

ALLERGEN MANAGEMENT GUIDELINES FOR FOOD MANUFACTURERS

User guide

With over **3 million Canadians living with food allergy**, it is imperative for food manufacturers to ensure that their products comply with food labelling requirements and have practices implemented to manage allergens throughout the manufacturing process.

The following User Guide provides you with an overview of the key components in the new **Allergen Management Guidelines for Food Manufacturers**. These Guidelines can assist you during the review of your facility's current allergen management practices or help you to implement an allergen management process within your facility.

We have embedded convenient hyperlinks to make it easy to find more detailed information along the way – simply click on the link to be redirected to the relevant area in the detailed guidelines.

Content Overview

1 Understanding Canadian food regulations

Learn more about Canada's current regulatory framework as it relates to food allergens. (See *Guidelines page 14*)

While Preventive Controls are required by law, Precautionary Allergen Labelling (PAL) continues to be voluntary and there is limited guidance to industry relating to its use. (See *Guidelines page 16*)



ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

2 How to Manage Allergens – Allergen Control Plan (ACP)

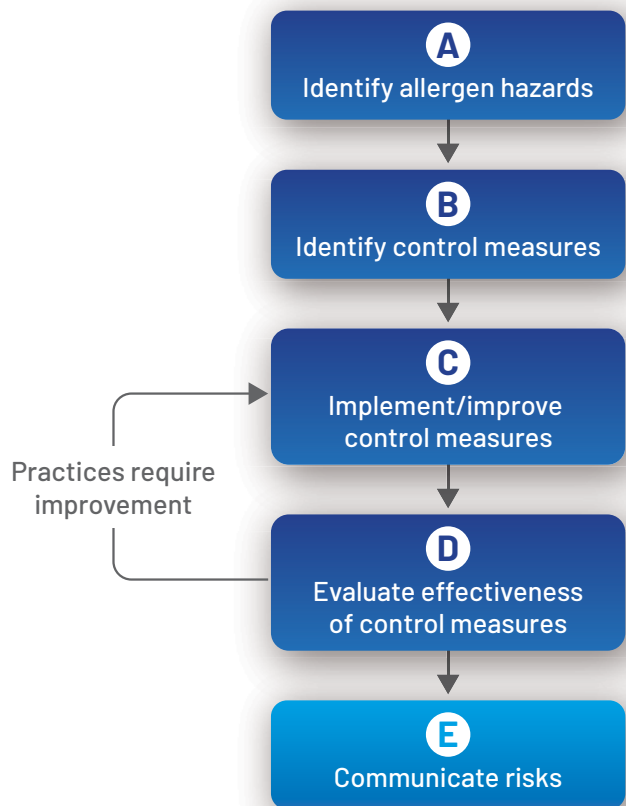
How to manage allergens, how to avoid or eliminate their unintentional presence, and how to ensure that products are appropriately labelled are covered in this section. (See *Guidelines page 20*)

To enhance allergen management, it is recommended that all food manufacturers develop an allergen-specific preventive control plan, called an Allergen Control Plan (ACP). An ACP outlines a strategy to prevent or minimize the risk of introducing unintended allergens to a product. It includes specific measures to be implemented and monitored and establishes how the effectiveness of those steps is to be determined. An ACP answers where? when? and who? types of questions for

every allergen management element covered. The ACP must be included within the facility's larger Preventive Control Plan (PCP).



This process map for developing an ACP offers a snapshot of what you need to know:



ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

A Identify allergen hazards

This section covers the steps needed to identify allergen hazards:



- 1 Identify all allergens that enter the facility** (See Guidelines [page 21](#))



- 3 Identify all allergens that may be indirectly added to each finished product as unintentional components of raw materials** (See Guidelines [page 24](#))



- 2 Identify all allergens that are directly added to each finished product from all raw materials** (See Guidelines [page 23](#))



- 4 Identify all allergens that may be unintentionally introduced into each finished product during receiving, handling, storage, processing, and packaging** (See Guidelines [page 24](#))

B Identify allergen control measures

This section describes the types of actions that can be taken to address the allergen hazards you have identified. Control measures can then be implemented as part of your facility's Preventive Control Plan (PCP) and/or ACP and should take into consideration the following factors: (See Guidelines [page 27](#))

- Amount of allergen protein in a given amount of allergenic material
- Allergen physical form (e.g. powder, liquid, paste, particulate, dust)
- Characteristics of the potential cross-contact event (e.g. introduction at a given processing step, spread to adjacent lines, carryover, accumulation in equipment)
- Cross-contact distribution in the food (e.g. in clusters, homogeneous)

These factors should be considered in an integrated manner. (See Guidelines [page 28](#))



ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

C Implement / improve control measures

This section highlights how to implement and improve your allergen control measures to avoid or eliminate the unintentional presence of allergens in products, and to ensure they are appropriately labelled. (See *Guidelines page 30*)

The following areas should be considered in the development of this process.

1 Human resources



Allergen management must be a priority for all staff. Employees from all departments and functions must understand why an ACP is necessary and why specific control measures are being implemented.

i Management (See *Guidelines page 30*)

Senior management's commitment is essential to set a positive example and to demonstrate the importance of an ACP for their business. Their direct involvement and ability to secure financial resources and funding related to allergen management are essential to the success of an ACP.

ii Allergen Management Team (See *Guidelines page 30*)

This team is comprised of representatives from upper management, food quality and safety, production, research & development, purchasing, and marketing departments. In smaller, less complex organizations, a smaller team may be sufficient.

iii Training (See *Guidelines page 31*)

Allergen training must be scheduled for all facility employees.

2 Supply chain



i Understanding the Risk (See *Guidelines page 32*)

The entire supply chain, not only the steps immediately before or after food manufacturing, must be included for effective allergen management.

ii Suppliers (See *Guidelines page 32*)

There are many considerations when working with suppliers:

- Supplier approval and raw material assessment
- Audits
- Allergen information requirements
- Regular reviews

iii Transportation (See *Guidelines page 34*)

Regardless of how complex or simple your distribution channel is, it is important to fully document the carrier's activity for all materials. Records should be completed consistently and made easily accessible.

iv Recall Plan (See *Guidelines page 34*)

All food manufacturers are expected to have a Recall Plan in place to remove non-compliant products rapidly and efficiently from the market.

ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

3 Purchasing/sourcing and procurement



Purchasing (sometimes called Sourcing & Procurement) is one of the first steps in a food manufacturing operation that allows or prevents the entry of allergens into the facility. When purchasing raw materials (including ingredients, packaging materials and processing aids), it is critical to conduct a thorough review and request up-to-date allergen information from suppliers. (See [Guidelines page 35](#))

4 Product development and reformulation



Any product that includes the introduction of new allergens (not previously present in the facility) requires adjustments to the manufacturing operation. Even reformulations that include new allergens (or that remove existing allergens) require a reassessment of risk communication strategies. (See [Guidelines page 35](#))

5 Receiving and storage of raw materials



The most effective allergen risk management strategy during raw materials receiving and storage is identification and segregation. (See [Guidelines page 36](#))

6 Process design



Identification and segregation strategies are also the basis of allergen risk management when designing a food production process. (See [Guidelines page 37](#))

7 In process



Consider risk mitigation strategies targeting the following elements in your production process:

i Personnel working with allergens

(See [Guidelines page 38](#))

ii Staging (See [Guidelines page 38](#))

iii Changeover (See [Guidelines page 39](#))

iv Rework and Work-in-process (See [Guidelines page 39](#))

v Other Considerations (See [Guidelines page 39](#))

8 Maintenance



Learn how to prevent allergen cross-contact that can occur through maintenance personnel, tools, and materials.

(See [Guidelines page 39](#))

9 Labelling – how to prevent labelling errors



Labelling errors can occur during the labelling process and may originate during the following:

(See [Guidelines page 40](#))

- label design stages
- label printing
- when an incorrect ingredient is received
- receiving, storage, movement, or staging of packaging material
- inadequate line clearance
- when a new ingredient with a different allergen profile was purchased from a new supplier and added to the recipe without a label update

It is critical to systematically review the entire label process flow, identifying practices or steps that can lead to labelling errors, and include a label verification control point. (See [Guidelines page 40](#))

Learn why it is important to document the results of this review process for each finished product. (See [Guidelines page 41](#))

10 Review other communication channels



Consider all communication channels when providing ingredient information to consumers, including:

i E-Commerce (See [Guidelines page 42](#))

ii Digital Communication (See [Guidelines page 43](#))

iii Machine-Readable Optical Labels

(See [Guidelines page 43](#))

iv Engagement with Consumer Associations

(See [Guidelines page 43](#))

ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

11 Cleaning



It is necessary to develop and validate cleaning procedures targeting the removal or reduction of allergen residues specific to their operations. When designing an allergen cleaning procedure, the nature of the food residue, the characteristics of the equipment and food contact surfaces, and the type of cleaning method must be considered.

Cleaning procedures must address the removal or reduction of allergens from the processing environment, equipment, conveyors, surfaces, tools and utensils, maintenance tools, reusable containers, carts, trolleys, pallets, coats, and all materials exposed to allergens. (See *Guidelines page 44*)

12 Deviation management



A facility's ACP must include procedures on how to address any deviations from allergen control measures. (See *Guidelines page 45*)

13 Record keeping



Food manufacturers must maintain records which show how foods and raw materials are handled to prove food safety, to comply with regulations, and to facilitate traceability. All of these are critical to effective allergen management. (See *Guidelines page 45*)

D Evaluate effectiveness of control measures

In addition to monitoring activities, a regular evaluation of your facility's ACP is necessary to confirm its effectiveness. At a minimum, schedule an annual review or audit. (See *Guidelines page 46*)



ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

E Communicate risks

Assessing the Need for Precautionary Allergen Labelling

In this section you will find a proposed approach for communicating allergen risks and assessing the need for Precautionary Allergen Labelling (PAL).

(See *Guidelines page 47*)

Allergens that are part of a finished product's recipe must be declared as ingredients. Other allergen risks that cannot be avoided must be communicated to allow consumers to make informed and safe choices. PAL must only be used to communicate the unintentional, unavoidable presence of allergens present at a level that poses a risk to food allergic consumers.

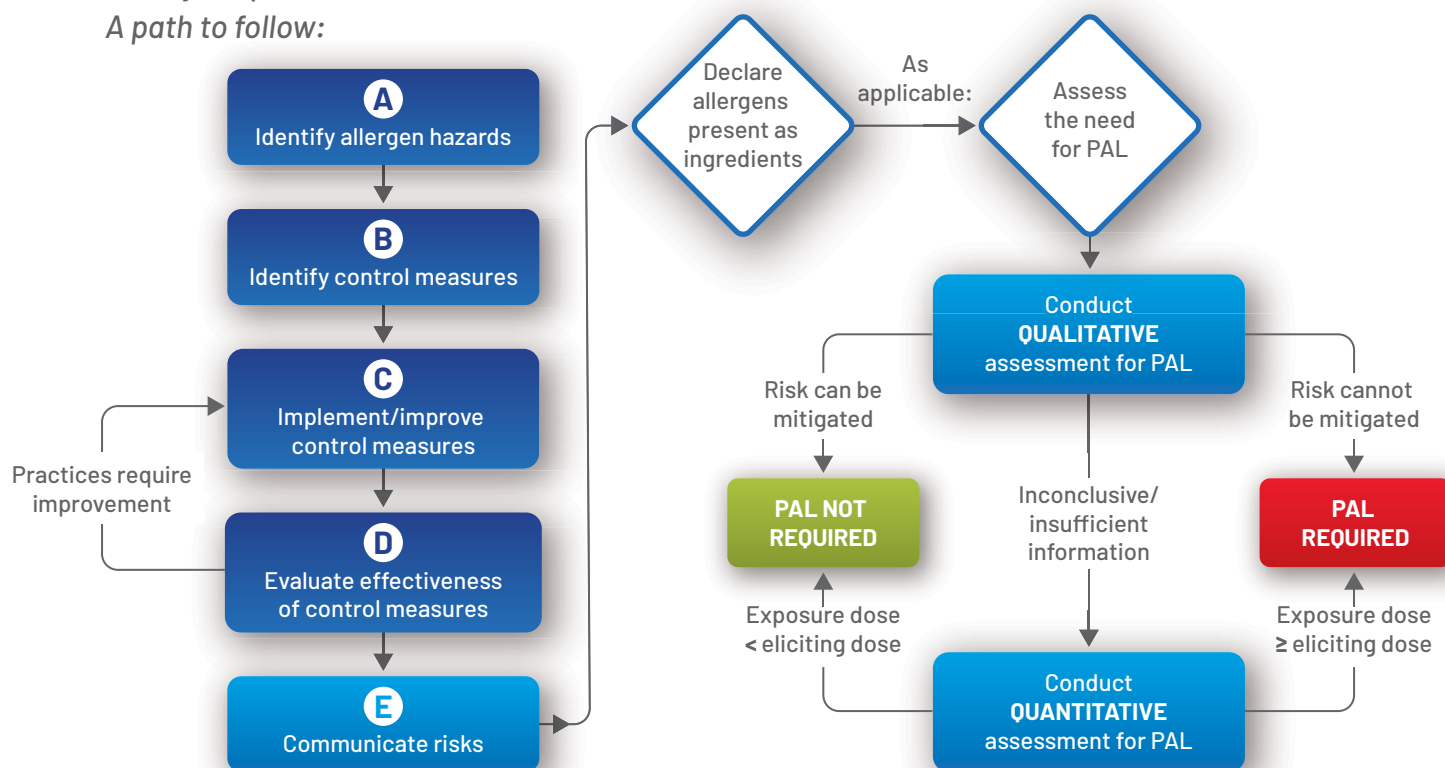
PAL must be consistently applied and based on sound risk assessment. Use PAL only when the following criteria

are met (adapted from the Grocery Manufacturers Association, 2009): (See *Guidelines page 50*)

- Where a food allergen in the manufacturing facility constitutes a risk of presence in products where such presence is unintended
- Where the risk of allergen presence of the food allergen in food products that are not intended to include the allergen cannot reasonably and feasibly be minimized without major revisions to manufacturing processes or equipment beyond GMPs
- Where the food allergen is likely to be present in some, but not all, of the food product where its presence is unintended
- Consuming the food allergen in a product where its presence is unintended would constitute a health risk to a consumer allergic to the allergen (as determined by a risk assessment).

Does your product need PAL?

A path to follow:



Review more detailed information on assessing the need for PAL (See *Guidelines page 49*)

ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

How to assess risk in a measurable way?

In this section, the importance of assessing and measuring the risk of unintentional allergen presence through qualitative and quantitative assessments will be discussed.

1 Qualitative assessment

A qualitative risk assessment is based on objective evidence that indicates the potential presence of unintentional allergens. This may provide sufficient information regarding the need for PAL. Such information would include the identification of where in the process allergen controls fail, combined with the evidence of such failure.

Consider the following factors:

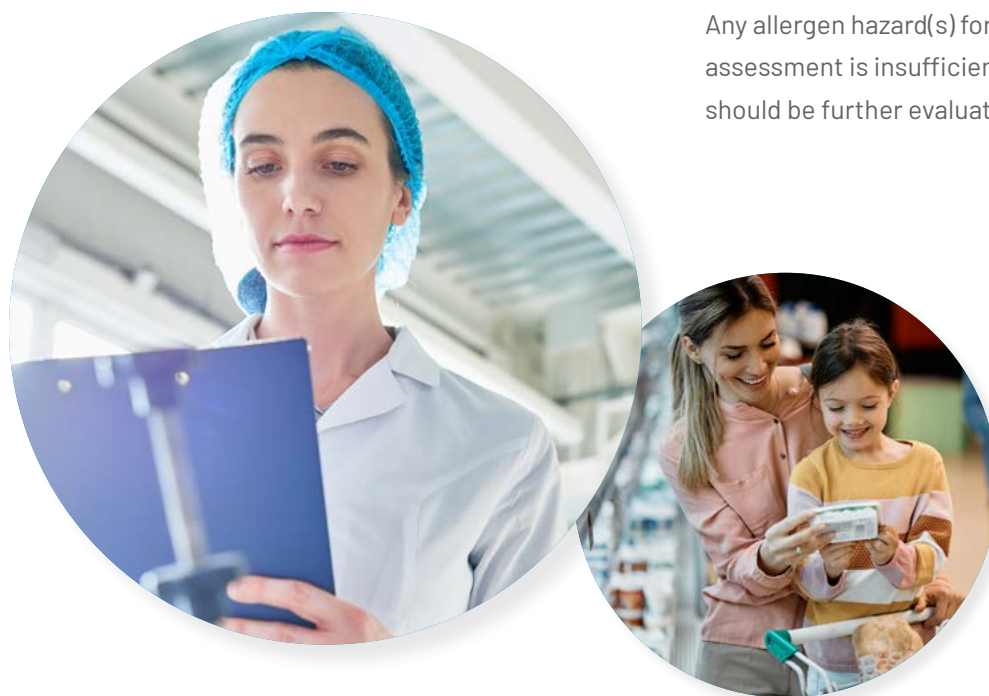
- **Raw Materials** (See Guidelines [page 51](#))
- **Receiving and Storage of Raw Materials** (See Guidelines [page 52](#))
- **Design of Premises and Equipment** (See Guidelines [page 52](#))
- **Production** (See Guidelines [page 52](#))
- **Cleaning** (See Guidelines [page 53](#))

This assessment will allow you to determine if:

- There is sufficient supporting evidence that the control measures in place can consistently prevent the occurrence of unintentional allergen(s)
– **PAL may not be considered necessary**
- There is sufficient supporting evidence that the control measures in place cannot consistently prevent the occurrence of unintentional allergen(s) despite all the measures in place to mitigate the risk
– **PAL is necessary**
- There is insufficient supporting evidence of the efficacy or inefficacy of the allergen control measures in place – **A quantitative assessment is required to reach PAL decisions**

Consider specific examples on how to conduct a qualitative risk assessment (See Guidelines [page 55](#))

Any allergen hazard(s) for which a qualitative assessment is insufficient to reach PAL decisions should be further evaluated using quantitative criteria.



ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

2 Quantitative assessment

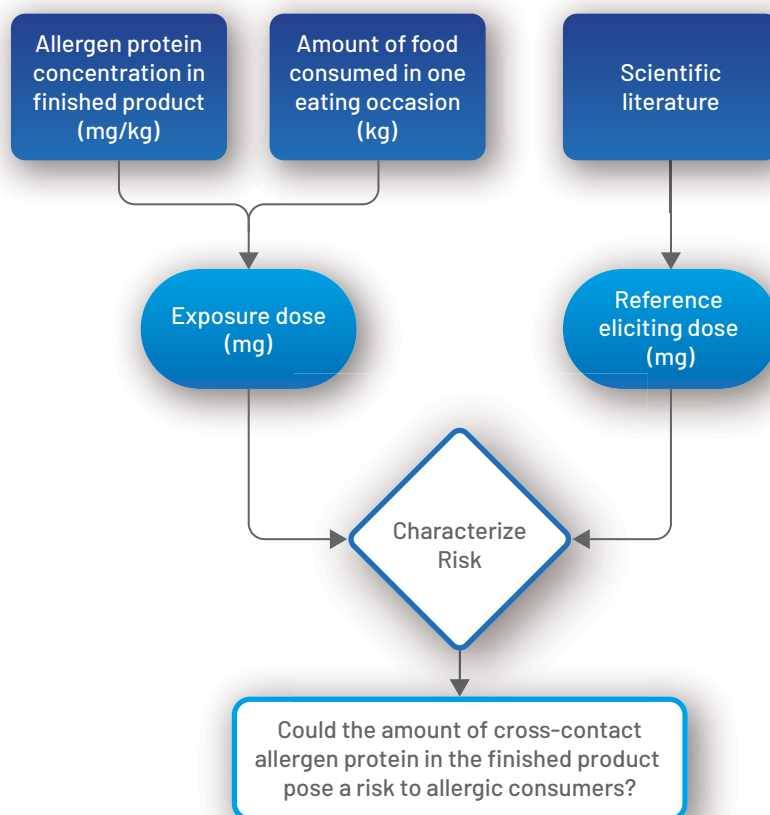
A quantitative allergen risk assessment considers the specific risk that an amount of unintended allergen poses to allergic consumers. An estimated allergen intake (or dose) consumed in a specific food product is compared to the dose predicted not to trigger an allergic reaction in most of the allergic population (called the eliciting dose). If the estimated exposure dose is higher than the eliciting dose, the food product may pose a risk to allergic consumers. (See [Guidelines page 61](#))

To conduct a quantitative allergen risk assessment in a food manufacturing context, the following values are needed: (See [Guidelines page 62](#))

- allergen protein concentration in the finished product (See [Guidelines page 63](#))
- amount of food consumed in one eating occasion (See [Guidelines page 69](#))
- exposure dose — determined from allergen protein concentration in the finished product and amount of food consumed in one eating occasion (See [Guidelines page 71](#))
- eliciting dose (See [Guidelines page 72](#))

Consider these specific examples on how to conduct a quantitative risk assessment (See [Guidelines page 66](#))

Conduct a quantitative allergen risk assessment:



ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

User guide

Additional resources

- **Allergen Hazard Identification Template** (See Guidelines [page 85](#))
- **Information from Suppliers Checklist** (See Guidelines [page 86](#))
- **Analytical Allergen Testing and Sampling** (See Guidelines [page 90](#))

Next steps

For more information on any recommendations provided in this User Guide, please consult the full guideline document – **Allergen Management Guidelines for Food Manufacturers**.



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