parera
Food Risk Analysis and Regulatory Excellence Platform

UNIVERSITÉ LAVAL

SUMMARY OF ALLERGEN MANAGEMENT GUIDELINES FOR THE FOOD INDUSTRY , AND OTHER RELATED DOCUMENTS

March, 2021

SUMMARY OF ALLERGEN MANAGEMENT GUIDELINES FOR THE FOOD INDUSTRY, AND OTHER RELATED DOCUMENTS

PURPOSE AND DESCRIPTION

The purpose of this document is to provide an overview of existing allergen management guidelines for the food industry, as proposed by international food safety competent authorities, with the aim of identifying general best practices, existing approaches to the use of precautionary allergen labelling (PAL), and areas where guidance is lacking or could be enhanced. This review is the first outcome of a project that aims at developing food allergen management guidelines for the Canadian food industry.

This document provides summaries of 22 references related to allergen management in the food industry (Table 1), authored by food safety competent authorities from various jurisdictions, international standard setting bodies and industry organizations. Although this review mainly focuses on allergen management guidelines for the food industry, other documents related to allergen labelling, cleaning, and risk assessment, were found to be relevant and were also included. The references reviewed were initially identified through and internet search using the keywords “food industry”, “allergen”, “management”, and “guidelines” simultaneously; documents authored by food safety competent authorities were prioritized. The document selection was enhanced and validated by industry stakeholders.

The summary is divided in five main sections: (i) general allergen management practices for the food industry, (ii) sector-specific allergen management practices, (iii) allergen labelling, (iv) allergen cleaning and (v) other documents. In each section, the references reviewed are presented chronologically starting from the earliest published. For each reference reviewed, a highlights table along with a brief summary is provided. Except for documents of particular interest (i.e. Canada—target jurisdiction; Argentina—original translation; United Kingdom’s Food Standards Agency—first extensive guidance document, and its update by FoodDrink Europe; and sector-specific references), where sections were found to be closely aligned with or based on previously reviewed documents, a reference to the earliest source is provided.

A snapshot of the main components of the guidance documents reviewed is presented in Table 2. The elements of an allergen control plan included in each of these documents are presented in Table 3.

ANALYSIS

Following the review of the selected references, the following general observations were noted:

- A **risk-based approach** is favoured when dealing with food allergens in a manufacturing environment. Although in different forms and levels of detail, the main steps of this approach may be described as: (i) hazard identification, (ii) risk assessment, (iii) risk management, i.e., design and implementation of measures to minimize or reduce risk, and (iv) risk communication to consumers.

- Although not all documents do so, a clear separation between (i) the **general approach** to address potential food allergen risks, e.g., risk-based; (ii) the required **foundations** for the successful implementation of any food safety program including allergen management, e.g., prerequisite programs; and (iii) the **specific components** of an allergen management program, provides a logical framework.

- Contrary to early references, recent guidelines do not discourage the inclusion of allergenic ingredients in product formulations, however awareness of its implications is emphasized.

- **Supply chain** controls have gained recognition as a critical element in allergen management over the years. Earlier documents refer mainly to supplier control, with a focus on raw materials when they are received at the manufacturing facility, and expectations regarding allergen management in the supplier operations (i.e., on-site and one-step-before). However, over the years, this has evolved to include requirements throughout entire supply chain, starting as early as primary production (Codex, 2020).

- Within supply chain controls, the importance of **suppliers** in allergen management is implied by the increasingly enhanced guidance provided in this matter in recent references. The implementation of procedures enabling clear communication with suppliers, as well as efficient traceability mechanisms, are regarded as essential. Recommendations on the level of detail regarding allergen declaration in raw material information sheets have significantly increased over the years. The development of a standard form for the collection of raw material information from suppliers, indicating minimum requirements and applicable to most food sectors, could be useful.

- **Cleaning** has always been recognized as one of the most important allergen control strategies, and the level of detail provided on this subject has progressively increased over the years. Recent references even include dedicated sections or annexes on allergen cleaning, and considerations on cleaning validation have notably gained weight.

- **Allergen testing** is also more extensively reviewed in recent documents. Fundamentals, limitations and applications of different analytical methods are often discussed. However, **sampling** considerations—essential to the interpretation and validation of any analytical test —are rarely explored (i.e., FoodDrink Europe, 2013; Dairy Food Safety Victoria, 2018).

- Like cleaning, employee **training** remains a pillar of allergen management. Earlier documents focused on production employees whereas more recent ones include all employees, temporary staff, visitors, and even recommend that strategic employees take action in certain high-risk instances. The role of senior management as a facilitator and example of commitment is also recognized in recent guidance.

- **Communication** with consumers regarding allergen risks, beyond the ingredients list on product labels, is an emerging component of allergen management. Examples include the use of digital communication channels (e.g., social media) and the development of real-time communication tools (e.g., Food Safety Authority of Ireland's food allergen alert system).

- **IT tools** represent an interesting complement to written documents, often in the form of interactive elements (e.g., Seasoning and Spice Association's risk assessment Excel file, Allergen Bureau's risk review online tool) that can be directly applied by food manufacturers. Referring the reader to online tools may increase engagement and awareness, and keeps the written document within a reasonable length. Also, beyond their role as an element of guidance documents, IT tools are evidently essential for efficient quality data management and traceability within the organization and throughout the supply chain.

- The role of the **purchasing** department in allergen management within a company is highlighted in Canadian references (FCPMC-FPACC, 1999; Alberta Agriculture and Rural Development, 2014). In other international references, it may have been incorporated into

research and development and/or supplier controls, however, bringing attention to this function seems relevant.

- **Precautionary allergen labelling** has been consistently regarded as an allergen risk management and communication tool that should be applied only under certain conditions. Specifically, its use is only recommended after all reasonable measures to minimize or control the risk of unintended presence of allergens have been implemented. However, guidance on how to approach instances where this risk is still present is vague or lacking—with the notable exception of the VITAL program.

- **Science-based evidence** as a foundation to allergen management is a recurring topic in recent references, especially when it comes to validation of control measures (i.e., cleaning) and justification of risk management decisions (e.g., use / not use of PAL).

Regarding allergen management **best practices** within food manufacturing operations, recent documents (Codex 2020; FoodDrink Europe, 2013) advocate for a harmonized, risk-based approach. Indeed, given the multiple guidance documents currently available on this subject, food manufacturers would benefit from consensus guidelines. One of the most thorough general guidance is provided by FoodDrink Europe (2013). This document builds on best practices previously proposed by the United Kingdom's Food Standards Agency (2006). The main areas for which allergen management recommendations are provided remain relatively unchanged in both documents (training, suppliers, raw materials, manufacturing, etc.), with the difference that cleaning is discussed in a dedicated section in FoodDrink Europe (2013). These areas, as well as the basic control strategies they fall under (e.g., accurately identify allergens in product formulations; prevent/minimize allergen cross-contact during storage, handling and in-process; prevent labelling errors), are also common to the majority of references reviewed.

Interestingly, although Food Standards Agency (2006) presents a qualitative, risk-based approach for the use of **PAL** (based on hazard characterization—e.g., physical form, distribution of contamination), FoodDrink Europe (2013) chose not to specify instances that would require PAL in its allergen risk analysis process. Instead, it is stated that "approaches for the application of advisory labelling need to be developed" (FoodDrink Europe, 2013). Similarly, Codex (2020) presents a thorough overview of allergen management best practices for food manufacturers; nevertheless, PAL is not discussed and was in fact deleted from previous draft versions. Among the documents that do provide guidance on the use of PAL, some propose a set of conditions that would justify its use (Grocery Manufacturers Association, 2009; Dairy Food Safety Victoria, 2018), others propose that PAL be used in all cases where allergens can be detected (Argentina Food Allergens Platform, 2013; Alberta Agricultural and Rural Development, 2014; FSIS, 2015), and only the VITAL program recommends the use of quantitative action levels based on reference doses that would elicit a reaction on a given percentage of the allergic population (Allergen Bureau, 2016 & 2019). Beyond Australia / New Zealand, the VITAL program's quantitative framework for the use of PAL has been recommended in the European Union (United Kingdom's Seasoning and Spice Association, 2017; FoodDrink Europe, 2020). Thus, while harmonization with respect to allergen management best practices may be readily achieved, the same cannot be said of guidance on the use of PAL.

In Canada, the former Food and Consumer Products Manufacturers of Canada (1999), was a pioneer in the development of best practice guidance for food allergens management. The main principles and elements proposed remain valid, although they have been expanded and updated in more recent documents. At the federal level, the Canadian Food Inspection Agency (2018) has developed guidance on preventive controls for food allergens, which focus on the identification of allergen sources and the implementation of control measures targeting the

food, the process and the establishment. The use of PAL however is not discussed. At the provincial level, Alberta Agriculture and Rural Development (2014), includes a comprehensive chapter on allergen control within its Food Safety Handbook. This chapter covers recognized best practice on food allergen control, and indicates that if the allergen control plan cannot remove allergens on the production line or equipment to a non-detectable level, PAL should be used. However, this approach brings up the issue of increasing sensitivity of analytical techniques, and the fact that food production cannot, in most cases, entirely avoid the unintended presence of allergens—further discussed in FoodDrink Europe (2020). Therefore, it is clear that allergen management guidelines for the Canadian food manufacturing industry would benefit from update and enhancement. Although best practices have been extensively described in international references, a document developed specifically for the Canadian industry would facilitate dissemination and harmonization. Also, the use of PAL, an issue currently being discussed at the international level, needs to be addressed within a risk assessment context. In terms of document structure, a clear separation between the foundation elements (e.g., pre-requisite programs, part of most manufacturing operations' food safety plans), the global approach recommended to manage food allergens (i.e., risk-based) and the specific best practice guidelines (grouped in a limited number of functions, rather than an extensive list of elements), would provide an upgrade to existing guidance documents.

Table 1. References reviewed

	Author	Year	Region	Title	Type
Allergen Management Guidelines for the Food Industry - General					
1	Food and Consumer Products Manufacturers of Canada (FCPMC - FPACC)	1999	Canada	Allergy Beware 2000: Guidelines. Allergen management best practices	Organization
2	Food Standards Agency	2006	UK	Guidance on allergen management and consumer information	Government agency
3	Food Allergy Research and Resource Program (FARRP)	2009	USA	Components of an effective allergen control plan - A framework for food processors	Organization
4	Grocery Manufacturers Association	2009	USA	Managing allergens in food processing establishments	Organization
5	Plataforma Alérgenos en Alimentos	2013	Argentina	Guía para la gestión de alérgenos en la industria alimentaria	Government agency
6	FoodDrink Europe	2013	Europe	Guidance on food allergen management for food manufacturers	Government agency
7	Alberta Agriculture and Rural Development	2014	Alberta (Canada)	Food safety guidebook. Chapter 11. Developing an allergen control program	Government agency
8	Canadian Food Inspection Agency	2018	Canada	Preventive controls for food allergens, gluten and added sulphites	Government agency
9	Australian Food & Grocery Council and Allergen Bureau	2019	Australia / New Zealand	Food industry guide to allergen management and labelling	Government agency
10	Codex Alimentarius Commission	2020	N/A	Draft code of practice on food allergen management for food business operators	International standards
Sector-Specific Allergen Management Guidelines					
11	United States Department of Agriculture - Food Safety and Inspection Service (FSIS)	2015	USA	FSIS Compliance Guidelines. Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling	Government agency
12	Dairy Food Safety Victoria	2018	Australia	A guide to managing allergens in the dairy industry	Government agency
Allergen Labelling					
13	Allergen Bureau	2016	Australia / New Zealand	VITAL Best Practice Labelling Guide	Government agency
14	Allergen Bureau	2019	Australia / New Zealand	Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program version 3.0	Government agency
15	FoodDrink Europe	2020	Europe	Precautionary Allergen Labelling (PAL): a science-based approach based on Quantitative Risk Assessment	Government agency
Allergen Cleaning					
16	SQFI	2012	N/A	Allergen Cleaning and Sanitation Practices	Quality program
17	Neogen / FARRP	2016	USA	Best practices for food allergen validation & verification	Analytical laboratory
18	United States Department of Agriculture - Food Safety and Inspection Service (FSIS)	2019	USA	Fish and fishery products hazard controls guidance Appendix10: Cleaning and sanitation for the control of allergens	Government agency
Other documents					
19	Food Standards Agency	2009	UK	Evaluation of 2006 Guidance on allergen management and consumer information	Government agency
20	Seasoning and Spice Association	2017	UK	Allergen risk assessment model for dried herbs and spices	Industry association
21	Allergen Bureau	2019	Australia / New Zealand	Summary of the 2019 VITAL Scientific Expert Panel Recommendations	Government agency
22	Food Safety Authority of Ireland	2019	Ireland	Information required for the risk assessment of undeclared food allergens in Ireland	Government agency

Table 2. Main components of the allergen management guidance documents reviewed

	General Guidelines										Sector-specific	
	FCPMC - FPACC (1999)	**FSA (2006)**	**FARRP (2009)**	**GMA (2009)**	**Argentina (2013)**	**FoodDrink Europe (2013)**	**Alberta (2014)**	**CFIA (2018)**	**Australian Food and Grocery Council + Allergen Bureau (2019)**	**Codex (2020)**	**FSIS (2015)**	**Dairy Food Safety Victoria (2018)**
ACP elements / fundamentals / principles	X	X	X	X	X	X	X	X	X	X	X	X
Templates / checklists					X (Letter of guarantee, supplier questionnaire)	X (Allergen risk analysis)	X (Various control measures)	X (Supplier checklist)			X (Principles checklist)	
PAL approach		X (Qualitative)		X (Conditions)	X (Detection = PAL)		X (Detection = PAL)		X (VITAL)		X (Detection = PAL)	X (Conditions)
Risk assessment		X			X	X (Annex)			X (Allergen Bureau definitions)			
Analysis (methods, applications)		X (Annex)				X (Annex)			X			X
Sampling						X (Annex)						X
Labelling regulatory framework		X (Annex)		X		X (Annex)	X		X			
Decision tree		X (PAL)					X (Labelling)				X (PAL)	
Examples / cases		X (PAL)							X (Annex: recall root-cause analysis)		X (Preventive measures)	X (Incident root-cause analysis)

ACP: Allergen control plan

Table 3. Allergen control plan elements considered in the guidance documents reviewed

	General Guidelines										Sector-specific	
	FCPMC - FPACC (1999)	FSA (2006)	FARRP (2009)	GMA (2009)	Argentina (2013)	FoodDrink Europe (2013)	Alberta (2014)	CFIA (2018)	Australian Food and Grocery Council and the Allergen Bureau (2019)	Codex (2020)	FSIS (2015)	Dairy Food Safety Victoria (2018)
Primary production										X		
Management commitment				X			X		X			
Team			X	X				X				X
Training / people		X	X	X	X	X	X	X	X	X	X	X
Supply chain / suppliers / ingredients / raw materials	X	X	X	X	X	X	X	X	X	X (Control of operation)	X (Identify)	X
Equipment / factory / process design	X	X	X	X		X		X	X	X	X	X
Manufacturing (segregation, production, scheduling, control of rework, etc.)	X	X	X	X	X	X	X	X	X	X	X (Prevent & Control)	X
Labelling / packaging / communication	X	X	X	X	X	X	X	X	X	X	X (Declare)	X
Product development / reformulation	X	X	X	X	X	X	X		X	X (Control of operation)		X
Documentation				X		X	X		X	X (Control of operation)		
ACP monitoring / review / evaluation / auditing			X	X		X	X		X	X (Control of operation)		X
Cleaning / cleaning validation / sanitation	X	X	X	X	X	X	X	X	X	X	X (Prevent & Control)	X
Traceability / tracking / recall procedures	X			X					X	X (Control of operation)	X (Prevent & Control)	X
Transportation										X		
Sales / marketing / promotions	X											

References reviewed

ALLERGEN MANAGEMENT GUIDELINES FOR THE FOOD INDUSTRY - GENERAL

Author	**Food and Consumer Products Manufacturers of Canada (FCPMC)**
Year	1999
Title	Allergy Beware 2000: Guidelines *Allergen management best practices*
Pages	24
Highlights	- General approach: **prevent cross contact, employee training, accurate labels** - **Prerequisite programs** = foundation - **Precautionary labelling** should provide relavant information to allergic consumers; used only after all reasonable steps have been taken to eliminate/control risk - Roles and responsibilities defined for **senior management, allergen management team, and local managers** - **Elements** (11) of an allergen management plan: product development/reformulation; process design/redesign; suppliers; raw material receiving, handling and storage; production scheduling; in-process controls; rework; sanitation; finished product labelling and handling; sales/marketing/promotions - Site-specific allergen control plan = **risk-based** (identify, evaluate, eliminate/control)

1. Introduction - The importance of managing food allergens
- Background information on food allergy
- Little information available on minimum amount of a given allergen required to elicit an allergic reaction; varies among sensitive individuals; can be extremely small
- Allergic consumers rely on the accuracy of ingredient information to establish product safety
- Food manufacturers must ensure that allergens are effectively managed, through (i) adequate **controls**, (ii) **training**, and (iii) **accurate ingredients listing**

2. Objective
To define general procedures and responsibilities for labelling and handling food allergens in the manufacturing process, to **minimize and control risks** to allergic consumers.

3. Strategy
Minimize and control potential for **crossover** and ensure product **labels** are accurate.

4. Scope
Vendors, consumer food plants, retail and foodservice, contract packer facilities. Raw materials, in-process and finished products. Manufacturing, handling and shipping.

5. Allergen management principles
i. **Controls and training** must be in place within **each establishment** to effectively manage food allergens
ii. Ingredient statements on **labels** and packaging must **accurately** reflect the presence of allergens
iii. **Precautionary labelling** statements should provide relevant information to allergic consumers and should be used only after all reasonable steps have been taken to eliminate or control risk

6. Definitions

Various allergy related terms.
Note: in this document, “PAL” is used as an acronym for “priority allergen list”.

7. Allergen management roles and responsibilities

7.1 Senior management

- Provide the necessary **resources** to identify and manage allergen controls. Includes establishing a task force (allergen **team**)
- Set allergen management **policies**
- Establish knowledgeable **contacts** within the organization to respond to regulatory, professional and consumer groups regarding allergen management
- Periodically **review** allergen management practices

7.2 A cross-functional allergen management task force should be formed

Responsibilities:

- **Identify** products, processes and raw materials that may present allergen management **risks**
- Develop **principles and policy** for effective and consistent allergen management
- Develop policy that reflects the company’s approach to:
  i. ensure that **labels** accurately reflect allergens present in the product
  ii. assess and prevent potential for **cross-contact** (within HACCP)
  iii. establish criteria and principles for the use of **precautionary labelling**
- Facilitate employee education and **training** on effective allergen management
- Facilitate the implementation of allergen management **practices** involving: product design/ redesign and development; process design/redesign; supplier selection approval and development; sales, marketing and promotional activities
- Conduct periodic **review** and scheduled audit of plant processing and allergen management principles and policy
- Ensure **consumer service representatives** have accurate ingredient information

7.3 Responsibilities of local manufacturing and project managers for effective management of allergens

- Ensure allergen management procedures and processes are in place within their facilities
- Ensure that processes are in place to eliminate or control the potential for allergen **cross-contact**, by:
  - **Assessing allergen crossover risk** within a manufacturing location
  - Designing and implementing an **allergen management plan** that covers product or process re-engineering, training, and other strategies (raw material receiving, handling and storage controls; production scheduling; in-process controls i.e. GMPs; sanitation; finished product labelling)

8. Allergen management process

8.1 Prerequisite programs

Allergen management is built upon an existing foundation of strong food safety and quality management processes:

- HACCP
- Product trace and retrieval (recall procedures)
- Hold and release controls
- Labelling policies and practices
- Manufacturing controls: GMPs/GWPs; design and maintenance of buildings and equipment; sanitation and cleaning; inventory management

- Internal quality auditing
- Consumer feedback and response systems
- Records and documentation (for all of the above)

8.2 Elements of an effective employee education/training program
- All employees working in the production area
- Documented
- Handling of allergen-containing samples
- Where possible, employees should wear dedicated clothing and use dedicated washing facilities

8.3 Elements of an effective allergen management plan

8.3.A Product design and development controls (including product reformulation)
- **Avoid** the inclusion of, or eliminate allergens in a product formula. Allergens should be present only in products where (i) the finished product in itself is an allergen or an allergen-containing product, (ii) the allergen performs a function that cannot be replaced with a non-allergen component
- Allergens intentionally included in a product should be **flagged** in raw material specifications, product formula/batching instructions, finished product specifications
- Plant trials require strict controls; all personnel involved must be aware that allergens are present
- Label and packaging control: design/pre-printing verification; processes to prevent mix up during production

8.3.B Process design/redesign controls
- When possible, dedicated facility for allergen-containing products
- When not possible, effective controls to avoid cross-contact of allergens with non-allergens:
  - Sanitary design
  - Segregation of allergen-containing products during storage, handling and processing
  - Dedicated equipment for handling and processing allergens
  - Shared processing areas require production scheduling + extensive sanitation

8.3.C Supplier selection and development
- Suppliers of raw materials must be aware of and in compliance with the purchaser's expectations for allergen management
- Supplier **selection criteria** must include:
  - A "Supplier information sheet", identifying the presence of allergens
  - Emphasis on the supplier's identification and management of **sub-ingredients**
  - If allergen is present, must state in what **form it appears and at what levels**
- Allergen management practices must be verified via a supplier assessment process
  - Basis for supplier approval and development
  - On-going interaction is required
- **Purchasing** must be be notified by the supplier of changes in their allergen management practices
- Packaging and labelling suppliers must ensure that labels/artwork are verified prior to printing, and bundles of mixed cartons/labels are not shipped to the purchaser

8.3.D Raw material receiving, handling and storage controls
- Ingredient declaration for all raw materials must clearly identify allergens, when present

- Dedicated vehicles, equipment and utensils for the transportation and handling of incoming materials containing allergens. If not possible, inspect meticulously for allergen cross-contact
- Upon receipt, each unit of allergen-containing raw material must be identified with an allergen alert sticker
- Allergen-containing raw materials should be segregated during storage

8.3.E Production scheduling and sequencing controls

When using shared equipment:
- Allergen-containing products should follow allergen-free products
- Different product formulas containing the same allergen(s) should run sequentially
- Adequate time to ensure thorough cleaning as part of changeover

8.3.F In-process controls
- Each location should develop a **site-specific allergen control plan**:
    1. Determine if allergen-containing products are made on the same line as products not containing that allergen
    2. **Identify** areas of potential risk (crossover, packaging errors, mislabelling)
    3. **Evaluate** the consumer risk of injury for each area identified
    4. **Eliminate or control** the risk
    5. **Primary strategy: isolation and segregation**
    6. When not possible, identify where there is a potential hazard of cross contact
    7. If allergen-containing dust is present, consider vacuum systems, positive air pressure
- Location management should re-evaluate the allergen control plan periodically
- Current and accurate lists of products containing allergens must be on hand

8.3.G Product rework and hold-over controls
- Clearly labeled to identify allergens, when present
- When possible, use dedicate vehicles, equipment and utensils for transportation and handling of rework/hold-over product containing allergens
- Store in segregation
- Added only to product having a similar formula containing the same allergen (“like into like”)

8.3.H Sanitation controls
- Written cleaning procedures for facilities and equipment must be thorough, accurate/ specific, current and readily on hand
- Clearly outline when product flushing vs dry cleaning vs wet cleaning constitute “effective” sanitation controls
- The final step should be a thorough post-cleaning inspection, with sign-off

8.3.I Finished product labelling and handling controls
- Ensure product labels match product formula
- Process to detect mixed packaging or labels received from suppliers
- Packaging and labels must be completely removed from the line during changeover
- Return unused packaging materials to the warehouse at the end of a product run
- Destroy obsolete labels, packaging, etc.
- Store finished product segregated from raw materials and rework that contain allergens

8.3.J Sales / marketing / promotions
- Current and accurate lists of products containing allergens must be available
- Packages of similar products but with different formulas should be designed with significant graphic differences

- Product for consumer testing/in-store demonstrations must be labeled such that consumers are aware of the presence of allergens
- Staff handling demonstration product samples must be trained in allergen awareness and cross contact controls, and must provide accurate ingredient information to consumers
- In-home promotions must provide products with ingredients lists

9. Effective management of allergens under a HACCP program
- HACCP principles
- Ingredient statements on packaging and labels must accurately reflect the presence of allergens
- Proper label application must be a CCP where the allergen is in the food by design and package label application is prone to error

Author	**Food Standards Agency (FSA) - United Kingdom**
Year	2006
Title	Guidance on allergen management and consumer information
Pages	63
Highlights	- **Best practice** guidance (generic, qualitative) for food producers on managing food allergens - **Principles** (7 manufacturing elements): people; raw materials and supply chain; premises, equipment and processes; cleaning; packaging; new product development and reformulation - Invest in cleaning = reduce likelihood of costly recalls - **Qualitative (i.e. no thresholds at the time) risk-based approach for PAL** - **PAL decision tree** follows **risk analysis framework** (risk assessment, risk management, risk communication + risk review)

1. Introduction

Voluntary best practice guidance for allergen management and labelling for food producers and retailers (plus leaflet for smaller businesses).
Advisory labelling should only be used when, following a thorough risk assessment, there is a **demonstrable and significant risk of allergen cross-contamination**. Since currently (*i.e. 2006*), there is no consensus on thresholds, this document applies a **qualitative approach** to allergen management and risk assessment.

2. Background and purpose

2.1 Food allergies and intolerances (2 page overview)
2.2 Purpose of this document
To set out **best practice guidance** that **could be used across the various sectors** of the food industry. Attempts to establish a **common understanding** by food producers and retailers, enforcement bodies, and consumers **of when warning labels might or might not be used,** and what they mean. This document **builds on previous advice** and provides best practice guidance on:
a) the **management** of allergens in the manufacturing of food products; and
b) the adoption of a **risk-based approach to the appropriate use of label** statements to advise consumers of the risk of unintentional allergen cross-contamination.

2.3 Scope: Any food allergen in any particular food-manufacturing environment.

3. Allergen risk assessment, management and communication

In order to avoid the unintentional presence of allergenic foods, it is necessary to evaluate the likelihood of unintentional allergen cross-contamination **across the supply chain**, from raw materials to the finished product.
Risk analysis stages: risk assessment, risk management, risk communication, risk review

Figure 4: Steps in the **decision tree for managing allergens** (theoretical worked examples in Appendix III)

No.	Step	Possible outcomes	Questions
1	Risk assessment from intentional presence	Yes / No	
2	Exposure assessment	Probable / Remote	What is the likelihood, under normal operating conditions, of cross-contamination from the **ingredients** (during growing, harvesting, processing, handling, distribution) or the **manufacturing environment** (production line or equipment comes into direct contact with allergen containing materials)?
2a	Check against ingredient labelling	Yes / No	Is potential cross-contaminating allergen already declared?
3	Check against exemptions list	Yes / No	Is potential cross-contaminating allergen exempt from mandatory labelling?
4	Hazard characterization	Physical form, highly refined? no protein present?, distribution of contamination, etc.	
5	Risk management of unintentional presence a. Highly refined / little or no protein b. Liquid or powder materials with homogenous distribution: appropriate measures should minimize the risk c. Particles or powdered materials with heterogeneous distribution	a. No PAL required b. No PAL required c. PAL required (**unless**: evidence of visually clean standard, or assessment of the end product as consumed indicates little or no allergenic protein remains)	Can the risk of cross-contamination be reduced or eliminated?
6	Risk communication	PAL requirements	
7	Check other relevant allergens. Repeat steps		

3.1. Risk assessment

First step: consider if the ingredient/product **intentionally** contains allergens, and if they have the potential to cross-contaminate foods produced on the premises, or ingredients coming into the premises.

Factors to consider when evaluating the need for allergen warning labels:
- Amount of the allergenic food generally needed to provoke a reaction (no conclusive information - 2006)
- How common adverse reactions are to that particular food in the population to which it will be marketed
- Particular subgroups likely to be at particular risk
- Relative allergenicity of the particular ingredient being used (e.g refined nut oil vs pieces of nuts)
- Physical nature of the particular ingredients being used and the geography of the manufacturing environment (e.g. powder vs liquid milk)

Second step: identify the probability of **unintentional** presence of allergens, by thinking about how cross-contamination could happen and how likely it is to happen.
Figure 2 - **Potential sources of cross-contamination**: raw material handling, storage, transport, people, cleaning, shared equipment, rework, air particles, supply chain, packaging, processing aids, other

Outcome of the initial risk assessment will be either:
- **Probable:** likely chance of risks occurring
- **Remote**: risks are unlikely to arise but are still possible. Low probability risks should not be ignored and should be managed and eliminated where appropriate.

3.2 Allergen risk management
Where a risk has been identified (as either probable or remote), attempts can be made to reduce it.

3.2.1 General principles
Allergens should be managed to avoid their unintentional presence in products wherever possible. Allergen management should be an **extension of existing food safety management** rather than a completely new system.

3.2.2 Manufacturing
People
All staff (including temporary and contractors) involved in handling ingredients, equipment, utensils, packaging and products should be aware of food allergens and the consequences of their ingestion by sensitive individuals. Appropriate procedures on the management of allergens should be available.

Training should include: recognising which ingredients are the allergens of concern and why; identifying potential allergen cross-contamination situations; hand washing; clothing requirements including laundering; re-work / waste management / cleaning procedures; dedicated equipment; people and equipment movement around the site.

Raw materials and supply chain

Food businesses should establish an appropriate and proportionate **policy for assessing the allergen status of ingredients** and if appropriate, for assessing ingredients used by their suppliers. Any change in supplier should be accompanied by the appropriate checks.

Manufacturers must be aware of the presence of the major allergens in all raw materials, particularly the **potential for allergen cross-contamination from manufacturing and handling activities on the raw material suppliers' sites**, as well as **earlier in the food chain**

during harvesting and transport. This may be through audits or from asking suppliers to provide the required information. Suppliers should notify changes in the allergen status of the materials they supply.

Manufacturers should ensure that materials are ordered against a **clear specification** and that they ask appropriate questions of their suppliers, e.g. does the ingredient contain any food allergens either as a major component, a minor component, or due to cross-contamination.

Steps should be taken to **ensure that non-allergenic ingredients do not come into contact with allergens** in subsequent handling and storage.

- Allergenic raw materials should be stored in clearly identified areas e.g. using colour-coded boxes or demarcation of storage areas
- Where allergenic raw materials are de-bagged or de-boxed, they should be placed in dedicated lidded and labelled containers, easily identifiable.
- If allergenic ingredients are sieved, the sieving unit should be either dedicated or thoroughly cleaned after sieving allergenic ingredients. If possible, allergenic ingredients should be sieved after all other raw ingredients have been sieved for the day.

Manufacturing Premises, Equipment and Processes

Where dedicated production facilities are not possible, the production of allergen-containing products from those that do not contain the allergen can be **separated**:

- In different parts of the production area
- By using physical barriers between the production lines
- By use of dedicated equipment
- By minimising unnecessary movement of materials
- By appropriate scheduling of production runs, including appropriate cleaning of equipment between production runs
- By ensuring that residual material containing an allergen is not re-worked into a product not containing the allergen
- By separating the air supply, where this is practical

Shared equipment

If **dedication of equipment/areas** within production facilities is possible, it is important to avoid
allergen cross-contamination between these and other operations (managing the movement of equipment, personnel, vehicles and maintenance tools). Consider colour coding equipment.

Physical Separation

Should be considered for ‘high risk’ ingredients. Avoid crossover of production lines. Allow adequate space for effective cleaning

Airborne Particles in Manufacturing Area

When scheduling production runs, products not containing the allergenic ingredient should go first. Long runs of allergenic products should be undertaken wherever possible, followed by a major clean down.

Storage

Temporary labelling of WIP: care should be taken that the product is not mistaken for another product with a different set of allergens.
Label and store packaging materials that are unused at the end of a production run.

Products which for quality reasons are not acceptable as finished product but could still be consumed by employees or sold through factory shops should be subject to the normal allergen labelling controls.

Re-work
Re-work that contains allergenic ingredients should be re-worked only into products that contain that allergen. Oils used for cooking allergenic foods should not be used subsequently for cooking products not containing that allergen.

Cleaning

- 'Visually and physically clean' standard: all of the trouble spots are sought out and inspected
- Cleaning practices that are satisfactory for hygiene purposes may not be adequate for removing some allergens
- Equipment may need to be dismantled and manually cleaned to ensure hard to clean areas are free from allergen residues
- Where adequate cleaning is not possible, then the risk of allergen cross-contamination should be assessed and advisory labelling used, if appropriate.
- Cleaning of one line must not contaminate another (e.g. by use of compressed air cleaning), or an area which has already been cleaned (e.g. clean dry mix areas from the top down)
- Any spillage should be cleaned up immediately
- Where known allergen contamination has occurred, the contaminated material should be labelled and physically moved away from the non-contaminated ingredients and WIP
- Cleaning equipment must be cleaned after use
- **Investment in developing and following appropriate cleaning regimes** will help to minimise food allergen cross-contamination and **can reduce the likelihood of product recalls**
- Cleaning regime should include **laundering of protective clothing**
- Cleaning regimes must be validated and monitored

Packaging

- Procedures for checking that the correct labels are applied to products should be implemented and audited regularly
- Following recipe changes or the introduction of a new allergen cross-contamination risk, the old packaging must be withdrawn from use and physically destroyed
- 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
- The correct outer packaging must be used for multi-pack products. Allergen information should appear on, or be visible through, both the inner and outer wrappers

New Product Development and Reformulation

- It is good practice not to include an allergenic ingredient in a product unless necessary
- Reformulation of a product with the introduction of a new allergenic ingredient may lead to accidental contamination of other lines produced in the same premises, for which advisory labelling might then become appropriate
- If it is decided to **extend a brand name** into a different product sector, the presence of any allergen not associated with the original product must be clearly indicated.
- If conducting factory trials of allergen-containing products, measures should be taken to avoid allergen cross-contamination with existing products. Information on the presence, or potential presence, of allergens should be made available to those involved in factory trials and in taste testing

- Following any changes to the production process, conduct a new assessment of the risks of allergen cross-contamination, including an evaluation of any advisory labelling
- Any changes to the allergen status of a product need to be made obvious to the consumer, e.g. by using prominent labelling flashes, in addition to the amended ingredients list.

3.3 Allergen risk communication
Following completion of the risk assessment and elimination or reduction of the risks where possible, a **decision on whether or not advisory labelling is appropriate** then needs to be made.

3.3.1 Advisory labelling
Overview of format considerations.
Advisory labelling on possible cross-contamination with allergens should be justifiable only on the basis of a risk assessment applied to a responsibly managed operation. **Warning labels should only be used where there is a demonstrable and significant risk of allergen cross-contamination**, and they should not be used as a substitute for GMPs.

3.3.2 Allergen-free foods
Gluten (also in Annex)

3.4 Allergen Risk Review
Allergen Management Systems should be monitored and reviewed to provide assurance that they are working correctly, e.g. through routine checks on manufacturing operations including an audit of the system.
Review annually, and when changes may introduce risks, e.g. introduction of new ingredients, new recipes or new processes; changes in scheduling, equipment, site, source of raw material, product storage, handling or manufacture; review of EFSA list of allergens for mandatory ingredients listing

Appendix I: Allergen Prevalence and Severity
Appendix II: Legal Considerations of Allergen Cross-Contamination
Appendix III: **Worked Examples**
Appendix IV: Allergen Testing Methods
Appendix V: Sources of Further Information

Author	**FARRP (USA)**
Year	2009
Title	Components of an effective allergen control plan - A framework for food processors
Pages	15
Highlights	- Concise overview of **allergen management best practices** - Allergen management protects consumers and company - **Fundamentals**: team, risk assessment, allergen map, ACP, regular review - **ACP elements** (7): product design (R&D), segregation (receiving, storage, handling, processing), supplier control, prevention of cross-contact, label (review, usage & control), **validated allergen cleaning** program, training

I. An Allergen Control Plan protects consumers —and your company
An ACP is about protecting the **health and confidence of consumers**, and also about protecting the **financial health and reputation of your company**.

II. The fundamentals
- Form a multi disciplinary allergen control team
- Conduct a risk assessment to determine the choice of specific allergen management procedures
- Develop an allergen process flow diagram ("allergen map") to understand where allergenic ingredients and foods exist in the plant and where they are introduced into the process
- Develop an ACP specific to each processing facility
- Review the ACP regularly and update when necessary

III. Product design (research and development)
- Only add allergens to new products when they make a difference in taste or functionality
- Question ingredient suppliers on the functionality and necessity of allergens in their formulation
- Understand the existing allergens or lack of allergens in the manufacturing facilities
- Create a process to review allergens in new products with the manufacturing facility prior to ordering ingredients and start up
- Avoid using allergenic ingredients in such low amounts that they have no or minimal functional effect in the finished product

IV. Segregation of allergenic foods or ingredients during receiving, storage, handling and processing
Keep allergenic foods and ingredients separate from all other products and ingredients from the time they enter the facility until they are introduced into the production line and beyond. Every attempt must be made to visibly identify allergens and isolate them at every step from other foods, ingredients and equipment.
General recommendations in line with FSA (2006).

V. Supplier control programs for ingredients and labels
The ACP should **outline expectations, documentation and validation** to ensure suppliers are diligent and dedicated to controlling and managing allergens.

General recommendations in line with FSA (2006). Also:

- Require suppliers to have sanitation **cleaning procedures in place which are validated** on a regular basis and whenever there is a change that may affect the allergen status of the line (i.e. new or changed product, ingredient, equipment, etc.)
- Conduct a supplier survey which includes:
  - The ACP of the supplier
  - The range of **allergenic products produced by the supplier, especially on shared equipment** with your ingredient(s)
  - The supplier's allergen cleaning program and protocols
  - Allergen training records for supplier's employees

VI. Prevention of cross-contact during processing

General recommendations in line with FSA (2006): scheduling of processing runs, during manufacture, rework and work in process, maintenance and engineering

VII. Product label review & label/packaging usage and control

Proper packaging labels not only help protect consumers, but protect the company from costly recalls, regulatory scrutiny, and potential liability.

General recommendations in line with FSA (2006). Also:

- Monitor, document, and verify the correct label at all changeovers as they occur
- Train line personnel on techniques for ensuring product labels are switched appropriately at product changeover on the production line

VIII. Validated allergen cleaning program

General recommendations in line with FSA (2006): overall plant design, sanitation SOPs, cleaning validation procedures, cleaning verification procedures, confirmation and compliance.

Also, regarding cleaning validation:

- Define the **intention and scope** of validation
- Describe the **sampling procedures and the reason for conducting them**
- Define and describe the analytical procedures to be used
- Define the **final acceptance/validation criteria**
- **Ensure all associated product is held pending test results**

IX. Staff training and education

General recommendations in line with FSA (2006).

Also: in all training, include information on the **reasons protocols are required—as well as the potential consequences** should the plan not be followed.

Allergen Precautionary Labeling: Food Manufacturers' Frequently Asked Questions

PAL: Its goal is to indicate a product not intended to contain specific allergen(s) may sporadically contain that allergen due to unintentional and unavoidable cross-contact in the manufacturing process even after implementing a comprehensive ACP.

Author	**Grocery manufacturers association (GMA)**
Year	2009
Title	Managing allergens in food processing establishments (Chapter 2: Basics of food allergen management; Chapter 3: Key components of a food allergy management program; Chapter 4: Labelling and packaging)
Pages	79
Highlights	- **Fundamentals**: management commitment, policies, resources, training, GMPs, documentation, evaluation and auditing, allergen control and product development - **Identify and evaluate hazards** of undeclared allergens following a 5-step risk-based approach - **Key components** of an ACP (6): ingredients, process design, control of rework and WIP, cleaning and sanitizing, tracking allergens, controls of food labels and packages - **PAL** should be used only if **4 criteria (qualitative)** are met

Chapter 2: Basics of food allergen management

Preliminary tasks for setting up an allergen management program:
- Commitment from senior management
- Allergen management policies
- Sufficient resources
- Employee training and awareness
- Adhering to current GMPs
- Documentation system: written procedures, operational and verification records, systematic audits

I. Management's responsibilities
- Establishment of allergen management policies and procedures; communicate them to employees
- Periodic reviews/audits
- Provide resources

II. Allergen management team
Multidisciplinary. Develop allergen management plan, based upon a risk evaluation.

III. Evaluating the hazards of undeclared allergens
Hazard identification and hazard evaluation:
1. Identify allergen-containing materials normally associated with each product and process
2. Map the flow of all ingredients, products, and allergen-containing materials through the process facility ("allergen mapping")
3. Identify specific areas/procedures where cross-contact may occur and evaluate the likelihood this could lead to an undeclared allergen in any finished product
   - Difficult and time-consuming: (i) detailed identification of potential for cross-contact, (ii) evaluate the likelihood that cross-contact could lead to the presence of an undeclared allergen in a finished product

4. Identify potential problems with labels and labeling/packaging of products containing allergens and evaluate if they could lead to an undeclared allergen in any finished product
5. Identify the potential presence of undeclared allergens in incoming materials and evaluate the likelihood that this could result in an undeclared allergen in any finished product

IV. Employee allergen training and awareness
General / For plant employees / For the allergen management team

V. Laws and regulations affecting allergen management
1. GMP regulations
Regulatory considerations.
Relationship of cGMPs to allergen management
Other plant control programs provide the basic environmental and operating conditions that are necessary for effective allergen control: sanitary design and construction, equipment, buildings and structures, air handling systems, maintenance, employee practices, outside contractors, cGMP modernization.

2. The food allergen labelling act and consumer protection act
Links to relevant references

VI. Documentation
1. Written procedures
- **Sanitation SOPs**

Allergen management depends to a large degree on maintaining sanitary conditions in a plant that go **beyond basic food plant sanitation or cGMP compliance**. Detailed procedures on how to achieve these conditions should be developed.

- **Validation and verification of sanitation** procedures

Validation:
To ensure the procedure removes all appreciable residues of target allergens.
Visual inspection followed by allergen testing is one approach.
If a test kist is not available, visual inspection may be the only tool.
Verification:
To ensure a validated program is being followed.
May include visual inspection, allergen testing or other methods.
Testing for the presence of residual allergen proteins can be done on the final rinse of a CIP cycle or on food contact surface swab samples after clean up operations.
“Push through” methods may require testing of the first product packaged for consumption after an allergen clean changeover. All finished product should be retained under the company’s control until the lab results are received.

- **Other allergen management activities**

Apart from sanitation, SOPs should be developed for: control of ingredients, storage and handling of ingredients and packaging material, scheduling, control or rework and WIP.
Also, written procedures should be developed to verify that these procedures are effective and are being implemented.

2. Records

Records are written evidence that procedures and processes are being followed in accordance with the requirements.

- **Background information on the allergen management program**

Hazard evaluation (including the identification of allergens of concern, “allergen mapping”, potential packaging and labelling problems); list of the allergen management measures (including rationale); validation of sanitation procedures; reasoning behind all monitoring, corrective action and verification activities; list of other plant operation programs that impact the management of allergens.

- **Monitoring records**

To assure that validated procedures are being followed, and for analysis of trends. Examples: confirmation that the proper ingredient statement is on the finished product, confirmation of clean equipment after a changeover, documentation that rework is being properly used, etc.

- **Corrective action records**
- **Verification records**

Activities, other than monitoring, that ensure the allergen management system is operating according to plan. Examples: pre-op sanitation inspections, equipment calibration logs, allergen test results, label reviews, yearly audit reports, etc.

- **Validation records:** for sanitation procedures
- **Training records**

VII. Evaluation and auditing

Periodically audit the overall allergen management plan.

1. Evaluation of written allergen management procedures

These documents should reveal the level of awareness and commitment the company has towards allergen management. Examples: company policy, allergen management team, procedures for approval of vendors, hazard evaluation, etc.

2. Audits of allergen management practices

To determine if they are being conducted according to the written allergen management procedures. Could include on-site review of operations and practices, interviews with employees and reviews of records.

VIII. Allergen control and product development

- Product formulation: avoid including allergenic ingredients if it is not critical to the identity of the product
- Reformulating products: deliberate formula modifications that introduce allergens should be made with caution. Requires clear communication with the consumer.
- Factory trials: require strict measures
- Consumer testing: these products should be clearly marked as containing allergenic ingredients

Chapter 3: Key components of a food allergen management program

I. Ingredients

1. Supplier control

Since almost all allergens enter facilities in ingredients or processing aids, a company's relationship with suppliers is important, especially regarding **knowledge of the supplier's allergen control procedures.**

Prior to **approving suppliers**, companies should:
- Verify that the supplier has procedures in place that can be used to highlight the presence of allergens and to minimize the potential for inadvertent presence of allergens
- Require evidence that the suppliers have written allergen control programs in place
- Agree on who is responsible for transporting ingredients and confirm that transportation practices are adequate, especially for **bulk ingredients**
- Require suppliers to fill up a questionnaire to determine the level of risk with the material they are receiving
- Seek additional information on the formula and all ingredients/components of the items being supplied
- Determine if any allergens are handled or produced in the supplier's facility that are not part of the supplied ingredients or materials
- In addition to specifications, require a **Letter of Guarantee,** and if applicable a Certificate of Analysis with each lot
- Develop a feedback mechanism to alert of any changes at the supplier's facility that might alter the allergen status of the supplied material
- Conduct audits

2. Ingredient receiving
General recommendations in line with FSA (2006): training, inspection, identification, integrity, verification of supplier status

3. Ingredient storage
Minimize risk of allergen cross-contact.
General recommendations in line with FSA (2006): closed packages, segregated storage, dedicated tools and utensils, color coding.
Also: **bulk storage** silos or tank farms need stringent controls.

II. Process design
Minimize potential for allergen cross-contact by physical and temporal means.
General recommendations in line with FSA (2006):
- Process design strategies
- Dedicated systems: lines, equipment, utensils, tools, storage areas, personnel, etc.
- Physical separation: walls, doors, designated rooms, protection of product conveyors, labelled / locked out equipment, designated staging areas, controlled traffic
- Production scheduling: order and timing of production, allergen changeovers,

III. Control of rework and work in process
Main concerns: wrongful inclusion of a material that contains an allergen in a product that does not list this allergen, and accidental cross-contact during during holding or storage
General recommendations in line with FSA (2006):
- Storage of rework and WIP: prevention of cross-contact, product identification and inventory control
- Use: "like into like", **tightly controlled re-entry procedures**, documentation on their reintroduction into the process stream

IV. Cleaning and sanitizing
1. Brief overview of wet cleaning, dry cleaning and “push through”.

2. Allergen clean procedures
“Allergen clean”: food contact surfaces and areas around and above the processing line are **visibly clean** e.g. free of visible residue. This concept is based on the premise that the absence of visible residue equates to the absence of detectable allergen-containing residue. This was valid when detection of allergens on food contact surfaces was difficult. With the availability of allergen test kits, in the future allergen clean may mean the **absence of detectable allergen-containing residues**.

- **Changeover** requirements: SOP, including forms and checklists
- **Validation** of cleaning and sanitation procedures

Collecting and evaluating scientific and technical information to determine that a process, when properly implemented, will effectively control a hazard or produce a desired endpoint. Within an allergen control program, a validated cleaning procedure adequately removes targeted food allergens from food contact surfaces.

Alternatives to validate SSOP effectiveness:

- Analyze the first product produced after the changeover for the presence of the allergen(s) present in the prior product produced. When using CIP, test the final rinse water for allergenic residues.
- Use a qualitative test kit to assess whether equipment surfaces are free of allergenic residues after application of an SSOP. However, it is impossible to predict how much contamination might exist in the finished product based on a positive swab test of a food contact surface. It is advisable to swab areas that are especially difficult to clean.

Validation is particularly important in the case of “push through” of thick, highly viscous liquids.
Validation tests should be performed enough times to provide statistical confidence that successful results can be repeated.

General recommendations in line with FSA (2006): repeat validation, changes may require reassessment / revalidation, ATP systems should not be used exclusively for validation of SSOPs.

Also: **once SSOPs are validated using allergen test kits, ATP values could be correlated with a successful completion of the validated SSOP. ATP could then be used as a verification of a successful clean up.**

- **Verification** of an SSOP

Those activities, other than monitoring, that determine the validated procedure is being implemented properly and the system is operating according to plan. Methods: visual inspection, ATP tests, allergen test kits, etc. The outcome of the verification will determine whether the system is considered allergen-clean.

V. Tracking allergens
Regulatory requirements: tracing goods along the food chain at least one step forward and one step backward.

Includes traceability; recall capability; and **system to account for the receipt, use and shipment of ingredients and products**.
It is important to know how much of an allergen was received and how much is in inventory; how much, when and in what product it was used; if it was part of a carried-over or reworked product; and how much of the finished product was shipped.
Challenges: bulk shipment added to storage silo containing flour from previous delivery; carrying over partial product lots from one production day to the next.

VI. Controls of food labels and packages
- Design controls: procedures to ensure accurate fulfillment of label design orders.
- Inventory and processing controls: procedures should be in place to monitor finished products and their labels back through all phases of production. There is a variety of available measures: check ingredient statements upon receipt, discard out-of-date labels/packaging, proper packaging staging procedures, account for numbers of labels used versus packages produced, bar code scanning, etc.

Chapter 4: Labeling and packaging

"May contain"-type labeling
Should only be used if, after an evaluation, **all four of these criteria are met**:
1. A food allergen is present in the food plant and constitutes a risk of presence in food products that are not intended to include the allergen as an ingredient;
2. This risk cannot reasonably and feasibly be minimized without major revisions to manufacturing processes or equipment above and beyond GMPs;
3. The food allergen is likely to be present in some, but not all, of the food product where its presence is not intended; and
4. Consuming the food allergen in a product where its presence is not intended would constitute a health hazard to a consumer allergic to the allergen

If some, but not all, of these 4 criteria are met, food and ingredient manufacturers should consider additional food allergen control and/or labelling strategies other than allergen advisory statements.

When using an ingredient that utilizes an allergen advisory statement, the food processor should consider the 4 criteria when deciding whether to carry that allergen advisory statement forward to the label of its food or use an alternate statement.

Author	**Plataforma Alérgenos en Alimentos / Food Allergens Platform (Argentina)**
Year	2013
Title	Guía para la gestión de alérgenos en la industria alimentaria / Allergen management guidelines for the food industry
Pages	40
Highlights	- **PAL not used in Argentina**. **Allergen control aims at eliminating cross-contact** allergens - **ACP elements (6)**: raw materials, product formulation, allergen management in the factory, cleaning, labelling, training - Emphasis on supplier control (including letter of guarantee, cross-contact risk assessment), and cross-contact preventive measures in the factory - **Original elements:** packaging materials as allergens, aromatic ingredients and proprietary information, co-packers, latex gloves, identification and management of lots with high risk of cross-contact

Introduction
A robust allergen control program must assure that:
(i) allergenic ingredients or additives added to the product are declared on the product's ingredients list, and
(ii) there are no allergens unintentionally contaminating the product via cross-contact

1. Raw materials
Establish:
- Objective definition of the ingredient and its requirements (specifications)
- Supplier evaluation and selection criteria
- Supplier cooperation, in order to achieve the required standards
- Improvement programs, as needed

Specifications must transmit accurate information to suppliers, including information on intended use. Suppliers should be evaluated for compliance with specifications.

1.1 Allergen management in raw materials
- First step: accurate identification of raw materials that may contain allergens, intentionally or unintentionally added (at the manufacturing stage or at other stages, e.g. transport, handling).
- Suppliers must provide objective evidence demonstrating that they have an adequate allergen control plan in place.
- Suppliers must provide accurate information allowing for the identification of raw materials that may contain allergens.
- Supplier changes should trigger a review of the identification of raw materials that may contain allergens.

1.2 Letter of Guarantee
The most effective way to get suppliers involved into the allergen management chain is requesting written documentation explicitly stating the presence or absence of allergens in each raw material supplied (**template** for letter of guarantee, plus minimum and optimum

requirements). Questionnaires for evaluating the presence/absence of allergens in raw materials are also very useful (**template**).

Basic information to be provided by suppliers:
- Specifications including complete list of allergenic ingredients or additives in the supplied raw material
- **Origin of the raw material** - may vary with seasons
- **Allergen cross-contact risk assessment** including production, storage and distribution
- **Guaranteed absence** of defined allergenic ingredients
- Objective evidence of an allergen control system in place
- Commitment to communicate any changes that would alter the potential presence of allergens in raw materials. It is important to design a system alerting of changes in the ingredients formulations.

1.3 Packaging materials
Should be included in the allergen control program, as they **may contain allergen-based diffusing agents.**

1.4 Other considerations
- Allergen control should be included in the suppliers' development and evaluation plan. It is critical to make sure that suppliers have adequate technical capacity for managing allergens.
- Awareness of the consequences of providing inaccurate allergen information, with respect to allergic consumers
- Since the presence of allergens in aromatic agents may be considered **proprietary information**, signing confidentiality agreements with the supplier in this respect should be considered

1.5 Supplier audits
Suppliers and distribution partners should be audited regularly. Elements to include: manufacturing, raw materials receiving, handling and storage, transport, product formulation, rework, packaging, labelling, traceability records, spill SOPs, etc.

1.6 Co-manufacturers / co-packers
Should be audited as suppliers, with additional attention to: sub-providers reliability, purchasing procedures integrity, receiving and storage of raw materials, product formulation, manufacturing and packaging, effective cleaning and sanitation programs, potential cross-contact stages such as rework, etc.

2. Product formulation
2.1 Formulation review
Formulation review should be conducted with the purpose of (i) identifying all the allergens present, and (ii) evaluating the need for including these allergens

Information provided by suppliers for each ingredient should be used to check for the presence of allergens in the finished product. These should be highlighted in the recipe's technical sheet. If possible, allergens should be replaced by non-allergenic ingredients.
For existing formulations, it is recommended to avoid using allergens in quantities without functional effect, which may be common in the development of flavours and aromatic agents.

2.2 Changes control
- Any change implying the addition of an allergenic additive or ingredient requires paying special attention to the risk of cross-contact affecting other products.

- Changes should be highlighted, for example in product labels
- Supplier changes should also be evaluated to avoid or manage the introduction of new allergens
- Attention should be paid to any updates to allergen regulations

2.3 New product development
- For new products, if possible, allergenic ingredients should be avoided.
- Product developers should receive allergen training.
- **Cleaning costs** should be considered when formulating new products with allergens.
- Non-regulated allergens should also be used with caution.

2.4 Factory trials
Before conducting factory trials, the risk of introducing allergens in the production environment should be considered and preventive measures should be implemented. Trials should be supervised by personnel trained in allergen management.

3. Allergen management in the factory
There is currently *(i.e. 2013)* no agreement on the dose of allergen that, if ingested, would trigger a reaction in sensitive individuals. This is why it is important to consider all potential cross-contact situations that would lead to presence of allergens in finished products.
A **risk assessment** of cross-contact allergens, which would allow for the development of preventive measures towards their reduction or ideally, elimination, **should consider**: **raw materials handling, storage, transport, employees, cleaning, shared equipment, rework, suspended particles, supply chain, packaging, processing aids, other factors.**

In order to identify high risk situations, the development of a **risk map** is recommended. This map should outline the products produced in each line, time sequences, shared equipment, shared storage areas, cleaning procedures and schedules, situations that may lead to environmental contamination (e.g. powders, nuts' peels).

The **physical characteristics** of the allergens should also be taken into consideration: soluble (more homogeneously distributed, and easier to remove) versus particulates (lead to sporadic contamination, harder to detect and control). Oils used to fry allergenic ingredients should not be reused.

Prevention of cross-contact allergens
3.1 Facilities, equipments and utensils
Dedicated processing lines, physically separated, would be ideal.
Other strategies:
- Physical barriers to limit dispersion (e.g. walls, double doors, air flow, positive pressure)
- Restrict movement of allergens to specific areas/utensils only
- Allergens identification (e.g. color coding)

3.2 Production scheduling
Products that do not contain allergens in their recipes should be processed first, and those containing allergens, last, followed by a deep cleaning.
- Allergen-containing products should always be produced in the same lines
- Products with similar allergens should be produced in sequence
- Fewer and longer production runs should be programmed for allergen-containing products
- Start production of allergen-containing products with those that have the highest allergen concentration to achieve a "dilution" effect
- The allergenic ingredient should be added as late as possible in the production line

3.3 Segregation during storage and transport
- Attention should be paid when unpacking raw materials containing allergens
- Strict segregation should be maintained during storage and transport
- Spill control procedures should be in place

3.4 Movement of employees, raw materials, in-process products
Identification is key (e.g. color-coded clothing, signs).
To prevent cross-contamination, a risk assessment of each area should be conducted, considering its layout. **Zones** with and without allergens must be identified and segregated. Employees, raw materials and in-process products should avoid crossing allergen areas on their way to areas without allergens. The flow should go from allergen-free areas to areas with allergens.

3.5 Use of gloves
Gloves can be cross-contact vehicles and must be changed as needed. Latex gloves should be avoided as they contain proteins that can cross-react with allergenic proteins from some tropical fruits.

3.6 Suspended particles and use of pressurized water/air
For powder: consider using air filters and positive pressure systems in certain areas.
If milling allergen-containing products is required, this should be done in a physically separated area, or ensure an effective cleaning after milling.
The use of pressurized water or air for cleaning should be avoided.

3.7 Rework
Rework should only be used in identical products or even only in the same product lot. Alternatively, a clear matrix indicating which type of rework can be used in which type of product, based on the allergen profile, should be made available.
Records for rework should be maintained.

3.8 Identification and management of lots with high risk of cross-contact
The first lot produced after the change of product is the most likely to be contaminated. Taking this into consideration, the following options may be considered:
- This lot may be discarded
- Could be used as a baseline for analysis, and if negative, an assurance of absence of allergens in the subsequent lot could be provided
- This lot may be identified in the label as “1st lot” in order to inform allergic consumers at the time of purchase

3.9 Packaging and transport
- Validated cleaning procedures must be in place
- A very efficient label control system is necessary
- Obsolete packaging materials should be discarded.

During transport, packages should be hermetically closed and properly identified.

4. Cleaning
- Cleaning procedures must be documented and **validated for allergens**
- For validation, swabbing of cleaned surfaces and analysis with adequate methods should be conducted
- Verification procedures: visual inspection, analytical methods
- Training is critical for effective cleaning

- Equipment should be hygienically designed to facilitate cleaning. Disassembling may be required.
- Cleaning with water is generally more efficient than dry cleaning to remove allergens
- The use of pressurized water or air for cleaning should be avoided.

5. Labelling
- Accurate and thorough information should be provided to consumers
- Manufacturers must ensure that accurate labels are used for each product

6. Training
Consider allergens training separately from other training programs.

Author	**FoodDrink Europe**
Year	2013
Title	Guidance of food allergen management for food manufacturers
Pages	85
Highlights	- Developed based on FSA (2006) - Promotes consistent, harmonized, good practice on allergen risk management in the EU - Allergen **risk assessment**: likelihood allergens are present, physical form, amount - **Risk management process (8 elements):** people, suppliers, raw materials, equipment and factory design, manufacturing, consumer information, product development and change, documentation - **Cleaning** (separate section): general considerations, methods, validation and verification - **Analytical methods** (separate section): quantitative data for risk assessment, raw materials composition, validation of allergen control measures, supplier's control capability, allergen claims - **Principles of allergen risk management (5):** policy and guidance, people, supply management, manufacturing, communication In **Annexes:** Allergen **risk analysis** and management **(steps & template)**; Allergen analysis (including **sampling**); Allergen change over (cleaning/flushing) **validation (physical and analytical;** refers to **VITAL action levels or test LOQ)**

I. Introduction

Main goals:

- Provide sound, **evidence-based and consistent information on good practice** in risk management of allergenic foods and certain food intolerances for food producers
- Ensure **consistent understanding and approach to food allergen management by harmonizing and disseminating good practice** across the European food industry
- Help minimise the risk to allergic consumers and enable them to make informed product choices

II. Risk management process

2.1 Overview

Allergen management in food businesses should be an **integral part of existing food safety management** and **must consider all operations.** Operating following **GMPs** is essential.

Risk management starts with **risk assessment.** For allergens, this requires consideration of the **likelihood** that they are present, their **physical form** (powder, liquid, pieces, etc), and the **amount** present.

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. Procedures should include information on:

- Product development guidelines in terms of allergens
- Good hygiene (e.g. clothing, hand washing, hand contact with foods)
- Cleaning of premises, equipment and tools
- Handling of rework materials (e.g. conditions for use)

- Waste management (e.g. labelling and segregation)
- Situations where potential cross-contamination can occur and each employee's responsibility for preventing this
- Production scheduling
- Labelling of raw materials, intermediate products and finished products

Situations that may require a **re-assessment of the original risk**, and potentially new risk management measures: changes in processing, introduction of new materials or product, moving production of a product to another site

2.2 People

2.2.1 Training

All individuals 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, and should receive training, specific to their job responsibilities. 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 risk of contamination is suspected.

Training should be provided to all new employees **during orientation, and repeated on a regular basis** (e.g. annual refresher). **Visitors** should be informed of the site **GMP** rules.

Training and awareness programs should include:

- **General allergen awareness**, including the nature and possible consequences of their unintended/undeclared presence 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 and the corrective and preventive measures, and the procedures applicable
- **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, e.g. hand washing, use of protective clothing including laundering
- Procedures for people **traffic patterns** around the site
- **Equipment movement** around the site, e.g. maintenance tools, food trays
- **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

- **Dedicated work wear** for use in areas handling specific allergens or where a high risk of cross-contact through clothing exists
- Employees should **not be permitted to bring food or drink** into areas where products, ingredients or primary packaging is exposed
- **Contractors and visitors** must comply with **GMPs**. An assigned host should be responsible for assuring compliance. Visitors should always be accompanied by the host.

2.3 Supplier management

Accurate information on the allergen status of the raw materials and ingredients is essential to perform risk assessment effectively.

- Ensure that allergen status is fully described in raw material, packaging, labelling and specifications
- **Assess each supplier** and the application of allergen management practices in their operations (e.g. questionnaire or audit) and document the assessment
- Understand the allergen risk analysis from each supplier
- Ensure that information from suppliers is correctly recorded, including complete allergen status i.e. intentionally added and cross-contact
- Establish procedures on how information received from the supplier is handled
- 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, or a particular ingredient can be purchased from different suppliers, the food operator needs to identify the impact on the allergen status of the resulting product(s).

2.4. Raw materials handling

2.4.1 Incoming raw materials handling

- Allergenic raw materials, semi-finished products, etc., should be **identified** upon receipt and kept in **sealed packaging or separate** from each other and from other foods
- All deliveries should be checked before unloading. A special **"allergen spillage"** procedure may be necessary.
- Where allergenic materials are sampled on delivery, measures should be in place to make sure that the sample and the **sampling tools** do not create a **cross-contact risk** (e.g.colour-coded and/or disposable)

2.4.2 Handling of raw materials and intermediate semi-finished products

Risk: cross-contamination; inadvertent selection for a recipe of an allergenic material not present in the product

Management: **clear identification** and **segregation** of each allergenic material

- Check that allergenic materials are delivered clearly labelled and securely packed
- Store allergenic raw materials in clearly identified areas (e.g. color-coded boxes, demarcation of storage areas)
- Allergenic materials should be stored in clearly marked packaging
- 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
- Special care should be taken with ingredients in **dry form** due to risk of cross-contamination
- When allergenic materials are stored in non-segregated areas, appropriate means of preventing cross contact should be used (e.g. of bottom-level racking)
- Information on the identity of raw materials must be readily accessible and available

2.5 Equipment and factory design

- **Equipment and layout design**: avoid cross-over of production lines, allow adequate space to permit effective cleaning and inspection
- **Dedicated** lines, areas and equipments, for a specific allergen profile (when possible), including weighing tools and containers. Tools should be color-coded or appropriately labelled, or a validated cleaning program should be in place

- **Movement** control: limit movement of equipment, personnel, vehicles and maintenance tools between physically separated areas or dedicated equipment
- **Cleaning**: the equipment must be capable of being cleaned effectively. Protocols must be in place to verify and validate cleaning
- **Air**: 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 should be cleaned up
- **Non-food materials** (e.g. peanut oil in lubricants, wheat flour in cardboard packaging release agents) use should be risk-assessed

2.6 Production process and manufacturing controls

2.6.1 Recipe verification

Systems should be designed to avoid recipe mistakes (verification of the recipe at the time of addition of materials, software and engineering design features to avoid use of the wrong ingredients).

2.6.2 Separation

- By use of dedicated facilities, designated areas for specific allergens, physical barriers between production lines
- By minimizing unnecessary movement of materials and personnel
- By scheduling production runs (i.e. products without allergenic materials are produced first, after the last full cleaning)
- By separating the air supply, if appropriate
- Combinations of the above

2.6.3 Internal labelling for handling and production

For finished packing materials of similar appearance, it is important to ensure that the correct packaging is used. A checklist to be signed by the person responsible is recommended.

Products that 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

- Procedures for checking that the correct labels are applied should be implemented and audited regularly
- Production planning should include the order in which different products are manufactured and packaged
- Obsolete packaging (e.g. change in recipe) should be physically destroyed
- There should be systems to ensure packaging is removed at the end of a run
- Finished products containing allergens should be securely stored
- The correct outer packaging should be used for multi-pack products

2.6.5 Rework - internally recycled product

- Procedures for the handling of rework must be in place
- Ideally, rework should go into another batch or run of the same product. If not feasible, rework should only be used in product where the same allergen is already present
- Oils used for cooking allergenic foods should not be used for cooking products not containing that allergen without undergoing a validated filtration step
- The use of rework material containing allergens must be properly managed and documented

2.7 Consumer information

2.7.1 Ingredient labelling
In the EU, labelling of 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**.

2.7.2 Non-commercial samples (e.g. for taste sessions, exhibitions)
Complete allergen information should be available to consumers prior to consumption. Alternatively, consumers could be pre-screened for food allergies or intolerances.

2.8 Product development and change

2.8.1 Reformulating products
When an existing recipe is changed or an ingredient is substituted for another one containing allergens, the consumer should be clearly informed about that change, e.g. using prominent labelling flashes, in addition to the amended ingredients list. Suitable warnings might be “New Recipe” or “Now Contains”. Consumers should also be informed through **websites, patient groups and organizations.**

2.8.2 New product development
It is **neither practical nor even desirable to exclude food allergens** from new products. However, in order **not to add complexity to existing allergen risk management practices**, product development technologists should be aware of the implications of using allergenic ingredients in new products, and of introducing new allergens into existing formulations.

Successful implementation of new products containing allergens into existing manufacturing facilities requires ensuring that:
- Relevant personnel is informed in advance
- Factory trials include measures to avoid allergen cross-contact
- Information on the presence, or potential presence, of allergens is made available to those involved in factory trials and taste testing
- Information is clearly conveyed with products presented for 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 program. Record-keeping should be **integrated using existing paperwork**.

A **record of the risk management program** should be kept **with the risk assessment**, to demonstrate how risks are managed and reduced. This document should include details on **how the program is validated**, and ongoing verification. **Internal compliance** should be verified regularly by trained internal auditors.

III. Cleaning and cleaning validation

3.1 General
- Effective cleaning is crucial for allergen risk management
- **“Visually and physically clean” standard** requires identification and inspection of trouble spots, which should be highlighted on cleaning schedules
- Cleaning considerations should be built into the design of equipment (e.g. easy dismantling)

- Line cleaning must be **verified**
  - **Heterogeneously-distributed allergenic material**: cleaning is considered effective only if entire line is visually assessed and complies with “visibly clean” standard
- **Documented and validated cleaning** procedures are essential, and should be in place for **production and packaging** machinery
- Cleaning practices that are satisfactory for microbiological safety may not be adequate for removing some allergens
- Where adequate cleaning cannot be assured (e.g. inaccessibility), the **residual risk from allergen cross-contact should be assessed** and **advisory labelling** used, if appropriate
- Cleaning procedures must not contaminate other areas, e.g. by using compressed air, or by cleaning dry mix areas from the bottom to the top
- Spills must be cleaned up immediately
- Where known allergen cross-contact has occurred, the contaminated material should be labelled and segregated
- **Investment in developing and following appropriate cleaning regimes** will help to minimise food allergen cross-contact and can reduce the likelihood of recalls

3.2 Cleaning methods

The most effective and cost efficient methods for prevention of allergen cross-contact may be based on a **combination approach** (e.g. scheduling, cleaning and flushing), as determined by risk assessment.

3.2.1 Wet cleaning
- Best option, where practicable and usable without introducing microbial risk
- Rinsing stage must be sufficient to flush the system

3.2.2 Dry cleaning
- Filtered/protected vacuum systems are preferred, but brushes, dustpans, etc. are also acceptable
- Compressed air is strongly discouraged
- Cleaning equipment should be itself cleaned
- Dedicated cleaning equipment can be used to minimise cross-contamination

3.2.3 Flushing
- Flushing inert, non-allergenic materials (e.g. salt) to reduce levels of allergens can be beneficial
- More effective when combined with other cleaning methods
- Should pass through all parts of the plant with which the allergen may have been in contact, not only the primary process
- Used flushing materials should be handled per procedure for the allergen it now potentially contains
- A risk assessment should be conducted if the used flushing material is to be reused as an ingredient in a product with the same allergen profile

3.2.4 Validation and verification of cleaning
- **Verification**: process line is inspected and signed back into normal use after cleaning to confirm all detailed measures, cleans, flushes, etc. have been completed
- **Validation**: proof that the cleaning protocol is effective.
  - Requires **physical validation** of the cleaning **combined with quantitative analytical evidence** by using validated analytical methods
  - Should be conducted regularly and when changes in the formula, process, equipment or cleaning procedures may present a risk of cross-contamination

- Define a “worst case” (e.g. most difficult to clean allergen, allergen used in the highest proportion in a recipe)
- Documented validation **should be part of the HACCP program**

IV. Analytical methods and their application

- Can help and support **understanding of allergen management capability and control** but should never be regarded as the sole tool sufficient for allergen management
- Inappropriate for quality control purposes but useful for **validation of cross-contamination control capability**
- **Applications:** quantitative data for risk assessment, raw materials composition, validation of allergen control measures, supplier’s control capability, allergen claims
- Available methods: ELISA, PCR, lateral flow devices, MS, ATP and protein assays
- **Considerations:**
  - Method’s sensitivity, selectivity, specificity and reproducibility
  - Validated for the food matrices to be tested
  - Risk-based **sampling program** is relevant to the site, production equipment and process, and product

V. Key principles of allergen risk management

1. Policy and guidance
- Manage potential risks from allergenic foods
- Operate in line with GMPs
- Integrate allergen risk management in existing food safety management
- Document procedures

2. People
- Identify training needs of all personnel and deliver training
- Implement personal hygiene rules

3. 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

4. Manufacturing
- Handle incoming raw materials and ingredients per Allergen Management Plan
- Clearly identify allergenic raw materials and segregate as appropriate
- Ensure that stored allergenic raw materials and ingredients will not pose a risk of cross-contact
- Ensure the handling of allergenic ingredients does not create a risk of cross-contact
- Check implications of any change of raw material supplier
- If applicable, **understand the rationale for suppliers using advisory labelling**
- Implement **validated cleaning procedures**

5. 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

Annex 1: Background on food allergies and intolerances (4 page overview)

Annex 2: Allergen risk analysis and management

1. Characterization of the risk from allergens
2. Stages of an allergen HACCP risk analysis

No.	Step	Considerations
2.1	Identify all allergens present on site	- From materials intentionally added - Opportunities for **cross-contact within suppliers' operations** - Repeat for allergens that may be introduced via **non-food packaging** materials
2.2	Identify potential opportunities for cross-contact within own operations	- List / map all the concerned products / processes / lines and their allergen profiles, all potential carry-overs, cross-contamination and rework added
2.3	Assess each potential issue identified in 2.2 for **compliance with the best practice** considerations and evaluate the **probability for cross-contact as 'likely' or 'unlikely'**	- Critical elements in section 3
2.4	Determine the **allergen hazard rating** of any identified allergen cross-contact presence	- Allergen potency and prevalence - Allergen protein presence - Physical form of allergenic ingredients. **Risk potential ranking**: particulates > viscous pastes, gels, agglomerates > liquid / powder
2.5	Determine whether appropriate control measures are currently in place or can be implemented to minimize the risk of allergen cross-contact	- Refer to best practice guidance for control measures - Confirm effectiveness of control measures through robust scientific validation - Confirm verification procedures in place are carried out and remain effective
2.6	Determine risk communication requirements to identify any intentionally present and unintentionally present allergens for the consumer.	- Mandatory requirements - Are advisory warnings of unintended presence needed?

3. Allergen risk analysis

Critical elements for HACCP Risk Analysis and Risk Management (template)
- Best practice consideration (per critical element e.g. people, manufacturing, suppliers)
- Cross-contact probability: likely / unlikely
- Rationale for cross-contact probability
- Allergen hazard rating
- Control measures

4. Considerations for risk prevention (checklist)

Guide to verify that the likely causes of common failures are considered and controlled within the allergen risk management programme, and to support root cause analysis in the event of a food allergy incident.

- **Potential issue** (i.e. intended product in intended pack that is wrongly labelled, mismatch of product to packaging, unintentional presence of allergen in product)
- **Critical preventive element** (e.g. information in product specification, packaging management, production management, cleaning)
- **Best practice considerations** (e.g. define effective cleaning standards to be achieved, separation in warehouse, airflow control, inner wrap consistent with outer wrap)

Annex 3: Allergen labelling
- Details on EU Regulations

Annex 4: Allergen change over (cleaning/flushing) validation

I. Considerations for designing a validation study

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. 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, 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 **visual inspection and quantitative analytical testing**. Analytical results are only useful if the **samples have been taken as part of a correctly designed study**.
- 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, followed by a recipe which does not contain the allergen
- When no commercial test kit is available and no other marker protein can be used, validations should follow the visual inspection protocol only
- **Heterogeneously distributed contamination** (e.g. pieces of nuts) might not be sufficiently captured by sampling; analytical testing might not provide reliable data. Visual inspection and confirmation that the visibly clean standard is met should be the only pass criteria.
- Validation should be part of the HACCP programme and repeated on a regular basis, and if changes in formulation, process, equipment or change-over procedure occur

II. Guideline for physical validation

1. Develop a detailed flow diagram. Highlight equipment that comes in direct contact with allergens, components where material can accumulate (should receive detailed allergen cleaning and visual inspection). Verify the flow diagram by walking through the line.
2. Identify equipment that will need disassembly, special attention, or access to be cleaned and where sampling for the analytical validation shall be done
3. Update existing documentation (e.g cleaning procedures, pre-operation check sheets) per the information gathered above
4. Validate the updated pre-operation inspection sheet by walking through the line
5. Document cleaning parameters in the cleaning procedure. **When the equipment cannot be inspected, adherence to these parameters should be verified** after each cleaning.

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, analytical validation should follow

III. Guideline for analytical validation

1. Validation sampling should meet acceptable criteria for **3 consecutive runs**. In the absence of actions limits (e.g. **VITAL**) for the specific allergen, all test results should be **less than the limit of quantification** of the specific validated, quantitative test.
2. 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. Consult laboratories or kit supplier.
4. A pre-cleaning sample should be tested as a positive control.
5. Options for sampling and testing:

- **Swabs** (surfaces): should not be done in isolation from product or rinsate testing. Swabs may be positive, while the first product through the line meets acceptable criteria. The important consideration is the extent to which any residue transfers to the product.
- **Rinsate**: collect and test 2 representative rinsate samples from the final rinse
- **Final product**: an **appropriate sampling plan** should be developed and applied, and its performance and limitations understood. Take samples of the finished product from first product coming off the line. Number of samples and times when samples are taken may vary. The validation is passed if at minimum, the last two samples meet acceptable criteria based on agreed reference values. All products tested before those two samples shall not be used.
- **Flushing**: collect first flushing material samples at reasonable intervals after start up. Validation is passed if at minimum the last two samples meet acceptable criteria.

Annex 5: Allergen analysis

- Overview of available analytical technologies
- Considerations: **comparability of methods, laboratory requirements, matrix effects, sampling, fit-for-purpose**

Sampling

The meaningfulness of analytical results is highly dependent on the sampling process. **Sampling, i.e. location and frequency, should be based on risk assessment.** The risk and frequency should be identified in the allergen management plan.

- Environmental swabs: monitor residual allergens on food contact surfaces
- Purge materials/flushing mass: where wet cleaning is not appropriate
- Air samples/settle plates: monitor dusting
- CIP rinsate: monitor effectiveness of CIP systems
- Finished product: monitor effectiveness of cleaning, in conjunction with other samples listed above

a. Cleaning validation samples: homogeneous cross-contamination assessment

- Samples should comprise the initial product, washing solutions (or cleaning/ flushing materials) and the subsequent product
- If the allergen containing product is likely to spread beyond the immediate production equipment, risk areas should be swabbed

- For dry manufacturing processes, 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

b. Cleaning validation samples: heterogeneous cross-contamination assessment (e.g. particulates, nuts, seeds)
The approach outlined in section (a) plus **detailed visual inspection and physical strip down of equipment**.

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 by lateral flow devices for the suspected allergen or by total protein assays provided product does not contain protein. Positive findings should be confirmed by a specific analysis in the laboratory.

Annex 6: Gluten-free foods (EU Regulations)

Author	**Alberta Agriculture and Rural Development - Canada**
Year	2014
Title	Food safety guidebook (Chapter 11: Developing an allergen control program)
Pages	21
Highlights	- **Components (5) of an ACP**: management commitment, allergen identification and mapping (includes R&D and **purchasing**), work instructions and procedures (e.g. segregation, cleaning), training, records. Includes **templates**. - If the ACP is not able to remove allergens on the production line or equipment to a **non-detectable level,** then **PAL** should be included - Addresses **cleaning validation and verification**

1.0 Allergen overview
Priority allergens per Health Canada and CFIA. Clarifications about sulphites and gluten.

1.1 Allergen control program
Overuse of allergen warning labels may limit consumer choice and may reduce the value of the warnings.
- An effective allergen plan needs to be accepted and understood by all food production staff
- Success depends on **management commitment**
- The best way to control allergens in the facility is through hazard analysis and hazard management (reference to Codex guidelines)

Most common ways for unidentified allergens to enter food products: cross-contamination of an ingredient, accidentally adding allergens to products that do not usually contain them, cross-contamination from a different product containing an unwanted allergen.

Components of an ACP
- **Allergen identification and mapping**: investigation of raw materials, formulations and steps in the production process
- **Work instructions and procedures:** to develop control over unintentional allergen contamination through **segregation and production controls**
- **Management commitment:** in-plant policies, management leading by example
- **Records:** evidence that the company is being diligent in the control of allergen hazards

1.2 Management commitment
- Demonstrate that management sees the ACP as important
- Communication between personnel and departments are clearly stated and strengthened
- Develop the ACP with input from production or other departments. Buy-in is needed from all departments
- Using various resources can strengthen allergen controls (e.g. segregation, labeling)
- Make sure employees receive the education, training and experience they need

2.0 Allergen identification and mapping
2.1 Assessing formulas and raw materials (Form: Ingredient Allergen Reference)
- Use a master list of all raw materials used in the facility
- Identify those raw materials that either contain, or may contain, allergens
- Consider both primary and secondary ingredients

- Ensure the core components are considered for all ingredients
- Make sure all possible sources are listed

2.2 Communicating with suppliers
- Create a complete list of allergens in the facility (Form: Allergen Checklist for Food Suppliers or Manufacturers - CFIA/Archived)
- **Packaging materials** and **production aides** may also contain allergens and must be assessed
- Require all the facility's suppliers of raw materials and packaging to have some form of allergen control program
- Once a master list of raw materials is created, include this information on the master list of finished products (will show clearly what allergens are found in each product). These two lists can then be cross referenced with final products that may share common equipment (Form: Formula/Product Allergen Reference).

2.3 Controlling product development and purchasing

General recommendations in line with FSA (2006), FDE (2013). Also:
- Once it is known what allergens are used in the facility, control allowing any new allergens in. Written allergen policies should include controls for incoming ingredients and for new product development.
- Product development and **purchasing** staff should be aware that changes to one production process can risk allergen cross-contamination in other processes and products. They should have a master list of current allergens in the facility.
- Inform those responsible for maintaining the ACP of any changes to raw materials or product formulation

2.4 Allergen mapping
- After it is decided what products have allergens, do a walk-through of the facility (determine if there is any shared equipment, point out and control possible allergen issues). Look for issues related to scheduling, ingredient substitution, cross-contamination, rework and labeling.
- Create a **process flow diagram and a plant schematic**. These will reveal key areas in the process or facility that might be sources of cross-contamination (Form: Production Process Allergen Assessment).

3.0 Procedures and work instructions

3.1 Receiving

General recommendations in line with FSA (2006), FDE (2013). Also:
- Make sure all incoming products have clear lot codes on all containers
- Supervise unloading
- Supervise off-hour deliveries to ensure materials are not damaged
- Reject suspicious incoming food, ingredients and other raw materials that are questionable
- Cross reference each incoming ingredient with a list of approved ingredients

(Form: Goods Receiving Record)

3.2 Segregation

General recommendations in line with FSA (2006), FDE (2013).

3.3 Allergen clean

General recommendations in line with FSA (2006), FDE (2013).

'Allergen Clean': cleaning the production lines in between allergen and non-allergen

product runs to reduce the risk of allergen cross-contamination.
- Validate the cleaning procedures with allergen testing
- For validation, use **tests which are specific to the allergen** of concern and sensitive enough to meet the critical limits for the allergen
- **Depending on risk, finished product testing** can be used to enhance the validation and verification of cleaning procedures, in combination with specific allergen testing on shared equipment
- **Current industry best practice for validating** the allergen clean program is to use and document some form of allergen residue testing program for product contact equipment.

3.4 Validation and verification

Validating an Allergen Clean program
- An allergen verification program should be built upon an initial validation study that demonstrates the cleaning procedures being used are effective for the targeted allergens.
- The validation study will provide proof that the allergen is removed, or reduced to an acceptable limit, by the "allergen clean" procedures.
- When there is a mixture of different allergens in the products it is **generally accepted to test for the highest risk allergens** (concentration of allergens, most difficult to remove)

(Form: Allergen Validation Record)

Verifying Allergen Clean procedures
- Verification procedures must be put in place to show that the validated clean procedure is effectively carried out each time
- **First step: visual examination.** Formally inspect the equipment and production areas and document the results. Wait until the equipment and surfaces have dried. There should be no visible product on any surface after a complete Allergen Clean.
- **Protein swabs**: test for total protein, not for specific allergens, therefore they are **not acceptable for validating the removal of specific allergens**
- **ATP swabs**: non-specific indicators of contamination, and may be positive when allergens are not present. **Not acceptable for validating the removal of specific allergens**
- Protein or ATP swabs must be calibrated with the validated cleaning procedure: when conducting validation by testing with allergen specific ELISA test kits, also test (immediately after the ELISA test) with the total protein swabs or the ATP swabs, and record both results.

3.5 Rework

General recommendations in line with FSA (2006), FDE (2013).

3.6 Labeling and packaging

Quick overview and links for allergen regulations in Canada

Figure: Allergen risk assessment and labelling

Is the ACP able to remove allergens on the production line or equipment to a **non-detectable** level? **NO = PAL**

General recommendations in line with FSA (2006), FDE (2013). Also:
- Use verification sheets to prove that labeling is being checked when the product is received, and where it is being used

4.0 Allergen training

General recommendations in line with FSA (2006), FDE (2013).

Author	**Canadian Food Inspection Agency**
Year	2018
Title	Preventive controls for food allergens, gluten and added sulphites
Link	https://www.inspection.gc.ca/preventive-controls/food-allergens-gluten-and-added-sulphites/eng/1517924742613/1528203218321
Highlights	Focus on preventive controls and accurate allergen declaration. 1. Establish an allergen prevention **team** 2. Identify **sources** of food allergens, gluten and added sulphites 3. Implement **control measures** - Food-related (ingredients, formulation) - Process-related (cross-contact, production scheduling, rework, storage & handling, packaging & labelling) - Establishment-related (equipment maintenance, sanitation, wet cleaning, dry cleaning, personnel hygiene and training) 4. **Verify the effectiveness** of the control measures In Annex: suppliers checklist

I. Purpose

Guideline to help food businesses comply with the *Safe Food for Canadians Regulations*. Outlines **preventive controls** a food operator should take to:

- **Prevent** ingredients and food that are allergens or contain allergens, gluten or added sulphites (AGS), from **contaminating a food in which they are not an intended ingredient**
- Ensure that ingredients that are allergens or contain AGS are **properly declared** in the list of ingredients on the food label

II. Preventive controls for allergens, gluten and added sulphites

Considerations:

- Cross-contact points along the processing lines
- Carry over from an ingredient used
- Dust or aerosols that get carried throughout the processing area
- Re-using an ingredient (e.g. cooking oil)
- Change, substitution or addition of an ingredient, or the supplier of ingredients
- Using the wrong ingredient
- Using unknown ingredients
- Ineffective cleaning: food proteins can be difficult to remove; reusing cleaning solutions

1. Establish an allergen prevention team

For smaller food businesses, food allergen preventive controls can be led by one person. Larger food businesses may require a multidisciplinary team.

2. Identify sources of food allergens, gluten and added sulphites

During **hazard analysis**, it is important to identify:

- **Ingredients** that are allergens or contain AGS
  - Prepare a list and indicate control measures
- **Processing steps** where AGS can come into contact with a food in which they are not an intended ingredient (e.g. receiving, storing, mixing, blending/formulation, labelling)

3. Implement control measures

3.1 Food-related control measures

Incoming ingredients

- Provide written specifications to each supplier of ingredients
- Verify ingredients and their labels upon receipt to ensure they meet specifications

Food formulation

- The **most current recipe** of each food should be available in writing for production staff

3.2 Process-related control measures

Areas where cross-contact can occur

- **Map** out the flow of ingredients in the establishment (through processing steps and air movement), and identify areas where cross-contact can occur
- Identify equipment that is used for both allergenic and non-allergenic foods
- Outline the traffic pattern flow for employees and visitors

Production scheduling

When possible, use dedicated production lines. If not feasible, equipment should be thoroughly cleaned.

Re-use of ingredients/reworked food

For foods/cooking media containing an AGS, rework/reuse should only be allowed in the preparation of the same product.

Storage and handling

Prevent contact with other ingredients and food that do not contain AGS.

- Dedicated storage areas
- Storing ingredients and food with AGS on shelves below other ingredients and food, away from packaging materials and labels
- Clearly identifying ingredients and food with AGS using signs or color codes
- Keeping ingredients, food, packaging materials and labels sealed until their use
- Conveyances used to transport ingredients, food, packaging and labels maintained and cleaned
- Ingredients and food that contain an AGS in sealed packages during transportation, or transported separately

Packaging and labelling

Ensure the right label is applied to the right food.

- Include a break in production when there is a change in the type of food prepared
- Use marked containers
- Verify labels prior to their application
- Verify that packaging and labelling for the inner and outer packaging are for the same food
- Include a label review and update when there is a substitution of ingredients or a change in formulation
- Dispose of incorrect or outdated labels

3.3 Establishment-related control measures

Equipment maintenance

Equipment is **designed, installed and maintained** in a manner that prevents cross-contact AGS.

- Identify lines used to prepare foods that are allergenic or contain gluten
- Proximity of pieces of equipment to each other and potential for cross-contact
- Avoid line cross-over

- Space to perform cleaning, sanitation and inspection
- Reduce the creation and spread of dust
- Dedicated lines for foods that are allergenic or contain gluten
- Isolate the ingredient addition steps and add ingredients that are allergenic, or contain gluten, near the end of the process, if possible
- Dedicate hard to clean equipment to the preparation of foods that contain AGS
- Separate, dedicate, color-code, or use other means to identify tools and equipment used for preparing and handling ingredients or foods that are allergenic or contain gluten

Sanitation controls
- Effective, validated cleaning is one of the most important strategies for preventing cross-contact
- Factors that affect the clean up of allergens: form, solubility, concentration, application of heat, type of food contact surface, length of processing time, build-up of food material, cleaning method
- Sanitation program should address: spills; equipment and utensils at the end of production; equipment, food contact surfaces and other areas during operations; disassembly and manual cleaning of equipment
- Details on wet and dry cleaning methods

Personnel hygiene and training
Consider the risk of cross-contact through clothing.
Provide training on:
- Priority allergens and gluten sensitivities
- Sources of AGS and areas of cross-contact
- Control measures used to prevent cross contact and remove residues of AGS
- Importance of proper labelling

4. Verifying the effectiveness of the control measures
Determine whether residues of ingredients that can cause food sensitivities remain in the processing environment—or end up in foods that should not contain them—using analytical methods. Brief overview of protein-based, DNA-based and non-specific methods.

Annex A: Food suppliers allergen, gluten and added sulphites checklist

Author	**Australian Food and Grocery Council and the Allergen Bureau**
Year	2019
Title	Food industry guide to allergen management and labelling - For Australia and New Zealand
Pages	43
Highlights	- Recommended approach: conduct **HACCP**; based on this information, develop Allergen Management Programme (**AMP**) - **Risk management**: documented procedures + **19 key principles** (management commitment, management review, regulation, food safety plans, people, supplier, premises & factory design, traceability, storage, production, labelling, cleaning, product development, waste, monitoring & review, training, allergen analysis, product specifications, food recall plan) - **Risk review**: investigate the manufacturing process for allergen risks (direct and cross-contact) - Reference to online tool for further details: http://allergenbureau.net/risk-review/ - Allergen analysis applications - **PAL** considerations, in the context of **VITAL** - Original element: **Management of reports of alleged allergen reaction** (Annex) - **Case studies**: recalls root-cause analysis

1. Introduction

Food companies have a responsibility to fully understand the **allergen status** of their products. If present, they need to determine what those allergens are, if the allergen is an ingredient, food additive or processing aid, or is present due to cross contact. Clear and accurate information about the allergen status of each product should be communicated through labelling, specifications and **electronic media** to enable consumers to make safe and informed choices.

Scope: all sectors of the food industry involved in the supply, handling, production, distribution and sale of foods including
- Food ingredient manufacture and supply (local and imported)
- Manufacture of packaged food for **bulk** sale, including business to business
- Manufacture of packaged finished product (retail ready)
- **Imported** packaged foods

1.1 Food allergy & anaphylaxis (2-page overview + Australia/New Zealand data)
1.2 Coeliac disease (1/2 page)
1.3 Food intolerance (1/2 page)

2. Regulatory requirements

2.1 Food acts & product liability law
2.2 Australia/New Zealand food standards
- Packaged and non-packaged foods allergen labelling requirements (examples of **labelling exceptions**)
- Mandatory allergen declaration requirements (overview of **labelling requirements and exceptions per allergen category**)
- Further information about sulphites, fish, milk, tree nuts

- Legibility requirements

2.3 **International** food allergen regulation

Allergen labelling differs across countries and regions. In addition to the allergens required to be labelled in Australia and New Zealand, there are other allergens that should be considered for products which are exported from or **imported into** Australia and/or New Zealand.

3. Allergen management

- Should be considered an **element of existing food safety management plans** and processes **including GMP**
- Recommended approach: **HACCP** (allergens as an independent category of hazard)
- Start with investigating the manufacturing process for allergen risks and the information obtained is used to develop an Allergen Management Program (AMP)

3.1 Allergen management

- **Procedures**, policies and practices contributing to the control of allergens within a food business. **Documented and systematic**.
- Summary table with brief **best practice** recommendations, in line with FSA (2006) and FDE (2013), for **19 key areas**: management commitment; management review; regulation; food safety plans; people management; supplier/vendor assurance; premises & factory design; traceability; storage; production process; labelling; cleaning; product development; waste; monitoring & review; training; allergen analysis; product specifications; food recall plan
- Reference to Allergen Bureau's Risk Review **website for further details** (http://allergenbureau.net/risk-review/)

3.2 Allergen risk review

Defined as the thorough **investigation of the allergen status of a food product,** which identifies the presence of allergens that are intentionally formulated into a product and quantifies the risk of allergens which may be unintentionally present (cross contact allergens). Applies to the entire manufacturing process from raw material sourcing to the labelled finished product. Reference to Allergen Bureau's Risk Review website **(interactive tool)** for further details (http://allergenbureau.net/risk-review/).

Allergen risks occur in two separate circumstances:

a. **Direct** incorporation of known allergenic material
- Intentional: added as part of the formulation or processing (e.g. ingredients, additives, processing aids)
- Accidental: errors in formulation, use of rework, etc.

b. **Cross-contact** with allergenic material: where the unintentional presence of food allergens occurs (e.g residue accumulated in processing equipment is incorporated into the next product manufactured on the same line)

3.3 Allergen analysis

Can provide assurance and verification of critical controls within an allergen management plan and assist the implementation of a quantitative risk assessment. Should be used for validation and verification purposes as part of a HACCP based food safety program.

Examples of **applications**: confirmation of allergen status of raw materials, validation of cleaning protocols, verification/monitoring of cleaning efficacy, environmental monitoring, identifying sources of cross contact

4. Allergen labelling and communication

4.1 Allergen labelling best practice

- Guidance beyond Australia New Zealand Food Standards Code requirements (i.e. consistent **formatting** recommendations + label examples for ingredients list, allergen summary statement and **PAL**).
- Considerations on **gluten, fermented foods, packaged foods that do not require labelling**
- Table with allergen labelling exceptions per Code

Steps for composing an allergen declaration for packaged foods:

1. Obtain the product formulation/recipe including amounts of each ingredient
2. Obtain specifications for all ingredients. Ensure all sources of allergens as ingredients and cross-contact allergens are identified and recorded
3. Identify allergens in the product using the formulation and ingredient information, including: ingredients, food additives, processing aids, compound ingredients, cross-contact from ingredients
4. Compose the ingredient list and declare the allergens formulated into the product
5. Conduct a **VITAL risk assessment** to determine the presence of cross-contact allergens from ingredients and processing
6. Finalise allergen labelling: confirm the allergens in the ingredient list, confirm the allergen summary statement, and compose the appropriate precautionary allergen statement

Precautionary allergen labelling (PAL)

- The declaration of a cross-contact allergen in a PAL statement does not diminish the requirement to apply HACCP and GMP to ensure that it is present at the lowest practicable level and is controlled at this level
- Inconsistent use of PAL statements can lead to consumer distrust and are sometimes seen as ‘manufacturers protecting themselves’ rather than informing the consumer of the true allergen status of the food
- When PAL is applied after a robust scientific **risk-based assessment** process and is described in a **clear, accurate and consistent** manner, it enables consumers to trust the information provided
- Formatting considerations
- Reference: **VITAL Best Practice Labelling Guide for Australia and New Zealand (2016)**
- Description of the VITAL program
- Label artwork approval and sign-off

Allergen-free claims

- The product must not have any cross contact for that allergen at any level, and therefore does not require a PAL statement
- No requirements set out in the Code. The criteria for making the claim falls to each company and consumer laws.

Allergen communication

Focus on consumers facing communications in relation to the allergen status of food products (i.e. communicating changes to allergen status, packaging differentiation, parallel imports, forms of communication other than labels).

5. Food recalls

- All food companies should have a documented Food Recall Plan. It should include an allergen-related communications plan with a designated, responsible person identified to

provide information to customers, consumers, and regulatory authorities in a timely manner. The plan should include an up to date allergen-related stakeholder contact list.
- References to other FSANZ and NZ MPI documents dealing with food recalls.

6. Appendix
- Alternative labelling formats
- **Management of reports of an alleged allergic reaction**
  - Each company should maintain, **as part of their food safety plan**, a recording and reporting process for contacts related to allergic reactions
  - Factors to consider as part of the investigation
- Recalls root-cause analysis **case studies**

Author	**JOINT FAO/WHO FOOD STANDARDS PROGRAMME, CODEX ALIMENTARIUS COMMISSION**
Year	2020
Title	43rd Session- REPORT OF THE 51st SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE, including Draft Code of Practice on Food Allergen Management for Food Business Operators (p. 24-44)
Pages	102
Highlights	- Promotes **harmonized, proactive, risk-based** approach to allergen management, as part of GHP/HACCP - Entire supply chain including **primary production,** manufacturing, and retail and food service - Focus on: prevent/minimize potential for allergen **cross-contact** and **undeclared allergens** being present due to errors arising in the **supply chain**; and ensure the correct allergen **label** is applied. - **Elements (9)**: primary production; design and facilities; control of operations; maintenance and sanitation; personal hygiene; transportation; product information and consumer awareness; training - Discusses cross-contact but text related to **PAL was deleted** from draft versions

Introduction

- FBOs must take steps to accurately **declare** the presence of allergenic ingredients, **minimize** the risk from, and, where possible, **prevent unintended allergen presence**
- In a global market, it is crucial that there is **harmonized** understanding of food allergies and of the measures required to address it
- Allergen management practices should be part of **GHPs/HACCP** systems, in manufacturing, retail and food service (*note: retail and food service will not be discussed in this summary*).
- Allergens need to be managed throughout the supply chain and production process

Hazard characterisation

Description of food allergy mechanisms and symptoms.

The majority of food allergies are caused by proteins in 8 foods/ food groups (and derived products): **cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains); crustaceans; eggs; fish; milk; peanuts; soybeans; and tree nuts.** Other food allergens such as sesame seeds, buckwheat, celery, mustard, molluscs and lupin are recognised as important in many countries. The controls outlined in this Code would be similar for any other allergens. FBOs should be aware of the food allergens recognised as important in countries they are exporting their product to.

Poor allergen management can result in the presence of varying levels of undeclared and/or unintended allergens in food. The **doses** that provoke reactions vary among individuals and are dependent in part on the type of allergen. The risk of allergic reactions within a larger proportion of the population suffering from food allergies increases with increasing concentration of undeclared allergen.

Control measures implemented to prevent or minimise the likelihood of allergen cross-contact should be based on **risk assessment conducted by FBOs**. FBOs must identify the allergenic nature of the foods, including ingredients, and processing aids, and take steps to manage any potential presence of undeclared allergens

Examples of **factors contributing to exposure** are provided for:
- **Harvesting**, handling, storage and transportation (e.g. inadequate cleaning of containers/ vehicles, inadvertent inclusion of foreign particulates)
- Packaged food manufacturing facilities (e.g labelling errors, cross-contact, undeclared allergen in a supplier ingredient)
- Retail and food service establishments

FBO Responsibilities
Have documented and detailed allergen management policies and procedures specific to the food business.

I. Objectives
Provide guidance to FBOs, **including primary producers**, to develop policies and procedures to identify allergens in all areas of **food production, preparation and service**, and implement allergen management practices, including **controls to**:

- prevent or minimise the potential for allergen **cross-contact**
- prevent or minimise the potential for undeclared allergens being present due to errors arising in the supply chain;
- ensure the correct allergen label is applied; and
- ensure that accurate information can be provided to consumers at point of sale when the food is **not prepackaged**.

Proactive approach.
References to labelling standards.

II. Scope, use and definitions
Allergen management throughout the supply chain **including at primary production**, during manufacturing, and at retail and food service end points. It complements GHP.
Does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity.
References to other standards.
Definitions.

III. Primary production
PRINCIPLE: Where the introduction of an allergen may adversely affect the allergen profile of food at later stages of the food chain, **primary production should be managed** in a way that reduces the likelihood of introducing such allergens.
Allergen management guidance provided with respect to **environmental hygiene, hygienic production of food sources, and handling, storage and transport.**

IV. Establishment: Design and facilities
PRINCIPLE: Establishment design should prevent or minimise the potential for allergen cross-contact with respect to delimitation and isolation of areas, location of equipment, process flow, personnel movement and ventilation systems.

4.1 Location

4.1.1 Establishments
If dedication of production facilities is not possible, the production could be separated in time or space, and the establishment may be designed to have a linear flow in the production.

4.1.2 Equipment
Consider the use of dedicated lines. Production sequencing (i.e., separation by time) should be considered as an option, especially for small businesses. Cross-over points should be eliminated.

4.2 Premises and rooms
Consider the need for a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas, or use screens to set up temporary segregated areas, for foods with different allergen profiles.
Allergenic ingredients should be stored separately.
Design should ensure appropriate allergen dust removal.

4.3 Equipment
Equipment, tools, utensils and containers in contact with foods that contain allergens should be designed and constructed to facilitate the effective removal of allergens during cleaning.

V. Control of operation
PRINCIPLE: The unintentional presence of allergens in food is prevented or minimised by taking preventive measures through GHPs and HACCP-based controls at appropriate stages in the operation.

5.1 Control of food hazards
FBOs should control allergens by **preventing or minimising the potential for allergen cross-contact**, and by ensuring that **information identifying the allergens present in foods** is clear and correct. Controls should be **risk-based**.

Information that may be helpful in assessing the **likelihood of allergen cross-contact**: allergens present in the facility; allergens that share the same processing line; the nature of the allergen; whether allergens are, or may be, present, as notified by the supplier; whether the allergen is a particle, powder, liquid or paste; the processing steps where the allergen is used; ease of preventing allergen cross-contact between processing lines; ease of cleaning the equipment used to process foods with different allergen profiles; and the maximum amount of an allergen due to allergen cross-contact (if the information is available).

FBOs should:
- identify any steps in their operations that pose the likelihood of allergen cross-contact, assess the level of risk and ascertain the ones that are critical;
- implement effective allergen management procedures;
- monitor, and when appropriate document, allergen management procedures;
- review allergen management procedures periodically;
- ensure suppliers are familiar and comply with food allergen specifications;
- notify customers in a timely manner of any changes to the allergen profile of the product; and
- ensure personnel are aware of and follow allergen management procedures.

Manufacturers should identify steps in the operation that are critical to **ensuring allergens are properly declared**, including reviewing recipes and labels on compound ingredients, ensuring that the correct ingredients are used, and ensuring that the correct product is packed in the correct package (i.e., with the correct label).

5.2 Key aspects of hygiene control systems

5.2.1 Minimizing allergen cross-contact during processing
- Production scheduling
- Allergenic ingredients added as late in the production process as possible, or as far downstream as possible in the processing line
- Design a traffic flow
- **"Allergen mapping"** can be useful in identifying areas where controls should be applied
- Clearly identify personnel working on lines manufacturing foods containing different allergens
- Containers and utensils used to hold or transfer foods that contain allergens should be dedicated to holding a specific allergen and be marked, tagged, or colour-coded to identify the allergen. If not possible, effective cleaning procedures should be in place.
- Exposed unpackaged product should be protected from allergen cross-contact
- Other considerations: cooking media, rework, dry ingredients, spills

5.2.2 Rework and work-in-process
Should be stored covered and labelled, and only added back to the same product

5.2.3 Application of product labels
- Ensure allergen information on labels is accurate and that correct product labels are used
- Labels should be stored in a way that prevents or minimises the potential to pull incorrect labels or containers during production. All labels should be removed at the end of the production run and returned to their designated storage area.

5.2.4 Monitoring and verification
Regular internal audits of production systems, and regular review of suppliers

5.2.5 Product development and change
- Consider whether it is feasible to use a non-allergenic ingredient
- Avoid cross-contact during factory trials or consumer testing
- Product labels should be designed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed
- Where there is a change in the formulation which results in a change of allergen profile, manufacturers should indicate this on the packaging and on their websites

5.3 Incoming material requirements
Manufacturers should:
- Indicate **requirements for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer**
- Have programs in place to assess the allergen control programs of suppliers when necessary, e.g. supplier questionnaire, audit
- Have procedures/policies in place for suppliers to **notify** them, in a timely manner, of any changes that could impact the allergen profile of the ingredient

At reception: label verification, container integrity, segregated storage

5.4 Packaging
Procedure for label review and approval

5.5 Water

Water that has come into contact with a food that is or that contains an allergen should not be recirculated for use on a food that does not contain that allergen.

5.6 Management and supervision
Must have enough knowledge and understanding of allergen control principles and practices.

5.7 Documentation and records
Suppliers' allergen management (e.g. questionnaire, audit); suppliers' allergen information; procedures for handling and storage of allergens; label review; label application; scheduling; rework; cleaning SOPs and verification; validation data for allergen cleaning efficacy; etc.

5.8 Recall procedures
Recall procedures, traceability/product tracking systems, and procedures for handling consumer complaints should be in place.

VI. Establishment: Maintenance and sanitation
PRINCIPLE: The effective management of food allergens is facilitated by establishing effective maintenance and cleaning programs that prevent or minimise the potential for allergen cross-contact.

6.1 Maintenance and cleaning
- Tools/utensils: discard those damaged or difficult to clean, dedicated tools, color coding
- Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning, and the equipment, tools and materials used for cleaning
- Also: equipment may need to be disassembled, high pressure hoses should be avoided, designated cleaning equipment and tools

6.2 Cleaning programmes
- Cleaning procedures should be specifically designed to remove food allergen
- **Validation** should be **specific to the allergen, process and product matrix** combination
- Cleaning processes should be **verified** through visual observation and, where feasible and appropriate, through an analytical testing program
- Where the use of allergen testing is feasible and appropriate, "push-through" material, or the first product through the line, should be evaluated to demonstrate that a food allergen from a previous production run has been adequately removed
- Also: spill clean-up, records

6.3 Pest control systems
Should not use allergens as bait in traps.

6.4 Waste management
Covered, identified and handled to prevent allergen cross-contact.

6.5 Monitoring effectiveness
Periodically conduct tests to detect food residues that remain on surfaces after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where feasible, these tests should include using an allergen-specific test kit that is fit for purpose.

VII. Establishment: Personal hygiene
PRINCIPLE: Personal hygiene practices should prevent or minimize the potential for food handlers to contribute to allergen cross-contact.

VIII. Transportation
PRINCIPLE: Foods containing allergens should be managed during transportation so that allergen cross-contact is prevented.

IX. Product information and consumer awareness
PRINCIPLE: Consumers should have access to adequate and correct information on the allergenic nature of a food. This should ensure that those with allergies can avoid allergenic foods and ingredients.

9.1 Lot identification (Codex reference)
9.2 Product information (Codex reference)
Manufacturers should have procedures in place to ensure that food is labelled appropriately
9.3 Labelling (Codex reference)
9.4 Consumer education (Codex reference)

X. Training
PRINCIPLE: Personnel engaged in food operations should have sufficient training in food allergen management to implement measures to prevent or minimise allergen cross-contact and ensure the correct label with appropriate allergen information is applied to food.

10.1 Awareness and responsibilities
All personnel (including temporary and maintenance personnel) should understand their role in allergen management and the food safety implications of the presence of undeclared food allergens.

10.2 Training programmes
All relevant personnel in a food business should receive food allergen training as appropriate to their job responsibilities (examples of elements to be covered is provided).
All appropriate personnel should be **encouraged to report and/or take immediate action**, if any labelling errors or an undeclared allergen is suspected.

10.3 Instruction and supervision (Codex reference)
10.4 Refresher training (Codex reference)

SECTOR-SPECIFIC GUIDELINES ALLERGEN MANAGEMENT GUIDELINES

Author	**FSIS (USA)**
Year	2015
Title	FSIS Compliance Guidelines. Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling
Pages	26
Highlights	- **Meat and poultry** products - **Principles**: **identify** (inspection of incoming ingredients, cross-referencing components, separation)**; prevent and control** (equipment, sanitation, and processing), **declare** (packaging, labeling, storage) - FSIS **does not recognize a threshold** for any allergenic ingredient; all allergenic ingredients need to be declared on the product label - **"May contain"** statement of a purchased ingredient **need not be listed on the final label if** rationale is well documented

I. Introduction and background

Meat and poultry products. Recommended practices should be **incorporated in HACCP plan, Sanitation SOPs or other prerequisite programs**.

Basic **principles**:

1. **Identify**: hazard analysis, inspection of incoming ingredients, cross-referencing product components, and separation of allergenic materials.
2. **Prevent and control**: preventing cross-contact in processing areas, e.g. sanitation and cleaning of equipment, maintaining appropriate process flow.
3. **Declare**: prevention of mislabeling during packing, labeling, and storage.

General information on food allergies.
Overview of Allergen Labeling and Consumer Protection Act (FALCPA).

II. Prevention and Control Measures for Undeclared Allergens

2.1 Identify: inspection of incoming ingredients, cross-referencing components, separation

A meticulous, comprehensive **hazard analysis is crucial** to identify and control allergens. Hazard analysis is the foundation for a strong and successful HACCP plan. As a result of the identification of chemical hazards, an establishment should have a **list of allergens** that are used in production.

Allergen identification should consider:

- Review a list of all ingredients and products to determine whether they are or contain allergens
- Using an establishment schematic, do a walk-through noting paths of allergenic ingredients and products and areas of concern where cross-contact may occur
- Keep a list of ingredients used in product formulations and label records at the receiving area to compare against incoming ingredients
- Ensure that all incoming ingredients containing allergenic material are clearly labeled and identified
- Use color coding for allergen-containing ingredients and products

- Store ingredients containing allergenic materials in separate, designated areas that are clearly identified and marked
- Maintain open communication of expectations with **suppliers** and inquire about their allergen control programs

Once the hazard evaluation is completed, develop approaches to control those hazards.

Suppliers / raw materials:
- Seek out information about the allergens used by suppliers and on their allergen control practices. This information may come in the form of a **Letter of Guarantee (LOG).**
- Maintain an **approved supplier list along with ingredient information from each supplier**. Use the list when receiving incoming ingredients to verify proper identification of each lot of ingredients.
- For accuracy, cross-reference the sketch **label** approval to the actual label being used and the formulation data. The label approval, the actual label, and formulation must match for proper ingredient identification.

2.2 Prevent and control: equipment, sanitation, and processing

- Address **cleaning** of equipment, utensils, and food contact surfaces to prevent cross-contact and misbranding
- Personnel should be trained on the cleaning procedures used to control food allergens and should be aware of which products contain allergenic ingredients.
- Establishments should track work-in-progress product
- Process non-allergenic products before handling and processing allergenic products to reduce the possibility of cross-contact and misbranding
- Avoid using the same cooking medium when processing both allergenic and non-allergenic products

Prevention of cross-contact in processing areas should consider:
- Color coding of ingredient packages, supplies, uniforms, and utensils used for products containing allergens
- Documenting cleaning procedures with checklists including procedures for spill clean-up
- Employing a method for the **verification and validation of cleaning**
- Maintaining documented process flow along with mapping the route of allergenic product through the establishment
- Employing a method for tracking of lot codes through production
- Carefully evaluating rework and work-in-progress
- Dedicating equipment or, if not feasible, separating allergenic products by time, space, etc.

Allergen testing may be considered to verify and document sanitation effectiveness, as a **supplement** to documenting cleaning procedures and a visual cleaning assessment.

2.3 Declare: packaging, labeling, storage

An establishment should set procedures for personnel to easily distinguish allergenic product from non-allergenic product. Procedures should also be in place to ensure that **the label being applied to a given product within a production lot is correct and matches the label on other packaged units of product within the lot.** The storage of the allergenic and non-allergenic products needs to be easily identifiable through product separation.

To **prevent mislabeling** during packing, labeling, and storage of final product:

- Systems and checklists in place for the labeling of final product
- Conduct simulations with inaccurate product labels to test systems, checklists, and procedures
- Color coding of products containing allergenic ingredients
- Procedures in place for labeling discrepancies to ensure product disposition is evaluated
- Verification of the accuracy of product labels
- Methods of tracking lot codes through production, storage, and shipping
- Storage of products containing allergenic materials

All the ingredients in a **"may contain"** or "produced in a facility" statement of a purchased ingredient **need not be listed on the final label if** the official establishment:

1) Contacts the supplier and confirms in writing that the statement is a cautionary statement, and no such ingredient is in the product; and
2) Includes a written statement in its hazard analysis documentation to support why the "may contain" or "produced in a facility" statement is not carried forward to the finished meat or poultry product label.

III. Allergen training commitment

The success of any system depends on education and training of management and employees in the importance of their role in producing safe foods.

Appendix 1: How to Handle Labels of Incoming and Outgoing Products (8 steps)

Appendix 3: Allergen risk evaluation and labeling (decision tree)

- If it can be documented that no allergen residue is in the product, **no special labeling** is needed
- If it cannot be documented that no allergen residue is in the product, **special labeling** should be applied. In some cases, "may contain" labeling may be applied

Appendix 4: Establishment checklists

Questions regarding best practices for the 3 principles: identify, prevent and control, and declare

Appendix 5: Allergen scenarios and possible preventive measures
Appendix 6: Allergenic ingredients and foods

Author	**Dairy Food Safety Victoria (Australia)**
Year	2018
Title	A guide to managing allergens in the dairy industry
Pages	32
Highlights	- Responsibilities: know the **allergen status of raw materials and ingredients;** identify and map allergens and manage **manufacturing environment;** and **declare** allergens on food labels - AMP **elements (13)**: team, identify allergens, allergen mapping, raw materials and ingredients, site design and modifications, scheduling manufacturing, labelling and packaging, cleaning validation and verification, analysis of allergens, maintenance, product development, training, verification of the AMP - **Suppliers should provide a quantitative amount of cross-contact allergens** present in the raw materials; precautionary statements are not acceptable - Conditions for using **PAL**: cross-contact risk is documented, uncontrollable, sporadic, and potentially hazardous - Discusses **cleaning validation, sampling, and environmental monitoring** - **Photos** of allergen control measures

I. Introduction
General information on food allergy. Brief overview of regulatory requirements and recall statistics.
Dairy manufacturer responsibilities:
- **Raw materials and ingredients**: know the allergen status of raw materials and ingredients
- Dairy **manufacturing**: identify and map allergens and manage entire manufacturing environment
- Product **labelling**: declare allergens on food labels

II. Allergen management for the dairy industry
Manufacturers must ensure products do not inadvertently contain allergenic ingredients and are correctly labelled. They can achieve this by **documenting their policy on allergen management,** and developing and complying with an allergen management plan **(AMP) within their food safety program**.

Food manufacturers must **manage the unintentional presence of allergens**, including:
- implementing an effective **AMP**
- **training** staff in food allergen risks, management and communication
- providing clear and **accurate information** on the allergen status of products

III. Developing your AMP
Principles, which apply regardless of the size of the manufacturing premises:
- **identifying** and mapping all allergens on the site
- **controlling** the presence of allergens in food as either unintentional contaminants or through cross-contact
- **communicating** the risk to the consumer through accurate labelling.

1. Assemble an allergen management team
Similar to establishing a team to develop the HACCP plan (multidisciplinary).

2. Identify allergens on site
Allergens may be introduced through: raw materials and ingredients, processing aids and additives, and **packaging materials**. The form allergens are in will affect their storage and handling, the equipment used for their handling, and cleaning processes.

The team should also identify any allergen introduced **via a raw material or ingredient through cross-contact**. This should be **reported by the supplier as a quantitative amount** e.g. 2 ppm soy protein. Raw materials that come with a cross-contact or **precautionary statement** (e.g. soy present because of cross-contact) are **not acceptable**.

An **ingredient matrix** (example in Table 2) should be developed, which lists the ingredient, the supplier, where it is stored, the allergens present as ingredients and any allergens present through cross-contact, the form of the allergen (liquid, solid, powder) and the level of allergenic protein, if known.

3. Allergen mapping
Provides a clear picture of areas where there is potential for cross-contact and assists in identifying control measures to mitigate the risk. Should start from receipt of raw materials and ingredients, and map all on-site manufacturing processes, including labelling of the finished product (example in Figure 2).

4. Controlling raw materials and ingredients
It is essential to ensure the allergen profile of raw materials and ingredients is known and accurate. **Regular testing of ingredients** can be used to verify the allergen profile.

4.1 Supplier approval
All suppliers to a manufacturing site should be identified as approved suppliers and have a **regularly audited** food safety program in place. Suppliers should retain records of the way they manage allergens and provide **certificates of analysis** showing the allergen profile of all supplied raw materials and ingredients.

4.2 Management and storage of ingredients
- Clearly identify all ingredients containing allergens when they arrive, and review specifications and certificates of analysis
- Segregate and identify all ingredients containing allergens during storage
- Store non-allergenic material above allergenic material to reduce risks from spills
- Before substituting any ingredients, ensure the allergenic ingredients and cross-contact risks are the same
- Warehouse staff must be fully trained in protocols and procedures for handling allergenic ingredients
- Allergen spill procedure in place

4.3 Segregation during manufacture
Where possible, use dedicated lines to segregate allergen and non-allergen containing food products. The use of separate lines or placing physical barriers will reduce the risk from spillage or cross-contact, but it is important to **have evidence to demonstrate that separation and control mechanisms are effective**.

4.4 In-progress work
Cross-contact risks can be reduced by: segregation of ingredients and products, visual identification systems and appropriate handling.

4.5 Sites where allergenic ingredients are added
- Where practical, isolate allergen addition points
- If allergens are added at the end of a processing line, fewer parts of the process line and equipment will require intensive cleaning to remove residues
- **Have control or lock out procedures for access to equipment that uses or supplies allergenic ingredients** to ensure that the equipment isn't used in another area of production without appropriate cleaning

5. Site design and modifications
- New production facilities should be designed, constructed and equipped considering the management of allergens
- Pre-existing premises may need to be modified to ensure all equipment is fit for purpose, can be effectively cleaned and maintained, and able to produce safe food
- Limit or eliminate cross-over of conveyor lines carrying allergenic ingredients or product. Alternatively, use shielding or cover systems.

6. Scheduling manufacturing
- Processing and packaging non-allergenic products prior to those containing allergenic ingredients
- Batch production of allergen containing products
- Begin with products with less allergenic ingredients or easier to clean to those with highest allergen levels
- Extended runs of allergenic products
- The success of scheduling for allergen control is based on an **effective, validated cleaning procedure** and evidence it has taken place.

6.1 Reformulation
Establish a process to manage reformulation that ensures product is handled appropriately, that any equipment impact is considered, and labels match the reformulated product.

6.2 Rework
Clearly designate any allergenic and non-allergenic rework and have systems in place to ensure 'like-into-like'.

7. Labelling and packaging
Regulations and formatting considerations.

- Process for checking label artwork, approving label changeovers, and visual checking of labelled product
- Clean, unused packaging and labels must be stored away from allergenic ingredients. Unused items should be removed from the production area once processing is completed.

7.1 Precautionary labelling (voluntary, not regulated)
Should be the result of **risk assessment and supported by evidence**, and should not be used as a substitute for appropriate allergen management. They should only be applied **when the cross-contact risk is**:
- documented e.g. through visual observation, test results or consumer feedback
- uncontrollable
- sporadic
- potentially hazardous

Reference to the **VITAL** program.

8. Cleaning validation and verification

- Soils containing allergens can be hard to remove; the best mechanism is by physical cleaning followed by rinsing, and washing with cleaning agents
- Avoid high-pressure hoses and compressed air
- The effectiveness of both manual and CIP systems need to be validated
- Visual inspection on its own is insufficient

8.1 Validation (More information: Appendix 1)

- Provides evidence that the cleaning process will remove the allergen and reduce the potential for cross-contact
- The allergen map is an important tool in identifying cross-contact points, guiding development of the cleaning protocol, and pinpointing sampling sites
- Validation should be **specific to the allergen and process**
- Once the cleaning protocol is shown to be effective it should be **repeated three times** to demonstrate a consistently acceptable outcome
- The protocol must be documented and **revalidated regularly (at least annually**) or if any substantial change occurs
- Once a cleaning validation has been performed for **each allergen on each production line**, a **cleaning matrix** (example Table 4) can be documented

8.2 Verification

Involves checking and reporting on the efficacy of cleaning procedures following each day's production and ahead of the processing and packaging of non-allergenic foods. **Environmental monitoring**: more information in Appendix 2.

9. Analysis of allergens

Brief overview of testing methods (+ Appendix 3) and reference to **VITAL**.

9.1 Sampling

Cross-contact allergens may be distributed to a food intermittently; even an extensive sampling program may not detect all cross-contact allergens. The number of samples should take into account the type of potential cross-contact, involve different time points within a batch, multiple batches, and possibly different production runs. Samples must not be composited.

10. Maintenance

Maintenance and repair teams must receive allergen training and be mindful of the risks of cross-contact presented by their tools.

11. Product development

Personnel need to understand and consider the implications of introducing new allergenic ingredients.

The site should have a plan in place to manage the storage and handling of trial ingredients; the production and appropriate labelling of any trial products; and allow for downtime for additional cleaning. All staff should be made aware of any changed protocols due to the trial of new products.

12. Training

The effective management of allergen risks requires training for **all staff, including management and administrative personnel**.

13. Verification of the AMP

Should be conducted regularly. **Typically includes:** periodic sampling and testing of final products for the presence of undeclared allergens, reviews of process controls, tracking of process control data, audit of records and documents, reviews of deviations from the plan during processing, and the extent to which documented corrective action has been implemented.

III. Be prepared: Response plan, linked to the food businesses' recall procedure.

IV. Conclusions
Summary of considerations when developing an AMP:
- Identify allergens in ingredients and on site
- Review the process steps and map the allergens
- Identify equipment that will be impacted
- Identify cross-contact points
- Review likelihood and impact of cross-contact
- Establish control measures
- Confirm effectiveness
- Train staff to ensure site culture supports AMP
- Monitor and regularly review AMP

Appendix 1: Allergen cleaning validation
Identify relevant sampling sites (i.e. potential cross-contact) and:
1. Run a product containing the allergen of concern through the product line
2. Before cleaning, swab sampling sites. This enables the identification of swabbing sites as valid cross-contact points, and establishes whether the allergen can be detected
3. Clean the product line according to the proposed cleaning procedure
4. Once the line and equipment has been cleaned, repeat the swabbing process. Always swab adjacent to the initial swab site, not the exact same area
5. Run a new product which does not contain the allergen of interest and collect samples of the finished product
6. Analyse samples (finished product and swabs) using a method appropriate for the allergen of concern. Where a reliable analysis is not available, use another allergen in its place to assess the effectiveness of the cleaning procedure. Non-specific methods such as **ATP or protein swabs are not appropriate for allergen cleaning validation purposes**.
7. If the swabs and samples are free from the specific allergen this indicates the cleaning procedure is effective. It should then be repeated to provide a **minimum of three sets of validation results**. If the procedure is found to be ineffective, further development of the allergen cleaning procedure will be necessary.

- As a guide, take a minimum of five samples of finished product
- The number of samples should reflect the size of the production run or batch, the nature of the process, and whether the allergen is likely to be evenly distributed or irregular and unevenly distributed
- If the cross-contact is likely to be irregular or unevenly distributed, or the allergen is present as a particulate, take a larger number of finished product samples

Appendix 2: Environmental monitoring for allergens
Product contact / non-contact surfaces, to be incorporated in cleaning verification.

Appendix 3: Laboratories and analysis
Appendix 4: Case studies (scenarios and preventive measures)

ALLERGEN LABELLING

Author	**Allergen Bureau - Australia / New Zealand**
Year	2016
Title	VITAL Best practice labelling guide - For Australia and New Zealand
Pages	36
Highlights	Intended to be used with the VITAL program - Steps for composing an ingredient list that declares allergens clearly - PAL approach: based on VITAL Action Levels - Worked examples (5) that show best practice for declaring food allergens on a label

1. VITAL labelling best practice

This Guide is intended to be used with the VITAL Program and to be read in conjunction with the relevant legislation and guidance documents in Australia/New Zealand.

1.3 Steps for composing a statement of ingredients with clear allergen status

1. Obtain the product formulation/recipe including amounts of each ingredient
2. Obtain **product information forms (PIF)** and/or specifications for all ingredients. Ensure all sources of allergens as ingredients and cross-contact allergens are identified and recorded
3. Identify allergens in the product using the formulation and ingredient information, including: ingredients, food additives, processing aids, compound ingredients, cross-contact ingredients
4. Compose the ingredient list and declare the allergens formulated into the product
5. Conduct a **VITAL risk assessment to determine the presence of cross contact allergens** from ingredients and processing
6. Using the VITAL summary of labelling outcomes: confirm the allergens in the ingredient list, confirm the allergen summary statement, and compose the appropriate precautionary statement

1.4 Allergen labelling format

Overview of relevant documents (Australian Food and Grocery Council 'Food Industry Guide to Allergen Management and Labelling').
The **'May be present: XXX' statement** is an indication to the consumer of a sporadic, unavoidable cross contact with an allergen which may present a risk to the person with food allergy. This precautionary statement is used where a VITAL assessment has been applied and the labelling recommendation for the allergen is at **Action Level 2**.

1.5 Labelling should be easy for consumers to understand

1.6 The regulatory framework
Reference to relevant Standard 1.2.3 of the Australia New Zealand Food Standards Code. **Does not specify any requirements for declaring an allergen that is unintentionally present**. In this instance the VITAL Program can be used.

1.7 The VITAL program

A **standardised allergen risk assessment process** for food industry.

- Consistent methodology to **assess the impact of allergen cross contact from raw materials and the processing environment**
- Determines appropriate **precautionary labelling based on risk by using Action Levels** that are underpinned by scientific evidence
- Assist food producers in presenting allergen labelling accurately and consistently

1.7.1 The VITAL program and allergen free claims

Free claims are regulated by consumer laws to prevent deceptive and misleading practices. Where cross contact from an allergen is identified using the VITAL Program, a claim that this product is free of that allergen is unlikely to be appropriate.

2. Worked examples

VITAL Online finished product labelling outcome rules

Allergen status	**VITAL online finished product labelling outcome**
The allergen is present at Action Level 1	**Action Level 1** - Low concentration of the relevant allergen under evaluation, low chance of adverse reaction and **no precautionary statement required**
The allergen is present at Action Level 2	**Action Level 2** - Significant concentration of relevant allergen under evaluation, significant chance of adverse reaction and a **precautionary statement** is required
The same allergen is present at Action Level 1 and 2	
The allergen is present as cross contact in particulate form	
The same allergen is present at Action Level 1 and/or Action Level 2 and as cross contact in particulate form	
The allergen is intentionally added	Intentionally added. Must be included in **ingredient list**.
The same allergen is present at Action Level 1 and/or Action Level 2 and and/or in particulate form and intentionally added	
Cereals containing gluten	Based upon total protein concentration (ppm) of cereals containing gluten
Tree nuts	Based upon the total protein concentration (ppm) of tree nut allergen

2.1 Whole grain soup

- Cereals containing gluten, added as ingredients and present from cross contact
- An allergen present from more than one source: peanut oil present both as an ingredient and from cross contact due to processing
- Particulates and readily dispersible materials

2.2 Snack bar
- Tree nuts, when present as an ingredient and as a cross contact allergen
- Coconut (a 'tree nut' that does not require mandatory declaration per FSC)
- Honey
- Highly refined ingredients and allergen labelling exemptions

2.3 Fish sauce
- Fish added as an ingredient
- Crustacea present as cross contact due to processing
- Common names, generic names and specific names
- Allergens within a compound ingredient: anchovy fillets as a compound ingredient added at less than 5% of the total recipe, with two allergens present
- Ingredients derived from allergenic substrates: white vinegar and xanthan gum produced by fermentation of allergenic substrates

2.4 Mayonnaise in a sachet
- Small package allergen labelling requirements
- Food additives derived from an allergenic source
  - Soy lecithin and caramel colour
  - Vegetable oil as a compound ingredient containing a food additive derived from an allergen source

2.5 Pork and prawn curry rice
- Processing aids: allergen in a substance used as a processing aid that does not perform a technological function in the final food
- Sulphites
- Cross contact allergens at Action Level 1 and Action Level 2

Author	**Allergen Bureau - Australia / New Zealand**
Year	2019
Title	Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (**VITAL®**) Program version 3.0
Pages	18
Highlights	- Computes **Action Levels** (concentration of cross contact allergen proteins in the product) and compares them against VITAL Reference Doses **to determine the need for PAL** - **Steps**: allergen identification; quantification of cross-contact allergens; determination of Action Levels; validation of VITAL assessment; determination of labelling outcomes; recording Assumptions & ongoing monitoring

1. Introduction

The **VITAL Program:**
- **Risk based methodology** for food manufacturers to use in assessing the impact of cross contact allergens and provide appropriate precautionary allergen labelling (**PAL**)
- Developed against the Australia/New Zealand regulatory background; also applicable in other jurisdictions
- Aim: avoid the indiscriminate use of PAL and preserve its value as a risk management tool
- Premise: **some products may have foreseeable, but minute, levels of an allergen present through incidental cross contact, and this will not be labelled where the level is below a specified Action Level**
- **Zero risk for allergen management does not exist.** The use of the VITAL Program must be supported by robust allergen management to minimise risk.

Action Levels:
- Concentrations of cross contact allergen proteins
- Determine when it is appropriate to use PAL
- Calculated using Reference Dose (set by the VITAL Scientific Expert Panel) and Reference Amount (consumption)
- Not developed to address “free from” claims

2. The VITAL procedure
2.1 Scope
Allergens listed in the VITAL Action Level Grid.
Not applicable to: food specifically formulated for infants or for special medical purposes.

2.2 Pre-requisites: HACCP-based food safety program and an allergen management program

Allergen identification

2.3 Determination of relevant allergens
All allergens regulated for mandatory or precautionary allergen labelling should be considered, including intentionally added and potential cross contact allergens.

2.4 Identification of intentionally added allergens

- Review the allergen information (e.g. product specification) from the supplier for each ingredient, raw material and processing aid
- Intentionally added allergens that are present in the product being assessed should be listed in the ingredient listing on the label (for packaged product), or in customer information (for **bulk product**, if requested) as per regulatory requirements

2.5 Identification of unintentional (cross contact) allergens from materials or ingredients
- Review allergen information (e.g. product specification) from the supplier for each ingredient, raw material and processing aid to establish absence or the possible presence of cross contact allergens
- For each identified cross contact allergen:
  - Determine the **likelihood of its presence,** and if present, whether it is in a **readily dispersible or particulate form**
  - Investigate whether the cross contact allergen can be avoided, reduced, or eliminated

2.6 Identification of unintentional (cross contact) allergens due to processing
- Establish the possible presence of cross contact allergens in the product being assessed due to **storage conditions, manufacturing processes, or the design and layout of the premises**
- Consider all areas of the manufacturing facility and all stages of manufacturing and storage
- Any cross contact allergens identified should be reflected in the HACCP plan
- For each identified cross contact allergen:
  - Determine the likelihood of its presence in the final product, and if present, whether it will be in a readily dispersible or particulate form
  - Investigate whether the cross contact allergen can be avoided, reduced, or eliminated

From **Table 1: Tips for determining cross contact due to processing**
- **Production errors** are not examples of cross contact and should not be included as possible sources of cross contact allergens. They should be addressed using the HACCP plan and appropriate procedures.
- Correctly identify hang up points in the manufacturing facility. Cross contact due to processing may be eliminated by having **cleaning programs validated** to eliminate product on or in the lines.
- Form a cross-functional **team** to perform the risk assessment
- **Quantifying** the cross contact allergens will depend on the nature of the manufacturing facility. If the hang up point is inside a pump, pipe or other area which is difficult to access, an engineer may be able to assist with estimating the amount of product that may be left in the line and become incorporated into a subsequent product. If there is a powder residue, it may be able to be swept up and weighed. If the hang up cannot be reached, it may be necessary to estimate based on the volume of the pipe or other factors.

Quantification of cross contact allergens

2.7 Particulate cross contact allergens
- Separate and discrete particles of material of localised concentration which do not mix homogeneously with other parts of the food, and may consist of, or are likely to aggregate into, an entity which contains a level equal to or greater than the relevant Reference Dose
- Where they cannot be eliminated, the allergen is determined to be Action Level 2 (requires **PAL**)

2.8 Readily dispersible cross contact allergens from materials or ingredients
Where they cannot be eliminated, determine:

Total protein concentration from cross contact allergen in formulation (ppm) = Concentration of cross contact protein in ingredient (ppm) x Amount of ingredient in formulation (%)

The total concentration of a particular allergenic protein due to raw materials or ingredients in the finished product is determined by summing the cross contact concentrations for the allergen from each source

2.9 Readily dispersible cross contact allergens due to processing
Where they cannot be eliminated, determine:

Amount of cross contact protein from hang up point (mg) = Amount of hang up (g) x Amount of allergen ingredient in formulation of product in hang up (%) x Protein level of cross contact allergen (%) x 1000.

To calculate the total concentration (ppm) of the cross contact allergen in the product formulation, divide the answer above by the amount of product into which this cross contact can become incorporated.

2.10 Calculation of total cross contact allergen in finished product
- For each cross contact allergen, sum the concentration of allergen protein from raw materials, ingredients and processing aids and those from processing
- It may be necessary to apply a **dehydration or hydration** factor. The maximum possible concentration should be used as this will provide the most conservative result.

*Concentration of cross contact after **hydration** (mg) = Concentration of cross contact allergen / (% dilution + 100%) (where % dilution = water added (kg) x weight original product (kg) x 100%)*

*Concentration of cross contact after **dehydration** (mg) = Concentration of cross contact allergen / (% concentration)*

Determination of Action Levels

2.11 Ingredients intended for further processing (e.g. bulk product)
Action Level calculations are only relevant for products which are intended for presentation to consumers.

2.12 Determination of Reference Amounts for packaged products
The Reference Amount is the maximum amount of food eaten in a typical eating occasion. This may or may not be the same as the nominal or declared serving size but it will not be an amount less than the declared serving size.

2.13 Determination of Reference Doses for packaged products
Protein level (total protein in milligrams from an allergenic food) below which only the most sensitive individuals (1%) of the allergic population are likely to experience an adverse reaction, per VITAL Scientific Expert Panel.

2.14 Establish Action Levels for each identified cross contact allergen in packaged products
- Concentrations of protein which define the labelling outcomes for each concentration of cross contact allergen in a VITAL risk assessment. For packaged products, they are determined using the Reference Dose and the Reference Amount.

Action Level 1: Low concentration of the relevant allergen under evaluation, low chance of adverse reaction and no PAL is required
Action Level 2: Significant concentration of relevant allergen under evaluation, significant chance of adverse reaction and PAL is required

- Determine the Action Levels for each identified cross contact allergen in every packaged product (VITAL Online or manually).

The Action Level transition point *(ppm) = Reference Dose (mg) x (1000/Reference Amount (g))
(*except gluten where formula above is applicable or 20ppm, whichever is lower)

Validation of VITAL Assessment
The concentration of cross contact allergen in a product may be validated using analytical allergen testing, but it is **not a requirement** of the VITAL Program. Analytical results should not be considered in isolation, however, they may be useful to support VITAL assumptions and product verification.

Determination of Labelling Outcomes
- Cross-contact: per Action Level
- Intentional: ingredients list

Recording Assumptions & Ongoing Monitoring

2.16 Recording of assumptions
- Assumptions: any relevant details used to inform the VITAL risk assessment must be recorded. Examples: relevant allergens to be assessed, considerations for setting the Reference Amount, source for Reference Doses, source of information for allergen status of ingredients, source of information for cross contact allergens due to processing, reference to other food safety/quality documentation
- When any of the assumptions change, this should trigger a review of the VITAL assessment

2.17 Ongoing monitoring
The VITAL risk assessment should be reviewed when (but not limited to) any assumptions are changed, ingredients or suppliers are changed, equipment or manufacturing processes are changed, cleaning procedures are changed, and consumer complaints are received regarding allergic reactions. Or, every 12 months, whichever occurs sooner.

3. Supporting information (VITAL/Allergen Bureau resources)

The VITAL Program and Allergen Analysis
There is a significant role for allergen analysis in:
- Validation of the VITAL risk assessment
- Verifying ingredient allergen statements and potential raw material cross contact
- Targeted analysis of problem pieces of processing equipment
- Confirming assumptions made during the implementation of VITAL (e.g. validation of cleaning)
- Testing allergen status of the final product to compare with calculated results from VITAL assessment (especially relevant to high risk environments)
- Monitoring the effect of critical changes

Decision Tree for Cross Contact Allergens (Figure)

Author	**FoodDrink Europe**
Year	2020
Title	Precautionary Allergen Labelling (PAL): a science-based approach based on Quantitative Risk Assessment
Pages	24
Highlights	- Calls for a consistent, harmonized approach for use of **PAL**, based on risk assessment - **Recommends adoption of VITAL reference doses** as benchmarks for quantitative risk assessment - **Emphasizes importance of risk communication for PAL:** basis of judgement (i.e. quantitative benchmarks); cannot avoid the occurrence of every mild reaction, but would be protective against life-threatening reactions - Clarity and transparency are also required **when PAL is not used** - Need to further develop analytical methods

The realities of food production cannot avoid the unintended presence of allergens.
PAL is losing credibility among stakeholders, specifically allergic consumers. This can be attributed in part to the **absence of generally agreed quantitative benchmarks for its application and the consequent lack of consistent harmonised standards**, leading to lack of transparency, and confusion among allergic consumers.

Adoption of the VITAL reference doses could form part of an EU-wide approach aligned with FIC Regulation (voluntary food information must not mislead the consumer, must not be ambiguous or confusing for the consumer, and it must, where appropriate, be based on the relevant scientific data).

FoodDrinkEurope would like to see a defined framework for the application of PAL, namely:
- PAL should be clear i.e “may contain [allergen]”
- PAL should not be misleading: it should only be applied where a defined, appreciable risk has been identified through a **quantitative risk assessment.**
- PAL should be based on relevant scientific data: **VITAL** 2.0 is the most fully elaborated system. It has been subjected to extensive peer review and therefore offers the best prospects. It has also been recognised by several European national authorities.
- **Consumers need to know that products have been through a risk assessment and that the presence or absence of PAL is a consequence of that process**.

In addition, PAL should be applicable in practice: analytical methods have limitations with regard to sensitivity and accuracy. **Quantitative benchmarks (reference doses) require the development of capable protocols and methodologies.**

1. Introduction

PAL serves both to **communicate risk, but also manage** it, its ultimate purpose being to avoid reactions to allergens in susceptible consumers. A food producer should be using PAL primarily to dissuade susceptible consumers from consuming their product.

Unintended allergen presence can occur due to cross-contact during manufacture of either the product or one of its components, **including agricultural raw materials**. Situations that can give rise to unintended allergen presence encompass the **whole supply chain**.
Unintended allergen presence can also manifest itself in different ways, e.g. very low level of allergen present in all units of the product; presence of the allergen in a proportion of units only, due to carryover at changeover. In cases of allergen in **particulate** form, most units may not have any allergen, but where it occurs, it may be sufficient to provoke a severe reaction, so resulting in a rare event, but with serious consequences.

Using PAL in a meaningful way for consumers **is not simply about setting limits so low that every allergic consumer is protected against every possible reaction,** however mild, but being realistic that excessive use of PAL undermines its purpose in minimising the number of reactions among susceptible consumers. The challenge is to **strike the right balance between reference doses that are highly protective of very reactive consumers, while ensuring that they do not result in such proliferation of PAL use that its credibility is undermined**, allergic consumers are driven towards risk-taking behaviours, and the overall risk to them is in practice driven up.

Use of **PAL cannot avoid the occurrence of every mild reaction, but would be protective against life-threatening reactions,** all by re-establishing the credibility of PAL and therefore offering a valuable and trustworthy risk communication tool to producers and consumers.

Enforcement authorities' attitudes to the use of PAL vary across countries. Some authorities consider that the presence of any detectable allergen which is not an ingredient, using any analytical technique, infringes the food safety laws unless a PAL is applied. This **zero tolerance approach leads to ever-increasing numbers of products bearing PAL, as the sensitivity of analytical techniques continues to increase**. Other authorities use **quantitative risk assessment** to determine whether a product warrants a PAL statement, even though allergen might be detectable. However, there remains a lack of transparency concerning the **benchmarks** which they use.

2. Allergen hazard characterisation and risk assessment

VITAL reference doses:
- A very small minority might still be at risk of more significant reactions, although they would still benefit, and this needs to be communicated clearly
- Can serve as benchmarks in risk assessments and have been used by some European food safety authorities (ANSES, FSA)
- Where food consumption data are available, more sophisticated assessments based on probabilistic modelling techniques can be used, which take account of the uncertainty and variability associated with each input variable
- Evidence indicates that lower doses of allergen are associated with a lower probability of severe reactions

The need for harmonised quantitative benchmarks (zero tolerance is not zero risk)

A prerequisite to restoring the credibility and value of PAL is to assure consistency of its application, such that a PAL statement indicates a defined level of risk. **Quantitative benchmarks** are a critical element in defining such levels of risk at a population level.

The role and limitations of analytical methodologies

- A necessary prerequisite of the practical application of PAL for all stakeholders, particularly producers and authorities, is the availability of reliable and practical analytical methods. Current technologies (ELISA, PCR) have limitations with regard to sensitivity, accuracy and specificity.
- Lack of certified reference material and methods for the effective quantification of allergens.
- Effective implementation of quantitative benchmarks (reference doses) **will require development and implementation of methods and protocols** capable of reliably and accurately detecting allergens at relevant concentrations.

Further considerations in the application of PAL

Its application is aimed at foods for normal consumption, with the implication that **there may be a very small number who cannot be protected totally against reactions** given current knowledge and practice.

The twin roles of PAL: risk communication and risk management

The **communication** element is to inform at-risk consumers that the product in question could precipitate a reaction. It is critical that those consumers understand the meaning of the warning. Manufacturers and suppliers must understand how consumers interpret such warnings, and must be clear about how they want their message to be interpreted. **The message should be clear and indicate that the food producer's considered judgement, based on a risk assessment, is that the product is not suitable for people with the relevant allergies**. The **basis of that judgement** should also be clear, hence the need for agreed, consistent benchmarks.

Clarity and transparency are also required when PAL is not used. Currently where no PAL is present, this may mean:

(1) the manufacturer has performed a risk assessment and deemed the product not to require PAL because the risk is negligible (allergen content per portion is below the reference dose), or

(2) the manufacturer has not done a risk assessment (unquantifiable risk to allergic consumers, rather than one to which an upper limit has been set). The nature and magnitude of the risk where no PAL is used still need to be accurately and clearly communicated so that allergic consumers can make an informed decision. This requires the use of **multiple channels of communication**, such as websites, carelines, etc., not just the label.

Risk management, i.e. the **minimisation of allergic reactions**, is the second role of PAL and it can only be discharged successfully if communication of the PAL message is successful. Foods not bearing PAL as a result of risk assessment, although not specifically designed for people with allergies, would not provoke adverse reactions in the vast majority of allergic individuals. The allergen may be analytically detectable but the amount is below the action level (reference dose).

3. Implementation of PAL: towards more consistent allergen risk communication
Formatting considerations

ALLERGEN CLEANING

Author	**SQFI**
Year	2012
Title	Allergen cleaning and sanitation practices
Pages	6
Highlights	- Hazards associated with allergens and their control must be incorporated into the food safety plan (HACCP) - **Validation and verification** of the effectiveness of the cleaning and sanitation must be **based on risk assessment** - Requires validation and verification of cleaning and sanitizing procedures for the **product contact equipment**; use of **finished product testing for validation of cleaning is not considered adequate**

I. Introduction

The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. **The allergen management program shall include**:

1. A risk **(hazard) analysis** of raw materials, ingredients and processing aids, including food grade lubricants that contain allergens
   - Ensure suppliers declare any allergenic substances, including the potential for cross contact allergens
   - Applies to ingredients used throughout the facility
   - The risk assessment must also apply to potential allergens in materials and products that are stored or produced on other lines in the same facility, or at other times on the same line
2. A **register of allergens** which is applicable in the country of manufacture and the country(ies) of destination
3. A **list of allergens**, accessible by relevant staff
   - Staff awareness is critical; **training** must be provided
4. The hazards associated with allergens and their control incorporated into the food safety plan (HACCP).
   - **Controls** may include: specifications for ingredients and raw materials; receipt and separate storage of raw materials and ingredients; separate storage of work-in-progress, and finished products; scheduling of allergen containing materials after non-allergen containing materials; equipment design; etc.
5. Instructions on how to identify, handle, store and segregate raw materials containing allergens provided to receiving staff
6. Provision to clearly identify and segregate foods that contain allergens
7. **Cleaning and sanitation of product contact surfaces between line changeovers** shall be effective, appropriate to the risk and legal requirements, and sufficient to **remove all potential target allergens** from product contact surfaces, including aerosols as appropriate to prevent cross contact
8. **Based on risk assessment**, procedures for **validation and verification** of the effectiveness of the cleaning shall be implemented

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

II. Cleaning validation and verification

SQF Code requires validation and verification of cleaning and sanitizing procedures for the **product contact equipment**, and therefore the use of **finished product testing for validation of cleaning is not considered adequate**. A program of **verification** needs to be built on an initial validation study that identifies the target allergen(s) , threshold levels, and the severity of contamination, and shows the cleaning process and testing used are effective to give the desired results consistently.

Validation
Requires evidence that the specific allergen was in fact removed, or reduced to an acceptable level by the cleaning procedure. Only an **allergen specific test** will provide that evidence.

Verification
Once a validated cleaning method has been shown to remove the allergenic material of concern, the facility must verify and document that the validated procedures were used each time. The **most common method used is direct observation of the validated cleaning procedure during the sanitation process.** Another acceptable verification method is the use of **proteins or ATP swabs, calibrated with the validated cleaning procedure by using them immediately after the validated method** is used and recording the results of both the allergen specific test and the protein or ATP swab test.

- When there is a mixture of different allergens in use, the acceptable method for confirming the thoroughness of cleaning is to **test for the highest risk allergens, the highest concentration allergens, or the ones that are most difficult to remove**
- Facilities using **whole or partial nuts** may have to verify removal of all the nuts fragments from the equipment based on **visual inspection**
- Finished product testing is not sufficient by itself to validate cleaning methods since any allergen present is diluted by the product and can become nearly undetectable thus rendering a questionable result
- For dry products, an inert product flush may be the most effective method to remove allergens. In this case, three product flushes may be required.

The methods for validation and verification of the cleaning procedures, as well as the other allergen safety procedures used in the facility, must be **scientifically valid and any exclusions or exemptions must be thoroughly documented with a detailed risk assessment**. There must be a documented re-assessment of the allergen control program performed **at least annually**.

Author	**Neogen / FARRP (USA)**
Year	2016
Title	Best practices for food allergen validation & verification
Pages	14
Highlights	- Guidance on selection of sites, test methods, procedures, frequency, for cleaning validation and verification - Emphasis on developing a solid rationale behind cleaning and sanitation program - Risk-based and factory/product/allergen-specific - **Final product testing should not be considered a validation or verification test,** as issues such as sampling, random distribution, and product dilution may render test results meaningless - Endorses GMA (2009) four criteria to justify use of PAL

Validation must be based on logical inferences and measurable results, and those results must be translatable to standards that can be utilized for routine monitoring during the normal production cycle.

- **Validation** determines if a process will be effective (**future**)
- **Monitoring** determines if the process is effective (**present**); real time and continuous (e.g. visual inspection)
- **Verification** determines if the process was effective (**past**)

I. Cleaning to a validated standard

Allergen cleaning validation is **specific to each unique product**. Once all cleaning processes have been established, a facility may choose to operate with separate SSOPs or standardize on the most rigorous SSOP across all product lines.

1. Test kit validation

- Any rapid food allergen method **must be validated for the product being used**
- Determine fit-for-use by running a positive control on each food type that contains the food allergen
- The **ability of the test kit to detect the allergen from actual food contact surfaces within the facility** should be challenged by sampling areas prior to cleaning to show the presence of the residue and following cleaning to demonstrate their absence

2. Best practice for validating the cleaning process

It is recommended to utilize a **scoring scale system** (e.g. green, yellow, red) for environmental swab results tested with a quantitative test, to eliminate the confusion of interpreting a ppm result.

Steps:

1. Produce the allergen-containing product
2. Clean following the established SSOP
3. Take swabs at each of the identified test points
4. Perform the tests
5. If any score falls outside of level Green (Green is <LOD if using quantitative tests, or negative if using screening tests), re-clean the respective area and perform additional tests until level Green status is achieved

6. In some cases it is recommended to test the “first off” product to validate areas where the visual inspection or swab collection are unavailable
7. Incorporate the new protocol into the next cleaning event
8. Repeat steps 1-5 until **ALL test sites** have achieved level Green for **three consecutive cleanings**
9. Document process and the test results to support it. Make appropriate changes to the SSOP

3. Determining appropriate testing sites

- Test each site that represents a unique surface (material, complexity, location), unique cleaning protocol and unique product composition, as well as those areas that represent unique cleaning challenges such as welds, corners and other harborage areas.
- Representative sampling for validation should also occur before and after thermal processes to ensure that the test can detect the allergen in raw and finished product

II. Migrating from validation to verification

Most facilities operate with a verification program that features **representative sampling with a combination of target allergen testing and a surrogate method** such as ATP, protein or visual examination. To interpret the results from a test such as ATP or protein, it is imperative to **incorporate that testing into the final stages of the validation process**.

1. Determining the quantity of tests necessary for verification

- Objective: achieve a representative sampling for each cleaning event
- The appropriate number of samples is process and facility specific and must be considered within real-world production and budget requirements
- The number may evolve over time
- A robust monitoring program identifies areas for additional consideration and can spot issues before they become problems
- The number of tests to perform must be based on a solid foundation of logical and supportable thought

2. Best practice for verification of cleaning in an allergen-containing production environment

Non-allergen specific tests (e.g. ATP, general protein, visual observation) may not correlate to allergen-specific ELISA tests, and will not be indicative for the presence of allergens. It is recommended to generate side-by-side data for a period of time to determine correlation between methods.

III. Multiple allergens in product

- **Particulate** risk materials should be screened separately and individually. Visual inspection is a critical first screen. It may be appropriate to perform flush testing or “first product off the line” testing.
- If particulate risk is low, choosing the most difficult to clean or most abundant allergen in the formulation is a suitable means of gauging the absence of the others
- If no test kit is available to screen for a particular allergen, visibly clean remains a first standard in sanitation and can be verified with a surrogate system

IV. Selection of test method

- Any analytical method selected for verification should be **validated on-site in the user's facility, under its specific conditions**
- Surrogate methods (e.g. ATP, general protein, visual observation) may be acceptable for verification when: specific immunodiagnostic test methods are unavailable for a particular allergen, or the method has been validated in-house against the specific allergen
- For multiple allergens, it may be acceptable to choose one allergen to demonstrate the effective removal of all allergens, provided the worst case scenario (i.e., allergen in highest concentration or most difficult to clean) is chosen

V. Other testing considerations

- Determine the **risk incurred from raw material suppliers** by evaluating ingredients for presence of an allergen to verify the supplier's COA
- The presence of cleaners and sanitizers can affect limit of detection of test kits

How often one should verify that there has been no drift in sanitation practices? Depends on level of tolerable risk:
- **Highest risk:** When the product has the highest risk for inadvertent allergen cross-contact the most conservative approach would be to monitor environmentally upon changeover of every allergen production run to verify the existing sanitation protocol is still effective and document that verification using an allergen-specific immunoassay.
- **High-Medium risk:** Quarterly monitoring upon changeover with an allergen-specific immunoassay represents a less conservative approach.
- **Medium-Low risk:** Using a general protein or ATP system to monitor product changeovers for allergen removal represents a greater level of risk due to the potential for allergens to be present below the level of detection of general protein tests and the unknown or variable correlation between ATP and allergenic protein presence.
- **Lowest risk:** Perform environmental monitoring through visual inspection but there is an increased level of risk to the subjectivity of the observer, lighting conditions and other variables.

VI. Revalidation
Validation should be undertaken **at least once each year** unless a specific event has occurred, e.g. changes in raw material suppliers, equipment layout or design, product formulation, etc.

VII. Allergen cleaning and sanitation documentation
Should include: methods to prevent cross-contact, risk analysis of ingredients that are a potential for cross contact, register of all allergens in the facility, all hazards associated with allergens, etc.

VIII. Where to test
Sampling areas for **Environmental Monitoring Programs** may be broken down into **zones** based on their proximity to the product: Zone 1 (food contact), Zones 2, 3 and 4 would be non-contact surfaces of lessening probability that could contribute contaminants through some interaction with people, equipment or air and water circulation. For allergen cleaning verification, testing sites should be concentrated in Zone 1.

IX. Final product testing
If during the risk analysis unintended food allergens are identified as a risk, preventative controls should be in place to ensure the risk is eliminated. In this case, final product testing is encouraged. However, for the purposes of this document, **final product testing should not be**

considered a validation or verification test, as issues such as sampling, random distribution, and product dilution may render test results meaningless.

X. What if I can't clean to the target level?
PAL may be the best course of action. It should be justified by meeting the GMA's four criteria (GMA, 2009).

XI. Should allergen advisory statements on ingredients be carried forward?
If it is determined that an Allergen Advisory Statement is required for the ingredient, then typically an Allergen Advisory Statement should be carried forward to the label of the finished product. However, you may choose to exercise discretion based on inclusion rate, protein load or other supportable logic.

Author	**Food and Drug Administration (FDA) - USA**
Year	2019
Title	Fish and fishery products hazard controls guidance. Appendix10: Cleaning and sanitation for the control of allergens
Pages	8
Highlights	Recommendations on **cleaning** and sanitation for allergen control. Refers to cleaning **validation and sampling plans**.

Introduction

Appendix created to assist a processor in developing a sanitation program and/or assess their current program to determine its adequacy and efficacy, to comply with the regulatory requirements of the **seafood HACCP** regulation.

Cleaning controls for allergens

Cleaning methods should be appropriate for the processing environment, the equipment, the type of product/ingredient, and the identified allergen.

Development of written sanitation standard operating procedures (SSOPs) for allergen management can ensure the desired results and a consistent application of controls. Should include (*more details in source document*):

- All instructions necessary to ensure that equipment and utensils are effectively cleaned and sanitized along with instructions for monitoring of cleaning procedures and verifying cleanliness, including:
  - Conduct **verification testing using analytical methods**
- Ensure that the cleaning practices and procedures do not result in transfer of allergens to other areas of the facility and prevent the dispersal of allergenic materials
- Establish **written validation procedures** when necessary to ensure that cleaning methods are effective at removing allergenic food residue
  - Conduct validation studies of the effectiveness of using “push-through” methods to clean food-contact surfaces to establish the critical factors for the process
  - **Validation** of cleaning procedures should occur: at least annually; when introducing a new product(s) or allergenic ingredient(s); when introducing or implementing new cleaning procedures, equipment, or chemicals; or when modifying (reducing) cleaning frequencies

Sampling plan in support of verification and/or validation activities

Obtaining and analyzing samples from hand-held tools, employee apparel, equipment surfaces, rinse water, push-through material, ingredients and final product for the presence of allergenic food residue can help support and verify the sanitation control program. Consider the following (*more details in source document*):

- Develop a **valid sampling plan** to accurately represent the condition of what is being sampled and the outcome of the cleaning and sanitation procedures
- Ensure that the sampling plan includes all the equipment where allergen build-up could occur, or residual allergenic proteins could be trapped. The identification of equipment should be based on the processor’s practices and allergenic ingredients.

- Obtain equipment **pre- and post-cleaning swabs** at multiple locations on each processing line. Swabs obtained pre-cleaning serve as positive control samples
- Obtain push-through samples at multiple locations in the processing line
- Use **validated analytical testing procedures** that are specific to the targeted allergen(s) and the type or matrix of sample(s) to be tested
- Define the **final criteria for acceptance of analytical results**

OTHER DOCUMENTS

Author	**Food Standards Agency (FSA) - United Kingdom**
Year	2009
Title	Guidance on allergen management and consumer information - Evaluation research
Pages	97 (includes questionnaires)
Highlights	Evaluates the uptake and effectiveness of the 2006 guidance by manufacturers and Enhancement Officers. Conclusions: need to increase awareness; very positive overall opinion; **more practical examples/solutions** were suggested.

Objectives
Main purpose: assessing the uptake and effectiveness of the 2006 guidance.
Research objectives:
- Ascertain levels of awareness amongst businesses and Enforcement Officers (and how they became aware)
- Explore attitudes towards the guidance
- Understand the impact of the guidance
- Identify any improvements to the content of the guidance
- Understand whether the dissemination of the guidance could be improved
- Establish whether the voluntary 'best practice' nature of the guidance is perceived to be better/more effective or otherwise than compulsory legislation

Methodology
35 in-depth **interviews** (manufacturers, retailers, training bodies and Enforcement Officers) and 382 semi-structured telephone interviews (manufacturers and Enforcement Officers)

Main findings
- 53% of manufacturers and 78% of Enforcement Officers were aware of the guidelines
- Awareness amongst retailers was mixed, whilst most training bodies were aware
- Regarding manufacturers, awareness was much higher among large businesses (81%)
- Most manufacturers became aware of the guidance either through **internet searches** on 'allergens' leading to the guidance on the FSA website or, particularly in the case of smaller organisations, through their enforcement officers
- Overall opinion of the guidelines was **very positive**: 100% of manufacturers and 80% of Enforcement Officers rated it as useful
- Both documents showed some relative **weakness** in terms of relevance, **ease of application and offering practical solutions** (although negative scores were very low)
- Over 90% of Enforcement Officers who have accessed the guidance are actually using it, either to inform their own approach to the issue or in their communications with businesses
- Reading the **documents had lead to most businesses doing something** as a result, ranging from checking their current procedures to fundamental changes to the way they tackle allergens and allergen labelling

Recommendations: Increase awareness
Respondents suggestions: Include more **practical examples** of how recommendations can be applied to the workplace (possibly as links to other sections of the FSA website in order to keep the guidance reasonably concise).

Author	**Seasoning and spice association (United Kingdom)**
Year	2017
Title	Allergen risk assessment model for dried herbs and spices
Pages	14 **+ Excel file**
Highlights	- Easy to use, quantitative risk assessment model + Excel sheet, specific to herbs and spices, and based on VITAL reference doses - Includes table with usage data of herbs and spices in various recipes - To be used **once an issue has been identified, or following a positive test result** - Sampling and analysis considerations, specific to herbs and spices

1. SSA approach to food safety and supply chain
Process controls based on well-established GMPs and sound food safety management systems (FSMS). Purchase all their products from **approved suppliers in order to ensure full traceability** at all stages of production, processing and distribution.

2. Objective
Provide members with a **systematic** way of assessing the need for PAL in herbs and spices based mainly on **VITAL** Reference Doses, **once an issue has been identified, or following a positive test result.**

3. Regulatory position on allergens
Brief overview of relevant EU regulations.

Despite all the supply chain controls and good manufacturing practices to control allergenic cross-contamination, a situation may arise where **low level cross-contamination** is detected. In these situations, it is advised to follow the SSA's risk assessment model which is based on the FSA's approach to allergen risk assessment.

4. Sampling, allergen cross-reactivity and false positives
Sampling of the material for allergen testing should be done on a statistical basis and allow for possible non-homogeneity in the sample. SSA recommends that its members use the **Square Root Sampling Plan**.

Herbs and spices are one of the most **complex and challenging matrices to analyse**. When interpreting test results, consideration should be given to the type of material being tested, how the sample was selected, the availability of UKAS accredited test methods and their limitations. Members are advised to consider the Measurement of Uncertainty (MU) when interpreting test results.

5. SSA's risk assessment model for allergens in spices (+ Excel file)
Procedure:
a. Identify ingredient being examined
b. Select allergen of concern (drop-down list)
c. Insert **test result** = allergen protein in ingredient (**ppm**)
d. Enter typical **ingredient content of a meal (g)**

- Best practice: identify worst case scenario usage. Should use company recipe data on herb and spice usage. If not available, refer to Annex III.

e. Enter the number of portions that the typical recipe/meal selected will generate
f. The spreadsheet automatically:
   - calculates the quantity of ingredient consumed (g) in one meal portion: f=d/e
   - calculates the quantity of allergen protein (mg) consumed: (f*c)/1000
   - compares it to the reference dose (mg)
   - indicates “action required”/“no action required” and refers user to decision tree
g. Use decision tree to determine next steps

6. Risk assessment decision tree

Based on the results of the risk assessment, whether product is or isn’t on the market, whether it has or does not have the right PAL, actions may be: contact FSA, no further action, or PAL required.

Annex I: Link to spreadsheet
Annex II: Summary - questions for laboratories; how the results will be expressed
Annex III: Typical usage of dried herbs and spices in recipes

Author	**Allergen Bureau**
Year	2019
Title	Summary of the 2019 VITAL scientific expert panel recommendations
Pages	9
Highlights	Updated Reference Doses

Eliciting dose (ED)
The dose of an allergen at which a proportion of the allergic population would be likely to react to. It **does not identify a dose below which no allergic individual would react**. The ED01 and ED05 are the doses at which only 1% and 5%, respectively, of the allergic population would react with objective symptoms.

Allergen threshold modelling
- Adoption of a new method (Stacked Model Averaging) to determine dose distribution relationships
- Recommends the adoption of ED_{01} values as the Reference Doses for VITAL 3.0

VSEP Recommended reference doses (mg protein)

Allergen	2019 VSEP Ref. Dose (mg protein) [ED_{01}]
Egg	0.2
Hazelnut	0.1
Lupin	2.6
Milk	0.2
Mustard	0.05
Peanut	0.2
Sesame	0.1
Shrimp	25
Soy (milk + flour)	0.5
Wheat	0.7
Cashew	0.05
Celery	0.05
Fish (finfish)	1.3
Walnut	0.03

Author	**Food Safety Authority of Ireland (FSAI)**
Year	2019
Title	Report of the Scientific Committee of the Food Safety Authority of Ireland - Information required for the risk assessment of undeclared food allergens in Ireland
Pages	32
Highlights	Report providing scientific advice to the FSAI on the data inputs needed for allergens risk assessment - FSAI food allergen alert system: interesting tool - Milk is the most frequently reported undeclared allergen in Ireland - FSAI required to conduct risk assessment when an unintended allergen as a result of cross-contamination is detected - **Maximum level of undeclared allergen that would ensure a high level of protection for vulnerable consumers cannot be established**. Evaluation must be conducted on a case-by-case basis. - Allergen risk management initiatives are in progress (EuroPrevall and harmonisation of detection methods) - Data collection efforts are encouraged

1. Background
Allergic individuals rely on the avoidance of foods containing the relevant allergen to manage their condition. EU legislation offers some protection as it requires declaration of 14 allergens when they are used as ingredients. When a food on the market is found to contain any of these allergens, not declared as an ingredient, remedial action may be required (relabelling, withdrawal, recall). The urgency and extent of this remedial action can be informed by a risk assessment.

2. Objective
To provide **scientific advice to the FSAI** on the data inputs needed for the risk assessment of undeclared allergens in foods to underpin proportionate risk management in order to protect public health.

3. Food allergies (1/2 page general overview)

4. Food allergens on the Irish market
The FSAI's **food allergen alert system** (https://www.fsai.ie/news_centre/food_allergy_alert_notification.html):
- In place since 2009
- Detection of undeclared allergens rapidly relayed to > 2000 subscribers by text or email
- 45 alerts issued in 2018, the highest number since the system was put in place
- Alerts origin: industry self-reporting, notifications by competent authorities in other countries, routine official controls carried out in Ireland
- The **number of alerts involving milk each year is significantly higher** than the number of alerts involving the other food allergens

5. EU and Irish legislation governing the labeling of food allergens
- Brief overview

- When a contaminating allergen (i.e. not an ingredient) is detected, a risk assessment is required in order to determine whether it constitutes an unsafe food, which cannot be placed on the market (Regulation (EC) No. 178/2002)

6. Ingredient versus contaminant
- Mandatory food allergen declaration per FIC Regulation is not required where a food allergen is present in a food due to cross-contamination
- Cross-contaminant: a constituent inadvertently present in a food at relatively low but undefined levels (allergens, even at low levels, can pose a risk to susceptible consumers)

7. Risk assessment and risk management
When a non-declared allergen is found in a particular food on the market, the **role of risk assessment depends on root cause**.

- Errors in production, processing or labelling: urgency and extent of any remedial action can be informed by a risk assessment to be carried out by the food business and/or the FSAI
- **Cross-contamination: a risk assessment**, **carried out by FSAI**, is required in order to inform any risk management actions

8. Risk assessment of food allergens (brief background)

9. Critical information required for effective food allergen risk assessment

a) Reliability of analytical results
ELISA is the preferred analytical technique for detecting and quantifying food allergens. However, it has limitations (e.g. food matrix effect, processing effect, cross-reactivity). Alternative methods are also available (e.g. PCR, mass spectrometry). Harmonisation of analytical techniques for the detection of food allergens is being considered in the EU.

b) Prevalence of individual food allergies in Ireland
Reliable data on the number of consumers who are allergic to each of the 14 regulated allergens are required to estimate the level of risk. The gold standard for food allergy diagnosis is oral challenge, but surveys can also yield useful information. Results of such surveys in Ireland reported **peanuts, tree nuts and eggs** as the sources of the most frequent adverse reactions.

c) Potential for a severe reaction
Irish statistics (limited) on hospital admissions associated with food-related anaphylaxis, per allergen and age group, and prescription of pre-filled adrenaline auto-injector devices.

d) Concentration of the allergen and reaction-eliciting dose
Overview of the VITAL program and reference to Taylor et al (2018) reference doses. Similar work has been conducted in Europe under the EuroPrevall project (results yet to be published).

e) Potential exposure to food containing an undeclared food allergen
- Exposure can only be assessed on a case-by-case basis as food incidents arise
- Information on the food category affected is crucial to identifying a possible increased risk to a particular subpopulation
- Data from food consumption surveys are available in most European countries. However, these surveys were not designed to specifically address the question of food allergies
- Food composition tables ignore the distribution of specific allergens present by cross-contamination in the general food supply, which is not known at present

- In Ireland, national food consumption surveys report data on portion sizes of a wide range of foods consumed by children and adults

10. Conclusions
- There is limited data on the prevalence of food allergies in Ireland
- Taylor et al (2018) is regarded as the most up-to-date source on reference doses
- The relative risk posed to the Irish population by the 14 regulated food allergens cannot be ranked due to limited data availability
- A **maximum level of undeclared allergen that would ensure a high level of protection for vulnerable consumers cannot be established**. Evaluation must be conducted on a case-by-case basis.

11. Recommendations
Relevant **data-collection efforts should be encouraged**, as effective risk assessment is highly dependent on the availability of reliable data.