management for allergens  -----  Capable training on allergen awareness  -----  Attentive supervision  -----  Removal of out of date packaging  -----</p>

Potential Issue	Critical Preventative Element	BEST PRACTICE CONSIDERATIONS
<b>Mismatch of product to packaging</b>	<b>Production management</b>	<p>Appropriate use of WIP on line</p> <p>Correct raw materials used or added to WIP</p> <p>Accurate and clear labelling of materials</p> <p>Procedures to control return of part-used materials to line</p> <p>Changeover management for allergens</p> <p>Procedures to control re-packing</p>
<b>Unintentional presence of allergen in product</b>	<b>Cleaning</b>	<p>Identify what should be cleaned</p> <p>Define effective cleaning standards to be achieved</p> <p>Document procedures for effective cleaning</p> <p>Validate cleaning procedures</p> <p>Identify accountable individuals for each activity and task</p> <p>Sign off for completion of cleaning</p> <p>Independent supervision to verify compliance</p> <p>Effective cleaning equipment and process</p> <p>Cleaning equipment always decontaminated after use</p> <p>Dedicated tools &amp; equipment</p> <p>Sufficient training</p> <p>Sufficient cleaning equipment</p> <p>Good hygienic design of plant and equipment to enable cleaning</p> <p>Clean work wear</p> <p>Effective waste / cleaning equipment removal procedures</p>
	<b>Segregation</b>	<p>Good plant layout</p> <p>Adequate physical barriers to separate allergens</p> <p>Adequate spatial separation to separate allergens</p> <p>Scheduling to minimise opportunities for carryover</p> <p>Allow sufficient time for cleaning</p> <p>Scheduling on manufacturing order</p> <p>Separation in warehouse</p> <p>Separation in preparation areas</p> <p>Separation of work-in-progress (WIP) or rework</p>

Potential Issue	Critical Preventative Element	BEST PRACTICE CONSIDERATIONS
<p><b>Unintentional presence of allergen in product</b></p>	<p><b>Segregation</b></p>	<p>Separation &amp; movement control of people</p> <p>Airflow control</p> <p>Procedures to prevent transfer of allergens from staff facilities to plant</p> <p>Changeover management between production runs</p> <p>Risk management upon introduction of new allergens into plant (new product or factory trial)</p>
	<p><b>Allergen awareness &amp; training</b></p>	<p>'Free-from' claims must match validated capability</p> <p>Line &amp; factory layout &amp; usage assessed for allergen management</p> <p>Impact of particulate sources of allergens is well managed</p> <p>Minimising allergens through product recipe design</p> <p>Designing equipment capable of effective allergen management &amp; cleaning</p> <p>Understanding of EU allergen list</p> <p>Understanding of 'hidden allergens' (e.g. Tahini / sesame, barley malt extract / gluten)</p> <p>Understanding of impact of processing aids as sources of allergens</p> <p>Understanding of segregation of allergens within allergen storage area</p>
	<p><b>Supplier Management - Ingredients</b></p>	<p>All of above are relevant for this section and:</p> <p>Vendor assurance / audit specifically for allergens control</p> <p>Allergen risk assessment for each supplier's line and site</p> <p>Audit approval process includes allergen management capability</p> <p>Contracting &amp; change management for allergens</p> <p>Supplier specifications include allergen information</p> <p>Effective communication business to business</p> <p>Consistent allergen controls across supply chain including third party contract manufacturing</p> <p>Allergen awareness of impact on consumer safety, specifically including EU allergen list</p>



# Annex 3

## Allergen Labelling



Regulation (EU) 1169/2011<sup>1</sup> on the provision of food information to consumers considerably changes existing legislation on food labelling, including information and requirements on allergens. The new rules will apply from 13 December 2014.

The Regulation outlines requirements relating to allergens such as mandatory particulars, the labelling of certain substances or products causing allergies and intolerances, additional voluntary information and allergen labelling of non-pre-packed foods.

## Summary

Substances or products causing allergies **must** be indicated, also for non-prepacked foods; Each ingredient or processing aid originating from a substance or product causing allergies or intolerances must be:

### **- Indicated in the list of ingredients with reference to the name of the substance or product as listed in Annex II;**

- Emphasised through a typeset that distinguishes it from the rest of the list of ingredients;

If no list of ingredients is provided, the substance or product causing allergies or intolerances **must** be indicated by means of “contains + [substance(s)/ product(s)]”.

When the name of the food clearly refers to the substance or product causing allergies or intolerances, it is not necessary to label the concerned substance or product.

- The European Commission **must** systematically re-examine and, where necessary, update the list of substances or products causing allergies or intolerances.
- The European Commission **must** establish implementing measures on the additional voluntary “may contain” labelling.

The following articles are relevant for allergen labelling<sup>2</sup>:

- Article 9.1(c): Mandatory particulars
- Article 21: Labelling of certain substances or products causing allergies or intolerances
- Article 36.3(a): Additional voluntary allergen labelling (“may contain”)
- Article 44.1(a) and 44.2: Allergen labelling of non pre-packed foods
- Annex II: List of substances or products causing allergies or intolerances

<sup>1</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

<sup>2</sup> For ease of reference, allergen labelling in this document refers to the labelling of substances or products causing allergies or intolerances.

## Article 9.1(c): Mandatory particulars

*In accordance with Articles 10 to 35 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory:*

[...]

*(c) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;*

[...]

Food business operators **must** label any ingredient or processing aid:

- listed in Annex II; or
- derived from a substance or product listed in Annex II

The list of Annex II is outlined in Annex 3 to this Guidance. Labelling of these ingredients, processing aids, substances or products causing allergies or intolerances is obligatory when they are used in the manufacture or preparation of a food and are still present in the finished product, even if in an altered form.

Further rules on how to label are specified in Article 21.

## Article 21: Labelling of certain substances or products causing allergies or intolerances

Article 21 is the main article covering allergen labelling.

It is structured as follows:

- **21.1: Presentation of the labelling of certain substances or products causing allergies or intolerances**
- **21.2: Systematic re-examination and possible update of the list of substances or products causing allergies or intolerances**

### 21.1: PRESENTATION OF THE LABELLING OF CERTAIN SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

*Without prejudice to the rules adopted under Article 44(2), the particulars referred to in point (c) of Article 9(1) shall meet the following requirements:*

Food business operators **must** indicate the substances or products causing allergies or intolerances in the way specified in the following sub-paragraphs.

Where specific national measures have been introduced by individual Member States on non-pre-packed foods with regard to the form of expression and presentation of the allergens that have to be provided on a mandatory basis (Art. 44.2), these precede over the requirements of Article 21.

*(a) they shall be indicated in the list of ingredients in accordance with the rules laid down in Article 18(1), with a clear reference to the name of the substance or product as listed in Annex II; and*

The ingredients that according to the Annex II of the Regulation are substances or products causing allergies or intolerances **must** be indicated in the list of ingredients “with a clear reference to the name of the substance or product as listed in Annex II”. Hence, there are no changes in this respect compared to the current allergen labelling situation in Directive 2000/13/EC.

*(b) the name of the substance or product as listed in Annex II shall be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour.*

The name **must** be emphasised through a typeset different than that from the rest of the list of ingredients, for example by means of the font, style or background colour.

Emphasis may best be achieved by indicating the ingredients concerned in **bold** in the list of ingredients. However, food business operators may use other ways of emphasis, amongst others, for reasons of technical feasibility, be it those mentioned in the provision (font, style, background colour) or others.

*In the absence of a list of ingredients, the indication of the particulars referred to in point (c) of Article 9(1) shall comprise the word 'contains' followed by the name of the substance or product as listed in Annex II.*

When no list of ingredients is given (e.g. for glass bottles intended for reuse which are indelibly marked and which therefore bear no label, ring or collar), the word "contains" followed by the name of the substance or product causing allergies or intolerances **must** be indicated.

*Where several ingredients or processing aids of a food originate from a single substance or product listed in Annex II, the labelling shall make it clear for each ingredient or processing aid concerned.*

Where the food contains several ingredients or processing aids that originate from one substance or product causing allergies or intolerances, the operator **must** either repeat the reference to the substance or product as many times as it is present or choose any other presentation which makes clear that different ingredients or processing aids originate from one single allergen.

*The indication of the particulars referred to in point (c) of Article 9(1) shall not be required in cases where the name of the food clearly refers to the substance or product concerned.*

In those cases where the name of the food clearly refers to the substance or product causing allergies or intolerances, it is not required to label the concerned substances or products.

#### Examples:

- **Strawberry-flavoured soy drink, where soy lecithin is used in the flavour;**
- **Wheat flour;**
- **All dairy products, e.g. cheese, yoghurt, cream, butter, as it is clear that they are derived from milk (see Annex XII and XIII of Reg. 1234/2007 for further explanation on the definition and designation of dairy products);**
- **Tuna paté.**

Furthermore, in those cases where the name of the ingredient clearly refers to the substance or product causing allergies or intolerances, it is also not required to label the concerned substances or products. The name of the food is the legal name of the food as determined in Article 9.1(a) and Article 17. For example, when the name of the food contains words such as yoghurt, cream, butter, cheese etc., it is clear for the consumer that these products contain milk.

#### **21.2: SYSTEMATIC RE-EXAMINATION AND POSSIBLE UPDATE OF THE LIST OF SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES**

In order to ensure better information for consumers and to take account of the most recent scientific progress and technical knowledge, the Commission shall systematically re-examine and, where necessary, update the list in Annex II by means of delegated acts, in accordance with Article 51.

The European Commission **must** systematically re-examine and, where necessary, update the list of substances or products causing allergies or intolerances.

Here, it needs to take into account:

- the objective of ensuring better information for consumers; and
- the most recent scientific progress and technical knowledge, supported by an EFSA Opinion.

**Where, in the case of the emergence of a risk to consumers' health, imperative grounds of urgency so require, the procedure provided for in Article 52 shall apply to delegated acts adopted pursuant to this Article.**

If there is an urgent need due to emergence of a risk to consumers' health, the urgency procedure must be applied. This means that the European Commission is able to adopt a delegated act in relation to Article 21 without delay, as long as no objection is expressed by the European Parliament or the Council.

### **Article 36.3(a): Additional voluntary allergen labelling ("may contain" – information on the possible and unintentional presence of substances or products causing allergies or intolerances)**

Article 36 covers the applicable requirements for voluntary food information and the implementing measures that the European Commission needs to take on the application of the requirements.

First, Article 36.2 covers the general requirements that voluntary food information **must** meet:

**Food information provided on a voluntary basis shall meet the following requirements:**

**(a) it shall not mislead the consumer, as referred to in Article 7;**

**(b) it shall not be ambiguous or confusing for the consumer; and**

**(c) it shall, where appropriate, be based on the relevant scientific data.**

*Then, Article 36.3 covers the implementing measures that the European Commission must adopt in order to facilitate the application of these requirements:*

**The Commission shall adopt implementing acts on the application of the requirements referred to in paragraph 2 of this Article to the following voluntary food information:**

**(a) information on the possible and unintentional presence in food of substances or products causing allergies or intolerances;**

**[...]**

*According to Article 36.3(a), the European Commission must adopt implementing measures detailing the application of the requirements related to voluntary information on "may contain" labelling (i.e. the possible and unintentional presence in food of substances or products causing allergies or intolerances). FoodDrinkEurope supports the development of European guidance related to "may contain" labelling.*

## Article 44.1(a) and 44.2: allergen labelling of non pre-packed foods

Article 44 covers national measures for non-pre-packed foods.

**1. Where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or pre-packed for direct sale:**

**(a) the provision of the particulars specified in point (c) of Article 9(1) is mandatory;**

**(b) the provision of other particulars referred to in Articles 9 and 10 is not mandatory unless Member States adopt national measures requiring the provision of some or all of those particulars or elements of those particulars.**

*Of particular relevance for allergen labelling is Article 44.1(a), which specifies that information concerning allergens must be available for non-prepacked foods.*

**2. Member States may adopt national measures concerning the means through which the particulars or elements of those particulars specified in paragraph 1 are to be made available and, where appropriate, their form of expression and presentation.**

*Paragraph 2 of Art. 44 indicates that Member States may adopt national rules concerning the means of communicating the particulars such as the allergen declaration (e.g. leaflet, website, etc.) and their form of expression and presentation.*



## Annex II of Regulation (EU) 1169/2011: List of Allergens and Exemptions

It is important that information on the presence of foods proven to produce an adverse allergenic or intolerance reaction should be available for sensitive consumers, to make informed choices which are safe for them. The list of allergenic foods and foods causing intolerance which require mandatory declaration in the EU is found in Annex II of Regulation (EU) No 1169/2011, see below. Labelling of these ingredients, processing aids,

substances or products causing allergies or intolerances is obligatory when they are used in the manufacture or preparation of a food and are still present in the finished product, even if in an altered form.

Note: This list will be systematically re-examined and, where necessary, updated taking into account the objective of better information for consumers and the most recent scientific progress and technical knowledge.

### **1 Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except:**

- (a) wheat based glucose syrups including dextrose<sup>1</sup>;
- (b) wheat based maltodextrins<sup>1</sup>;
- (c) glucose syrups based on barley;
- (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin.

### **2 Crustaceans and products thereof;**

### **3 Eggs and products thereof;**

### **4 Fish and products thereof, except:**

- (a) fish gelatine used as carrier for vitamin or carotenoid preparations;
- (b) fish gelatine or Isinglass used as fining agent in beer and wine.

### **5 Peanuts and products thereof;**

### **6 Soybeans and products thereof, except:**

- (a) fully refined soybean oil and fat<sup>1</sup>;
- (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
- (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
- (d) plant stanol ester produced from vegetable oil sterols from soybean sources.

### **7 Milk and products thereof (including lactose), except:**

- (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
- (b) lactitol.

### **8 Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;**

### **9 Celery and products thereof;**

### **10 Mustard and products thereof;**

### **11 Sesame seeds and products thereof;**

### **12 Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO<sub>2</sub> which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;**

### **13 Lupin and products thereof;**

### **14 Molluscs and products thereof.**

<sup>1</sup> And the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated.





# Annex 4

## Allergen Change Over (Cleaning/Flushing) Validation

## Purpose

This annex provides guidance on how to validate change-over practices (cleaning, flushing) where allergens and non-allergens products are produced on common food manufacturing equipment and to determine quantitatively the level of carryover in order to assess and, if necessary, mitigate the resulting risk.

## Definitions

**Validation:** Confirmation by examination and through provision of objective evidence that the allergen change-over is effective.

**Verification:** Confirmation by examination and through the provision of objective evidence that the requirements of the allergen change-over are applied at all times.

## General Considerations for Designing a Validation Study

The determination of carryover levels from a product which contains an allergen to another one is critical for quantitative assessments of allergen risks. A validation study should be completed to confirm that the changeover practices occurring between recipes which contain a specific allergen and those which do not are effective to control the risk.

A qualitative risk assessment is recommended as a starting point, followed by a semi-quantitative one in order to determine whether or not an analytically based validation study is required or applicable. For example, it may be possible to estimate levels of allergen carryover from one production run to another by 'worst-case scenario calculations' i.e. measuring how much material is left behind in a process (e.g. based on film thickness on equipment or weighing brushed out residual), what the levels of such material would be after dilution with the next product (or in the next process step), what amount of the material is allergen and therefore allergen levels in the final product that could be consumed.

Validation typically consists of a visual inspection (physical validation) of accessible direct and indirect food contact surfaces and quantitative analytical testing using appropriate methods, such as ELISA, and protocols (analytical validation). Rapid lateral-flow devices testing may be used to support verification, but are not appropriate tools for validation (see annex 5).

If an analytical study is required, accurate and robust analytical results are only useful if the samples analysed have been taken as part of a correctly designed study. Therefore, the sampling procedures and subsequent analyses shall be appropriately selected and implemented.

For conducting the validation at a manufacturing line the "worst case" scenario should be chosen, i.e. the most difficult to clean recipe and the recipe with the highest concentration of the allergen used on that line, followed by a recipe which does not contain the allergen (marker protein).

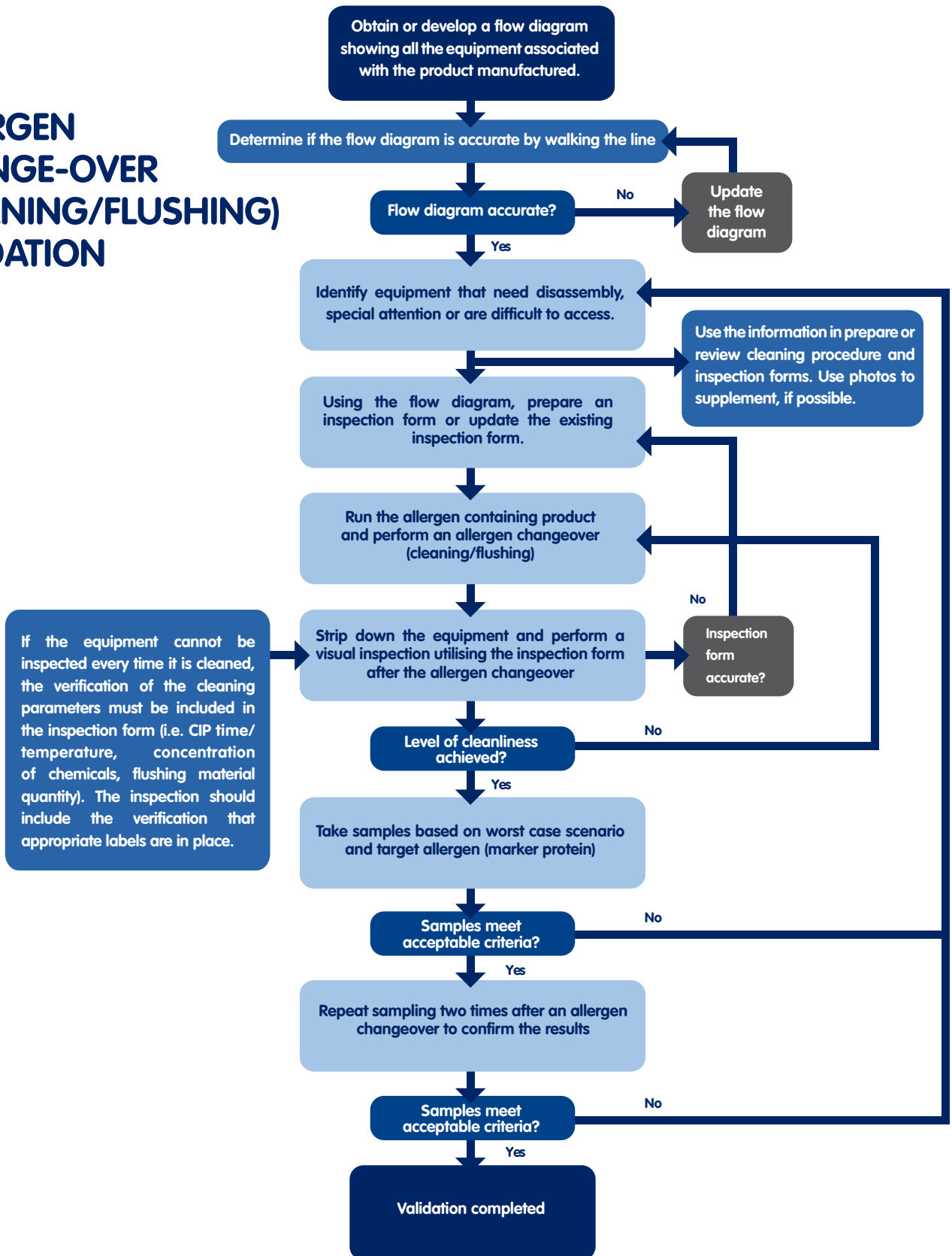
When no commercial test kit for the analytical validation is available and no other marker protein can be used, allergen line validations should follow the visual inspection protocol only and then comply with the visibly-clean Standard.

Heterogeneously distributed contamination (for example, pieces of nuts) might not be sufficiently captured by sampling depending on the size of particulates and thus analytical testing might not provide reliable data. In such cases, visual inspection and confirmation that the visibly clean Standard is met (no product residue) should be considered as the only pass criteria for a successful validation study.

The validation should be considered part of the plants' HACCP programme and repeated on a regular basis (for example, every two years), and if changes in formulation, process, equipment or change-over procedure occur. The documentation should be maintained at each manufacturing location.

Validation of all individual lines might not be necessary, if they are essentially of the same design. Different lines might need to be assessed individually depending on the nature of the differences in the design and how these will affect cleaning and carryover effectiveness.

## ALLERGEN CHANGE-OVER (CLEANING/FLUSHING) VALIDATION





# I Guideline for Physical Validation

**1.** A flow diagram showing all equipment associated with the process used to manufacture product on a production line should be developed. Equipment that comes in direct contact with allergens as an ingredient or finished product should be highlighted. Components through which product or ingredients do not flow, but where material can accumulate must be included (e.g. vacuum filters in pneumatic transport systems). Highlighted areas should receive a detailed allergen cleaning and a visual inspection or a cleaning combined with flushing where areas exist, which cannot be accessed for cleaning and inspection. By utilising the flow diagram, a walkthrough of the production line during the cleaning process (with cleaning procedure) with employees knowledgeable about the cleaning and manufacturing process should be undertaken to ensure completeness.

**2.** Equipment that will need disassembly, special attention, or access to be cleaned and where sampling for the analytical validation shall be done should be identified and made note of. Specific steps or actions needed to effectively clean the line must be included in the change-over procedure. Photographs of the identified difficult to clean or access

areas may be used for training purposes and placement in the cleaning procedure as appropriate.

**3.** Existing documentation, like cleaning procedures (including specific instructions for disassembly), pre-operation check sheets, HACCP check sheets, post cleaning check sheets, should be updated by utilising the information gathered above.

**4.** The updated detailed pre-operation inspection sheet should be validated by a physical walk through of the line, with trained employees who are knowledgeable about manufacturing, quality and the allergen change over process. Corrections should be made as needed in the pre-operation form to account for any learning.

**5.** Relevant cleaning parameters should be documented in the cleaning procedure to assure removal of allergens and this should be considered as part of the cleaning protocol needed for an effective allergen clean (e.g. caustic wash at 2 % v/v, 75°C, for 10 minutes). When the equipment cannot be inspected after cleaning, adherence to these parameters should be verified after each cleaning, for example, for complex CIP (clean in place) installations.

**6.** Once the physical validation is complete, the cleaning protocol and pre-operation checklist should be used for each allergen changeover.

**7.** If validated commercial allergen test kits are available for the allergen(s) (marker protein), the analytical validation step as described in Section II should follow.

## II Guideline for Analytical Validation

**1.** The validation sampling should meet acceptable criteria for three (3) consecutive runs. In the absence of operational actions limits (e.g. VITAL) for the specific allergen all test results should be less than the limit of quantification (LOQ) of the specific validated, quantitative test method.

**2.** If contamination is deemed to be non-homogeneous the number of samples per validation should be increased to maximise to probability of detecting residual contamination. This may include a combination of swabbing and product/flushing mass testing. If the physical constitution of the contaminant will not allow for representative samples (large pieces, chunks), analytical testing is not recommended. Instead a quantitative risk assessment should be done by evaluating the amount of pieces or chunks, their size and their distribution in a sample along with an estimate of the occurrence.

**3.** Disinfection agents may interfere with analytical tests and should be rinsed off before sampling. Labs or kit suppliers should be consulted to confirm.

**4.** To minimise potential product hold in case of results not meeting acceptable criteria, there is the option to simulate a changeover by cleaning as the line would normally

be cleaned for the allergen changeover (after sampling production will be resumed with a similar allergen profile). If this is not possible, the samples should be analysed as soon as possible, and either the test results awaited before resuming production or the product placed on hold until the results are available. Another alternative would be to clean the line a second time and re-check it.

**5.** When the allergen validation is performed the product containing the allergen should be tested for the presence of the allergen. Therefore a pre-cleaning sample should be taken as a positive control. This will serve to ensure that the test kit is effective in detecting the specified allergen.

**6.** Options for sampling and testing are:

### 1.1. Swabs (surfaces)

a) For product contact surface swab samples (10 cm X 10 cm) are to be taken after the line has been cleaned.

b) Take swab from representative product contact locations. Target surfaces on a worst case scenario basis (difficult to clean, rough or pitted surfaces/welds, bends or anywhere where the product could hang up). If swabbing buffers contain additives, a re-clean or

sanitising of the swabbed surfaces is required.

c) If an external lab is used, swabs should be kept cool during shipping and tested within 24 hours. Shipping information should be obtained from the lab before sampling.

d) NOTE: Though delivering quantitative results, surface swabbing is a comparative method and should not be done in isolation from product or rinsate testing. It might be that swabs will be positive, while the first product through the line will meet acceptable criteria. In risk assessment terms, the important consideration is the extent to which any residue transfers to the product.

### 1.2. Rinsate (e.g. CIP, crate washing machines, manual foam cleaning regimes)

a) Two representative (e.g. covering all CIP loops) rinsate samples from the final rinse should be collected and tested.

b) For testing purposes, the pH is required to be between 6.0 and 8.0. If the pH is outside these limits, it is required continue to rinse the system until the pH of the final rinse is 6.0 – 8.0. If the final rinse does not fall in that range, the final rinse time needs to be revised.



c) Testing should be done within 24 hours. If samples need to be shipped to an external laboratory, they should be collected, stored and shipped to avoid degradation, for instance by using a refrigerated courier.

### 1.3. Final Product

An appropriate sampling plan should be developed and applied, and its performance and limitations clearly understood.

a) Samples of the finished product from first product coming off the line should be taken. Depending upon product type and situations (e.g. held-up areas down the line) the number of samples and times when samples are taken may vary. As an example: samples taken at 0,1, 5 and 10 minutes, minimum 3 samples per time-period (for a total of about 1 kg/time period).

b) If samples are taken at various times, the validation is passed if at minimum, the last two samples (with the examples above: after 5 and 10 minutes) meet acceptable criteria based on agreed reference values. All products tested before those two samples shall not be used as finished product for the product of concern.

### 1.4. Flushing with inert material (e.g. product, salt, sugar)

a) Perform a cleaning first to remove as much residue from product contact surfaces and adjacent areas as possible.

b) Once the line starts, collect first flushing material samples at reasonable intervals after start up, as an example after 1.5 and 10 minutes.

c) The validation is passed, if at minimum the last two samples (with the examples above: after 5 and 10 minutes) meet acceptable criteria.

d) Time and amount of material utilised for the flushing should be recorded and documented and the allergen change over procedure for future production runs should be changed accordingly.



# Annex 5

## Allergen Analysis

## Introduction

This annex is intended to give an overview of the analytical techniques and protocols that can aid decision-making in the management of allergenic/foodstuffs or those causing intolerances. However, due to the complex nature of food products and the broad range of food business operators, the annex will not cover specific analytical questions.

Analytical techniques used for detecting the presence or absence of residual or cross-contaminating allergenic or intolerance substances vary. A “visually and physically clean” standard forms the basic starting point for allergen management and can provide a good basis for safe operation once it has been validated and periodically verified, using one (or more) of the methods described. Absence of an allergen above a specified detection limit on visually clean equipment can be used as the basis for a limited quantitative risk assessment if the sampling is representative.

The methods and techniques mentioned can also aid in the confirmation of material composition, batch qualification and to contribute to the due diligence of any product claims. Analytical techniques for allergen analysis continue to be developed and it is advisable for all users to keep up-to-date with Regional and National initiatives on methods, matrixes and analytic validation.

Another issue, impacting on the comparability of methods is the availability of reference materials. The European Commission-funded 6th Framework Programme Network of Excellence, MoniQA ([www.moniqa.org/allergens](http://www.moniqa.org/allergens)) has produced and validated reference materials for allergen detection methods for milk in an inter-laboratory study with 5 ELISA kits across 20 laboratories worldwide. Further reference materials are being produced for other important allergen and intolerance targets.

## The Analytical Laboratory

Laboratories conducting analysis of allergens should be appropriately equipped, have the facilities to perform this type of analysis and have staff trained accordingly. Any laboratory performing such analysis should be accredited according to ISO 17025, and additionally, specifically accredited for the methods it performs. It should also be able to demonstrate regular and successful participation in proficiency tests for these methods.

The laboratory should handle all tasks according to Good Laboratory Practice or equivalent guidelines.

Additional laboratory requirements specific to the methodologies used will be described in the appropriate section of this annex.

It is good practice before a laboratory is tasked with analysis to obtain confirmation on its ISO 17025 accreditation for allergen analytical methods as well as several results from proficiency test programmes for allergens (e.g. FAPAS<sup>1</sup>) should be requested.



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<sup>1</sup> FAPAS: Food Analysis Performance Assessment Scheme; <http://www.fapas.com/>

## Food Matrices

Food matrices can have a significant impact on the analytical result. Also, the choice of methods and sampling procedures often depend on the information regarding the food matrix.

While liquid samples are usually considered homogeneous or can easily be homogenised by stirring, composite samples where components have different characteristics are more difficult to handle. Muesli bars, for instance, have typically several different dispersed ingredients and may have a very inhomogeneous distribution of allergens in only one component. For analysis, these need to be fully homogenised before a test sample is taken for analysis.

The matrix may also have components which make it unsuitable for certain types of analysis and may give rise to either false positive or negative results. These components can sometimes either mask the allergen if present (i.e. tannins or polyphenols) or appear very similar to the allergen being detected (false positives). Other components also influence results: high acidity impacts on DNA detection as it destroys the DNA while proteins may still be present. High sugar can also interrupt DNA clean-up, depending on the process. Ethanol denatures antibodies leading to a false-negative result. Therefore, it is absolutely essential to provide the laboratory with information on the composition of the sample to allow it to choose the best methodology<sup>2</sup>.

To reduce the risk of generating false negative or false positive results due to matrix effects, each matrix should ideally be validated to demonstrate that the allergen is detectable by the method chosen. Although it is not practically feasible to validate all matrices as the number of possible matrices is infinite, a laboratory should have sufficiently demonstrated its ability to analyse for the allergen in comparable matrices (e.g. high sugar, high fat, acidic). It is however advisable for the laboratory undertaking the analysis to perform a small-scale validation on new or novel matrices that

it has not previously analysed. Ideally, manufacturers should provide a control sample of the matrix in which cross-contact allergen is to be measured, which is known not to contain the allergen under investigation. This sample serves to check for the presence of the allergen in the raw materials and to demonstrate spiking with and recovery of the allergen.

## Sampling

Testing protocols can play an important part in the validation and on going verification of allergen management plans and need careful consideration. The meaningfulness of analytical results is highly dependent on the sampling process. A sample taken in a non-representative way (e.g. too small, only single location) is unlikely to give an analytical result that is representative for the production process. Therefore, sample sizes and locations where the samples are taken should be representative, as should any intermediate or final product samples.

Sampling, i.e. location and frequency, should be based on risk assessment. As an example, strictly separated components with no risk of contamination by allergens need only be sampled on an infrequent basis for confirmation, while commonly used equipment (e.g. conching equipment, mills, mixers) on or in which allergens are also being used, should be sampled more frequently. The risk and frequency should be identified in the allergen management plan (see core document).

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<sup>2</sup> Ideally, a free (confirmed by other approach) allergen sample of food matrix spiked with the allergen should be given to the lab to validate sampling preparation and detection.

Samples should be taken using clean equipment, preferably single use spoons or spatulas. Samples should be placed in clean, also preferably single use, containers to avoid false positive results through contaminated sample equipment and storage containers. Samples should be sent to the laboratory in conditions that prevent deterioration of samples. Dry samples tend to be less susceptible to deterioration compared to liquid or moist samples. While the former can be sent without chilling, the latter should, depending on the expected transport time, preferably be sent chilled.

## Type of Samples:

The type of sample taken for analysis will ultimately depend on the specific activity being monitored and the manufacturing environment. This can be broadly categorised as follows:

- Environmental Swabs – monitoring residual allergens on food contact surfaces.
- Purge Materials/ Flushing Mass – monitoring system where wet cleaning is not appropriate.
- Air Samples/ Settle Plates – used to monitor dusting.
- CIP Rinsate – used to monitor effectiveness of clean-in-place systems.
- Finished product – used to monitor effectiveness of cleaning following cleaning in conjunction with other samples listed above.

### a) Cleaning validation samples: Homogeneous Cross-Contamination Assessment

For cleaning validation of a re-occurring process (e.g. changing production from allergen containing product to non-allergen containing product), samples should be taken before the cleaning process, and after the cleaning process. Samples should comprise the initial product, washing solutions (or cleaning/ flushing materials like fat, sugar if water based cleaning is not possible) and the subsequent product.

If the allergen containing product is likely to spread beyond the immediate production equipment (e.g. powder or spray), the risk areas should be swabbed to identify any possible contamination.

For dry manufacturing processes, it may be more appropriate to monitor levels of allergen contamination using settle plate or air monitoring samples.

To confirm the effectiveness of cleaning, quantitative analysis is required, showing the reduction of allergen after cleaning. Care has to be taken as some cleaning agents can negatively influence the ELISA and PCR leading to false negative results. Before cleaning validation, the laboratory should be consulted to advise on possible adverse effects of cleaning agents.

### b) Cleaning validation samples: Heterogeneous Cross-Contamination Assessment.

In the event that the risk of allergen contamination is deemed to be heterogeneous (particulates, nuts, seeds etc.), the approach outlined in section (a) also needs to include a detailed visual inspection and physical strip down of equipment. This will highlight those points in the process where more rigorous sampling is required. For further guidance refer to the annex on cleaning validation.

### c) Confirmation of absence samples/routine environmental monitoring/verification samples

If a process has been validated and demonstrated to not contain detectable amounts of allergens, routine control checks may be advisable for verification purposes. These checks can be conducted on site by lateral flow devices (LFD) for the suspected allergen or by non-specific total protein assays or by total protein assays provided product does not contain protein. Positive findings should be confirmed by a specific analysis in the laboratory as some generic tests also can lead to false positive results.

## Technology According to Purpose

Generally, protein or peptide detecting methods are to be preferred over DNA detection methodologies (usually polymerase chain reaction, PCR) since the presence of DNA may not indicate the presence of allergenic protein, and a negative PCR result may not indicate the absence of protein<sup>3</sup>.

## Technologies Recommended for Typical Purposes

- For validation of cleaning processes, or for ingredient or finished product testing enzyme linked immunosorbent assays (ELISA) should be used as the technique is generally quantitative.
- For routine cleaning verification checks, LFDs can be used on site but should be supported by regular confirmation by ELISA.
- In case of ambiguous results by a protein-based method, PCR results can serve as a secondary confirmatory check. However, this typically only makes sense, due to PCR sensitivity for certain allergens, when ELISA results are higher than 10-20 mg/ kg (ppm).
- PCR should only be used where no other protein detection technology is available (e.g. celery detection or tree-nuts other than almond, hazelnut, walnut).
- Mass spectrometric methodology, as it is not a routine technology yet, should be used where secondary confirmatory checks are required where results differ using conventional methodology.
- LFD should be used on site for routine cleaning validation checks and can also be used for release testing of finished products.

## Technologies in Detail - Advantages and Disadvantages

### Protein Based Methods

Since all food allergens listed in annex IIIa of 2007/68/EC are, with the exception of sulphur dioxide and sulphites, proteins, protein is the primary analyte that should be targeted. Protein based methods can be divided into two groups: immunological methods and protein separation methods. Immunological methods are antibody-based, i.e. an antibody, similar to the one causing the allergic reaction in humans, detects the proteins. Typical methods are ELISA (Enzyme Linked Immuno Sorbent Assay) and LFD (Lateral Flow Device; commonly known as dipstick/ rapid lateral flow devices). Immunological methods are long established in many routine laboratories and are the method of choice for industry and regulatory bodies because of the specificity and sensitivity of the antibodies. They are used in food industry laboratories and by official food-control bodies to detect and quantify allergens present in food. Protein separation methods like mass spectrometry (MS) are based on the separation of proteins or their fragments (peptides) due to their variable size and charge. They are mostly used as an alternative method of analysis when an ambiguous result is recorded by other methodology. Recent developments in LC MS-MS methodology have shown encouraging results, and in the future, it is likely that it will serve as a confirmatory method for the analysis of formal samples.

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<sup>3</sup> NOTE: The European Directive 2007/68/EC for the labelling of food allergens does not differentiate between proteins and other compounds (e.g. metabolites or DNA). Any derivative requires labelling if part of the ingredient list



## ELISA

ELISAs have been much favoured in allergen analysis. The specificity and sensitivity of ELISA technology, with limits of detection or quantification at low mg/kg level, make it a simple tool for allergen detection and quantification, allowing relatively fast and high throughput analysis. It is widely used in food industry laboratories and by official food-control bodies to detect and quantify allergens present in allergenic food or commodities. So far, ELISA test kits validated for defined matrices include peanut (in cereals, cookies, ice cream and chocolate; under the auspices of AOAC and EC JRC, Park et al 2005, Poms et al 2005) and hazelnut (in cereals, ice cream and chocolate; under the auspices of the German Federal Office for Consumer Protection and Food Safety, BVL). However, many others are routinely used by food laboratories.

It is important to realise that ELISAs have some drawbacks: these include that only one target allergen can be detected/quantified per test, i.e. a composite food containing potentially 5 allergens require 5 different ELISA assays which may provide a resource challenge. In addition, several companies offer antibody kits for the same allergen, all with somewhat different specificities and sensitivities. This can generate divergent results if the same sample is tested using two different kits. Frequently found differences are between ELISA kits for the detection of gluten. Here, alternative methods like MS could be used for confirmation.

Results can also be influenced by a number of other factors. If, for example, only the whey fraction of milk is used but the ELISA test detects casein since the laboratory does not have the relevant information, it may generate a false negative result. Hydrolysis and oil/ fat fractions are further examples.

ELISA should be used when quantitative results are required, like for cleaning validation procedures, and to confirm results of other methods, like LFD.

## Lateral Flow Devices (LFD)

LFDs (also called dipsticks) are a rapid immunochromatographic technique, available as a single-use format device that allows qualitative detection of the allergen. The typical LFD is a colorimetric test that contains a control line (ensuring the validity of the assay) and a test line, which determines the presence/absence of the target allergen. These assays are typically used on site for rapid analysis (typically absence of allergen). While the costs of LFDs are lower than ELISA, they provide only a yes/ no answer. In some instances, results may vary depending on the LFD lot used. Therefore a regular comparison of LFD with ELISA results is recommended.

LFDs should be used when quick on-site presence/absence checks for individual allergens need to be performed as part of the continuing risk assessment.

## Mass Spectrometry (MS)

In the near future, MS methods will likely play an important role, providing a viable alternative confirmatory method since MS has the potential to directly detect proteins/peptides (and therefore, the hazard itself) at low levels similar to those achieved by ELISA and PCR. The highest potential of mass spectrometry lies in its capability to analyse multiple targets (multiple allergens) in a single analysis (the so-called 'screening'). This distinguishes mass spectrometry from ELISA, and as a direct detection tool, from PCR. Another advantage is that, unlike antibody based technologies, processing has a lesser impact since MS detects the weight, not the structure which is often changed during processing. The accurate detection of the allergen relies on the identification of peptide fragments which are cleaved by the enzyme trypsin during sample extraction. Studies on highly processed foods where the peptides become highly modified, can impede the cleavage of the peptides and hence detectability of the allergen. As with other methods matrix validation must be conducted to provide confidence in the analytical results.

MS also has the potential to be semi- or fully automated potentially allowing high throughput of samples. As with any new methodology, its future application on analysis of food allergens is still somewhat restricted due to high equipment costs and the need for specialist expertise in method development. However, easy-to-use toolkits are already in the pipeline by several major equipment manufacturers, essentially simplifying the use of the methodology for the non-expert user.

## DNA Based Methods

The most popular DNA-based techniques are PCR and real-time PCR. Both are used qualitatively for the detection of food allergenic compounds. These techniques typically amplify a part of the species-specific- or allergen-encoding DNA sequence.

The detection of food allergens by DNA-based techniques is controversial because they do not detect the target protein but the marker DNA that may or may not correlate with the amount of the allergen in the food product. Examples are those food components that are formulated with protein-rich ingredients, e.g. egg- or milk powder. The quantity of DNA in the sample, the presence of interfering compounds in the DNA preparation as well as its quality determines the success of the assay. An advantage of PCR over ELISA is that all the assay components are available commercially and it is easy to develop. PCR is the only alternative for those regulated allergens for which ELISA is not available (e.g. celery). One of the drawbacks of PCR detection is that DNA is highly unstable in acidic environments (e.g. tomato sauce). Here, protein or peptide based assays should be used if at all possible. Also, issues can arise in laboratories from cross contamination when small amounts of target DNA from previous assays contaminate the PCR mix and generate false positive results. Other issues are found with animal products which trigger allergic responses while others from the same animal, do not. As an example, PCR analysis cannot distinguish between DNA originating from non-allergenic beef meat and allergenic milk, or non-allergenic chicken meat and allergenic egg<sup>4</sup>. Laboratories operating PCR equipment should have at least four separate areas, ideally separate rooms for sample preparation, PCR mix preparation, PCR and post PCR handling (e.g. gel electrophoresis)<sup>5</sup>. Therefore, PCR analysis should only be requested where needed and the laboratory conducting the analysis should have geographically separated areas to minimise the risk of cross-contamination with amplified DNA.

DNA methods should be used if no alternative protein methods are available or as supporting information to confirm ELISA/ LFD results when contamination levels of 10mg/ kg (ppm) or higher are expected.



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<sup>4</sup> NOTE: Egg is actually unsuitable for PCR analysis as mentioned earlier since it contains very little, or in case of egg white, no DNA despite having a high allergenic potential due to the presence of specific proteins.

<sup>5</sup> EN 15634-1: Foodstuffs - Detection of food allergens by molecular biological methods; Part 1 - General Considerations; Section 4.2 Laboratory Organisation

# Analytical Technologies at a Glance

All techniques can be prone to interferences (false positive/negative), which is why rigorous validation is required.

TECHNOLOGY	Type	Advantage	Disadvantage	Good for	Not good for	Watch out for
ELISA (Enzyme Linked Immuno Sorbent Assay)	Detects proteins using antibodies	Common technique, well established in laboratories; qualitative and quantitative results	Laboratory based assay. Actual analysis time: 2-3 hours, laboratory turnaround time typically 1-3 days. Method can be prone to interference and processing can impact detection of allergen	Detects the allergenic food component i.e. protein. Can be used on ingredients, semi-finished and finished products. Can also be used for assessment of cleaning effectiveness. Can generate quantitative results	Multi-allergen detection (only one allergen per ELISA can be detected; expensive when analysing several allergens in same matrix )	Processing of foods can affect immunoreactivity (detectability) but not allergenicity.  ELISA kits are not available for all allergens (e.g. celery). Some assays show cross reactions to non-allergens (e.g. mustard - canola), generating false positive results. ELISA kits for the same allergen can provide different results due to different specificities and different standards used in the kit. Since kits report in different units (protein or whole food), the reporting unit needs to be paid attention to. Conversion factors (if not provided by the kit) can be often obtained from publicly available nutrient databases)
LFD (Lateral Flow Device; Dipstick)	Detects proteins using antibodies	Fast. Can be done on-site; no laboratory experience necessary	No quantitative results possible. Method can be prone to interference and processing can impact detection of allergen	Quick on site check for allergen presence/absence. Good for cleaning controls (environmental swabs, rinse water etc.). Low cost	Quantitative assessment. Multi-allergen detection. Ingredient or finished product testing	No quantitative results possible. LFDs are not available for all allergens. Quality and sensitivity between lots may vary. LFDs suffer from the same 'issues' as ELISA as both use antibodies to detect proteins (see box above). Residues of cleaning agents can result in false negative results
Non-Specific Total Protein Assays (Comassie Blue, BCA, Bradford)	Detects total protein using a colorimetric test	Fast, sensitive. Limited equipment required. Test can be done on-site	Does not discriminate between allergenic and non-allergenic proteins		Foods containing several different proteins from different sources	

TECHNOLOGY	Type	Advantage	Disadvantage	Good for	Not good for	Watch out for
PCR (Polymerase Chain Reaction)	Detects DNA, not proteins (indirect assay)	Multiple allergen detection possible. Good for plant based allergens. Tests available for allergens not currently covered by ELISA methods.	Specialized laboratory required. Actual analysis time 2-3 hours, laboratory turnaround time typically 1-3 days. Not suitable for egg and milk DNA (due to low DNA levels). Sophisticated equipment and highly trained staff required	Presence/ absence detection of plant-based allergen DNA (soya, nuts, celery, mustard etc.).	Egg, milk (insufficient sensitivity). Quantitation in most cases not possible.	DNA level and protein level may vary, e.g. in soya oil. A positive result for DNA does not always indicate the presence of (allergenic) protein and vice versa. Difficult to correlate the amount of DNA copies to protein concentration. With PCR, DNA from chicken/ egg or milk/ beef cannot be differentiated
MS (Mass spectrometry)	Detects protein fragments (peptides)	Direct detection of peptides; detection of many allergens in one analysis possible	Specialised laboratory required; Actual analysis time 2-3 hours, laboratory turnaround time typically 5 days. Sophisticated, expensive equipment; trained staff; published literature indicates some issues with processing and allergen extraction. Not adapted for routine analysis yet	Confirmation of positive/ negative results (e.g. evidence in court); ideal for multi-allergen screening, some processed materials	Automated routine analysis;	MS analysis is still expensive and only available in a few laboratories to date. Processing can impact allergen extraction and subsequent detection
Monier-Williams	Total sulphite determination in foods by steam distillation and titration	Simple and rapid with very good reproducibility	AOAC method requires 2 hours distillation time. Some interference in high vinegar matrices. Simple laboratory glassware required, and readily available chemicals. Main pitfall is leaks in glassware.			
Lactose analysis (1. commercial UV-enzyme kits 2. liquid and gas chromatography)	1. Measure of enzyme kinetics of hydrolysed lactose/ galactose  2. Detects lactose	1. Fast. Low investment in equipment. Relatively sensitive  2. Direct detection of lactose; good sensitivity	1. Can be prone to interference especially with complex matrices  2. Specialised laboratory required. Actual analysis time 2-3 hours, laboratory turnaround time typically 5 days. Sophisticated, expensive equipment; trained staff			

# Annex 6

## Gluten-Free Foods



This annex provides an overview of the rules governing the use of claims to indicate the suitability of foods for people intolerant to gluten and the compositional requirements that must be met in order to use such claims.

It must be noted that the legislative framework covering the rules on the composition and labelling of foodstuffs suitable for people intolerant to gluten is currently being reviewed by the European Commission. The location of the gluten provisions will be affected by this review. Further information is provided in section 3 below.

## 1. EC Regulation 41/2009 Concerning the Composition and Labelling of Foodstuffs Suitable for People Intolerant to Gluten<sup>1</sup>

### a) Background

Prior to this Regulation there were no legally defined compositional standards for gluten-free foods, however manufacturers were encouraged to work to the international standard set by Codex Alimentarius. This standard was recently revised to take account of the latest scientific advice. The new standard<sup>2</sup>, adopted in July 2008, sets a maximum level of 20mg/kg of gluten in order for food to be labelled as 'gluten free', and 100mg/kg of gluten for foods labelled as 'very low gluten'- restricted to foods processed to remove gluten.

Use of the term 'gluten-free' is permitted by Regulation (EC) No 41/2009 which applies to food for people intolerant to gluten. Coeliac disease is a permanent food intolerance, where scientific evidence has shown that very low amounts of gluten up to 20 mg/kg are safe to these consumers. Gluten-free foods may, therefore, contain levels of gluten, which are above the limit of detection of the analytical tests used, but less than the new Codex Standard for 'gluten-free' foods of 20mg/kg.

### b) Purpose

This Regulation aligns EC legislation with the new Codex Standard. Harmonisation at an EU level of the conditions under which the terms 'gluten free' and 'very low gluten' can be used will ensure a high level of protection for people intolerant to gluten. In addition, consistent labelling will help consumers with different sensitivities to gluten to make informed choices about the foods that are most suitable for them.

### c) Scope

The Commission Regulation applies to all foods (including alcohol, food supplements, etc.), pre-packed and non pre-packed, except infant formulae and follow-on formulae. However, the PARNUTS Framework Directive states that PARNUTS<sup>3</sup> shall only be sold pre-packed, unless Member States provide exemption from this rule.

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<sup>1</sup> EC Regulation 41/2009/EC concerning the composition and labelling of foodstuffs for people intolerant to gluten: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:016:0003:0005:EN:PDF>

<sup>2</sup> CODEX STAN 118-1979: [http://www.codexalimentarius.net/download/standards/291/cxs\\_118e.pdf](http://www.codexalimentarius.net/download/standards/291/cxs_118e.pdf)

<sup>3</sup> Parnuts are foodstuffs which are intended for particular nutritional uses, which owing to their special composition or manufacturing process are intended to satisfy the particular nutritional requirements of specific groups of the population.

The Commission Regulation applies to the labelling, presentation and advertising of foods. Therefore, the provisions related to the use of the claims 'very low gluten' and 'gluten free' do not apply solely to the labelling of foods but also to any form of advertising and presentation, which includes, for example, off-pack labelling, such as websites, leaflets, product lists, customer care lines and shelf labels.

When the claim 'gluten-free' is used, this must not mislead the consumer by suggesting that the particular food is special in having that property, when all other foods of that type are also 'gluten free'.

#### **d) Requirements**

Under this Regulation, the term 'gluten-free' may only be used for PARNUTS foods or 'normal foods'<sup>4</sup> with a level of gluten below 20mg/kg in the food as sold to

the final consumer. The term 'very low gluten' can only be used for PARNUTS foods, prepared specifically for those intolerant to gluten, and with a level of between 20mg/kg and 100mg/kg in the food as sold to the final consumer. A flow chart to help you to determine the most appropriate claim for your product is enclosed as Figure 1.

The term 'suitable for coeliacs' (or logos which are intended to indicate this) can only be used in conjunction with the claims permitted by the Regulation (i.e. alongside 'gluten free' or 'very low gluten').

These new rules came into effect on 9 February 2009. Manufacturers had until 1 January 2012 to comply with the new requirements, but were allowed to use the new terms from February 2009, provided that the products comply with the compositional criteria. Products that did not comply by 1 January 2012 should have been removed from the market.

## **2. Other Relevant Legislation**

### **• PARNUTS Foods**

PARNUTS Framework Directive: Directive 2009/39/EC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses can be found at:

[www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:124:0021:0029:EN:PDF](http://www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:124:0021:0029:EN:PDF)

Foods specially prepared for people intolerant to gluten making either 'gluten-free' or 'very low gluten' claims must be notified to the relevant authority when placed on the market for the first time. This is because of an EC obligation to monitor the market. It is therefore the responsibility of the manufacturer, or in the case of imported foods, the importer, to notify the relevant authority whenever products are marketed in one or more Member States. Notification is required in each country in which the product is marketed.

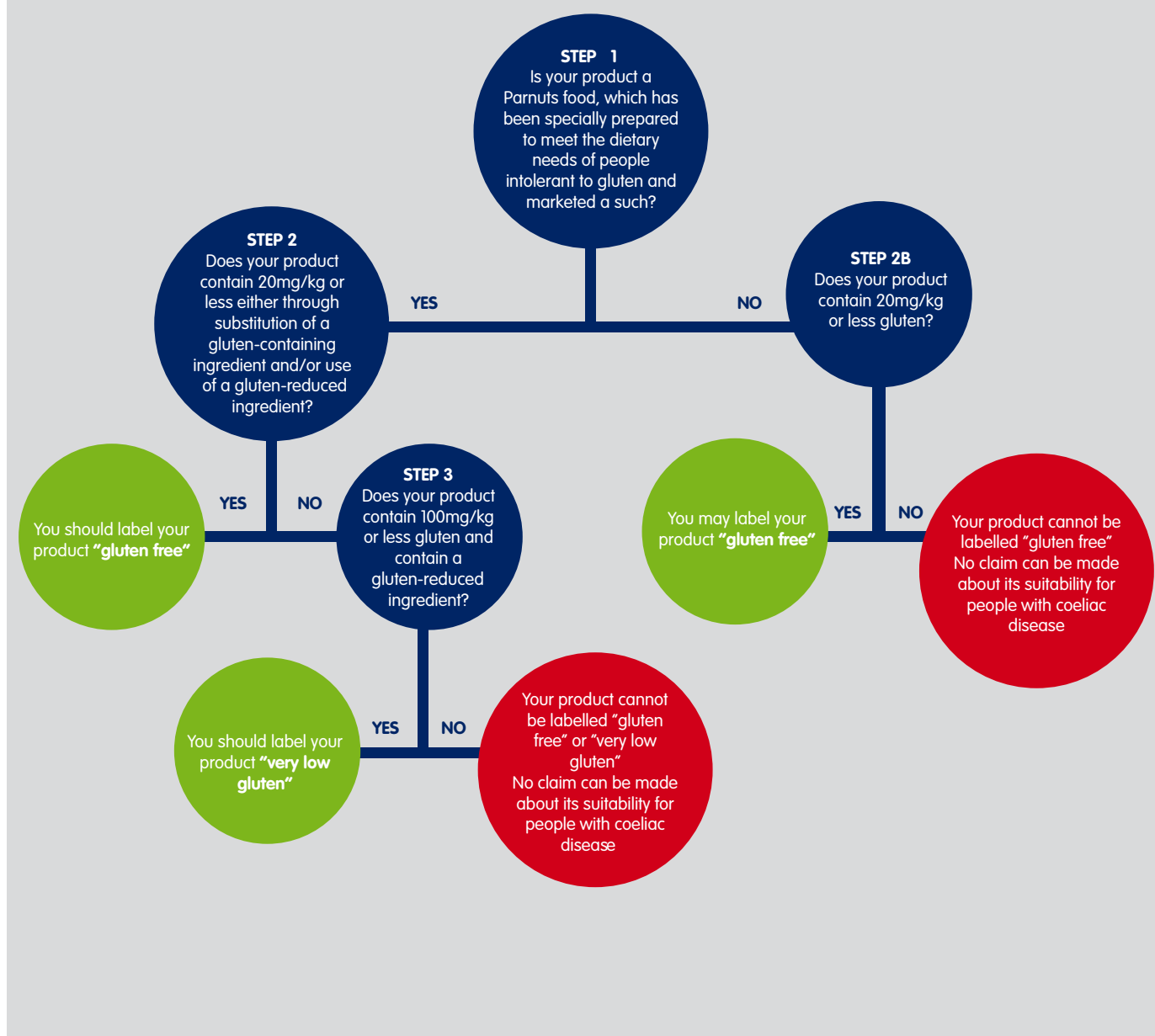
### **• General Labelling (Including Allergen Labelling):**

Regulation (EU) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>

The allergen labelling rules continue to apply alongside rules for 'gluten free' claims. These rules require products containing gluten-containing cereals to make this clear on the label. This may be in the ingredients listing or, in the absence of a list of ingredients, in a statement prefixed by the word 'contains'.

**Figure 1: How to label your product if you would like to make a claim about its suitability for people intolerant to gluten**



<sup>4</sup> 'Normal Foods' or 'foods for normal consumption' have not been processed, manufactured or prepared in a way to meet the specific needs of people with a particular nutritional requirement, e.g. malt vinegar, a cereal bar that is traditionally made with puffed rice.

## 3. Review European PARNUTS Legislation

### a) General

The European institutions, on the basis of a proposal submitted by the Commission as part of its on-going programme of simplification and reducing legislative burden, are reviewing the current Framework Directive on PARNUT foods (**Directive 2009/39/EC**).

This proposal for a Regulation<sup>5</sup> on 'food intended for infants and young children and on food for special medical purposes' repeals the provisions of Directive 2009/39/EC (the majority of the provisions laid down date back to 1977) and intends to address the difficulty experienced by consumers in making an informed choice between dietetic foods, fortified foods, foods bearing claims and foods for normal consumption. The proposal abolishes the concept of 'dietetic foods' for the benefit of the expression 'specialised nutrition'.

The adoption and entry into force of updated European legislations as, inter alia, Regulation 1924/2006 on nutrition and health claims made on foods, Regulation 1925/2006 on the addition of vitamins and minerals and other substances to food and Regulation 1169/2011 on the provision of food information to consumers, is a additional factor making necessary the thorough review of Directive 2009/39/EC.

### b) Rules Covering Gluten-Free Labelling

The initial Commission proposal suggested that the existing gluten-free foods governed by Regulation (EC) 41/2009 move under the general food law with no special provisions.

Following intensive discussions around this issue, the European institutions ultimately decided to move the provisions of Regulation 41/2009 into the revised Food Information to Consumers Regulation, taking into account that coeliacs are vulnerable consumers who require more specific provisions.

A specific recital has been included in the last compromise text ensuring the future labelling differentiation between specially formulated gluten free products and those for general consumption, via the adoption of delegated and implementing acts.

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<sup>5</sup> European Commission Proposal for a Regulation on Food Intended for Infants and Young Children and on Food for Special Medical Purposes (June 2011):

[http://ec.europa.eu/food/food/labellingnutrition/nutritional/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm)



# Annex 7

## Precautionary Allergen Labelling



# FoodDrinkEurope Statement on Precautionary Allergen Labelling<sup>1</sup>

- Allergens are common constituents of consumer products with valuable functional and/or nutritional attributes which can cause adverse, even life-threatening, reactions in susceptible individuals. The unintended presence of small amounts of certain allergens which are not part of a product's formulation as a result of manufacturing and other operations (and which are therefore not labelled) can pose a risk to allergic consumers.
- Progressively over the last decades, the food industry has made significant efforts in reducing the unintended exposure of allergic consumers to major allergens. In particular, FoodDrinkEurope has developed this Guidance for practical use by operators, which encourages a shift from the current hazard-based approach to a risk-based approach.
- While current practices in the management of major allergens have increased the safety of food products for allergic consumers, the lack of an agreed approach to quantitative risk assessment has led to divergent standards applied by different manufacturers, as well as divergent approaches by enforcement authorities across Europe. The subsequent increase in precautionary allergen labelling, in turn, has resulted in reduced amounts of foods that allergic/intolerant consumers can choose from.
- FoodDrinkEurope considers that precautionary labelling has an important role to play in protecting allergic consumers, but in order to fulfil that role, it needs to be applied consistently, in a circumspect manner and in accordance with defined and agreed principles. FoodDrinkEurope therefore supports a risk-based approach to major allergen management and the application of precautionary 'may contain' labelling.
- Precautionary labelling should only be used where a thorough risk assessment demonstrates that there is a real risk of a significant but unavoidable amount of allergen in the consumed product due to cross-contact within the ingredient supply chain or from manufacturing operations. Although we recognize that following a risk-based approach may cause reactions in a very small proportion of susceptible individuals, this approach will minimize risk to consumers with food allergies, while maximizing their food choices.
- To clarify when precautionary allergen labelling applies and to further facilitate its optimal use for consumers, FoodDrinkEurope supports the development of EU-wide, transparent management threshold levels based on latest scientific evidence and guidance on appropriate forms of wording for labelling statements. This will allow industry to consistently apply precautionary labelling and clearly communicate the allergen status of a food. In the context of Article 36.3a of Regulation (EU) 1169/2011, we therefore strongly support the early adoption by the European Commission of guidance on the use of precautionary labelling and thresholds. The latter should be based on EFSA Opinions and should take into consideration approaches already established in other parts of the world.

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<sup>1</sup> For ease of reference, precautionary allergen labelling referred to in this statement refers to the labelling of substances and/or products causing allergies or intolerances in accordance with Regulation (EU) 1169/2011 on the provision of food information to consumers.



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