UNIVERSITÉ LAVAL

parera
Food Risk Analysis and Regulatory Excellence Platform

Food Allergy Canada

ALLERGEN MANAGEMENT GUIDELINES

FOR FOOD MANUFACTURERS

September 2022

Foreword
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Foreword

In Canada, there are over **3 million Canadians** who self-report a food allergy, and **1-in-2 households** are impacted. Since there is **no known cure** for this condition, at-risk individuals must rely on **avoidance of their allergen(s) to prevent reactions**. Given that allergic reactions pose a significant health risk, their prevention is increasingly attracting the attention of public health agencies, the clinical community, food regulators, the food industry and consumer organizations. **Support for people who live with food allergy** requires that this community has access to **accurate ingredient information and food labelling** that they can trust, as well as access to adequate food choices.

CANADIAN AGRICULTURAL PARTNERSHIP

Funded in part by the Government of Canada under the Canadian Agricultural Partnership's AgriAssurance Program, a federal, provincial, territorial initiative.

Canada

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Despite the progress that has been made, challenges remain especially when considering the following:

- Consumers managing food allergy are not overly confident in the accuracy of ingredient information on pre-packaged foods
- Because of the proliferation of *"may contain"* statements on food labels, consumers are questioning the relevance of those statements and they are attempting to make their own risk assessments to create more food options for themselves
- Inadequate or inaccurate labelling of food allergens and shortcomings in the management of allergenic ingredients by some food manufacturers contribute to the growing number of food recalls, both for imported and domestic products

Over the past 20 years, actions have been taken globally by numerous stakeholders to enhance the protection of consumers living with food allergy. These actions included food labelling measures targeting the improvement of ingredient declaration, with an emphasis on allergenic ingredients — in particular, ingredients that are deliberately added to food — pursuant to the international food labelling standard from the Codex Alimentarius Commission (CAC), (1999). Despite the issuing of several guidance documents by industry groups and science organizations regarding the management of allergen cross-contact — the adventitious

presence of low levels of allergens and the way in which these situations may lead to the use of Precautionary Allergen Labelling (PAL) — formal international guidance was still lacking until very recently. In 2020, the CAC adopted a new code of practice for the management of food allergens by food business operators and committed to new guidelines relying more heavily on risk assessments to guide food labelling decisions.

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In Canada, the Safe Food for Canadians Regulations of 2019, require that preventive controls be followed to manage allergens and to ensure accurate labelling. However, the use of PAL continues to be voluntary, and there is limited guidance available to the industry relating to its use. As a result, there continues to be an inconsistent application of allergen precautionary statements not always supported by a risk assessment. This contributes to confusing labelling practices for food allergic consumers and their families. Industry efforts to adopt a consistent food allergen management approach — with clear guidance on when and how to use and apply PAL — are challenged by the numerous international guidance documents that exist and by the difficulty in identifying these documents' relevance and suitability for Canadian manufacturers.

To address these challenges, a unique multi-stakeholder collaboration was initiated to engage representatives from the food industry, consumers, academia, healthcare, and government.

Through this collaboration, a specific sub-committee was created to work on the development of consensus-based industry guidance for allergen risk management and the use of PAL. Led by Food Allergy Canada, Université Laval's Food Risk Analysis and Regulatory Excellence Platform (PARERA), and Maple Leaf Foods, a broad representation from Canada's food manufacturing sector was brought together to spearhead this project. This group developed guidance materials to support manufacturers in the implementation of effective allergen control plans, including the responsible use of PAL, to better meet the needs of Canadians managing food allergy. The team also benefitted from the valuable input and review from Canadian allergists and international food allergy experts from the Food Allergy Research and Resource Program (FARRP), and the European branch of the International Life Sciences Institute (ILSI Europe).

The development of this guidance material truly is a collective initiative, supported by a drafting team of food manufacturers and reviewed by additional industry representatives and associations — acknowledged at the end of this document. It benefits from the review of the latest information and allergen guidelines issued by various organizations in Canada and globally (e.g. Canadian Food Inspection Agency, 2018a; Australian Food and Grocery Council & Allergen Bureau, 2019; Food Allergy Research & Resource Program & University of Nebraska Lincoln, n.d.; Food Standards Agency, 2006; FoodDrink Europe, 2022). By leveraging and incorporating this guidance and by drawing upon the expertise of each member of the drafting team to address food allergen management within their businesses, a core set of recommendations was developed. These recommendations aim to adapt the guidance to address the issues and challenges faced by Canadian producers and to put risk considerations at the forefront of the decision-making process, particularly as it relates to the possible reliance on PAL as part of the risk management process.

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As is the case with any document drafted by a team of multidisciplinary experts, this document represents the consensus of the collaborators and is a reflection of their collective knowledge and experience. Undoubtedly, this guidance material will continue to be updated and adapted to meet the needs of specific food production sectors, and to include developments in science and in food allergen risk assessment approaches. This will include the guidance expected from the FAO/WHO Expert Consultation on Risk Assessment of Food Allergens and other food allergen expert groups (i.e. ILSI Europe's Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment).

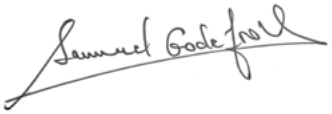
We would like to acknowledge the funding for this project has been provided through the *AgriAssurance Program* under the *Canadian Agricultural Partnership*, a federal-provincial-territorial initiative. This program aims to help industry develop and adopt systems, standards and tools to support health, safety and quality claims about Canadian agricultural and agri-food products. This work could not have been completed without the continued support received from Agriculture and Agri-Food Canada.

We believe that this guidance material will be useful and will facilitate progress on the prioritization of food safety in the food industry. We will continue our dialogue with key stakeholders on allergen management and a risk-based approach to precautionary allergen labelling. Our common goal is to create safe food options for Canadians with food allergy.

We welcome all input from our partners and stakeholders.

Sincerely,

Jennifer Gerdts
Executive Director, Food Allergy Canada



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Purpose and scope

This guidance document aims to provide food business operators with recommendations on food allergen management, based on international industry guidelines, scientific and expert community reports, and Canadian food manufacturers expertise. The recommendations in this document are presented as general best practice, and apply to prepackaged food processing operations — within all manufacturing sectors and business sizes — that manage any type of food allergens. They do not apply to the manufacturing of finished products with allergen-free or other related claims targeting specific population sectors. Food business operators are expected to adapt the general principles outlined in this guidance to their own operations and to identify any additional risks, if applicable.

Legal disclaimer

This document is intended as a general source of information for food processing and manufacturing companies in developing or reviewing their food safety plans with respect to allergen management, communication and labelling and is not intended for consumer use. The information in this document is not legal, medical or other professional advice. You must seek your own professional advice if you intend to use the information provided in this document, including to create, review or revise your allergen control plans.

While measures have been taken with respect to the accuracy of the information, the accuracy of the information presented is not guaranteed, and Food Allergy Canada and Université Laval will not be responsible in any manner for direct, indirect or special damages, loss, injury or death arising out of the use of this information in this document, whether in whole or in part.

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Food allergy in Canada

What is food allergy?

What is celiac disease?

Impact on daily life

Food allergy: a food safety priority

Food industry response – recognizing the need for change

Allergen recalls – costly for industry

Food allergy in Canada

Food allergy is a **serious medical condition** that affects individuals and families across the country. Over **3 million Canadians** self-report a food allergy, including more than **600,000 children**[1] and 50% of households make decisions on safe food choices on their behalf.[2] With **no cure**, and with the possibility that even a small amount of an ingested food allergen can lead to **anaphylaxis** – a severe allergic reaction that is potentially life threatening – at-risk individuals must be vigilant in avoiding their food allergen(s). These consumers, and those who purchase products on their behalf (family, friends, schools, daycares, etc.) depend on having access to complete, easy-to-understand, accurate **food labelling that they can trust**.

[1] Clarke et al., 2020
[2] Harrington et al., 2012

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What is food allergy?

Food allergy is a serious medical condition where the immune system mistakenly treats something in a particular food (most often the protein) as if it were dangerous. When that food (allergen) is ingested, the body reacts by having an allergic reaction – the most severe form being anaphylaxis.

Signs and symptoms of an allergic reaction to food can vary from person to person but generally, they can affect two or more of the following body systems: skin, respiratory, gastrointestinal and/or cardiovascular. Symptoms can include hives, nausea, abdominal pain, vomiting, difficulty breathing and a sudden drop in blood pressure. These symptoms can occur within minutes or hours following exposure. An epinephrine auto-injector (e.g. EpiPen®, ALLERJECT® and Emerade™) is the first-line treatment for anaphylaxis. Currently, there is no way to predict who is at greatest risk of anaphylaxis; therefore, individuals managing this condition, must be vigilant in avoiding their food allergen(s).

More than 170 foods have been identified as being potential triggers of an allergic reaction, however, only a minority of them account for most reactions.[3] In Canada, food accounts for 80% of all cases of anaphylaxis in children and 60% in adults.[4] Although any food can trigger an allergic reaction, the most common foods that cause anaphylaxis are peanuts, tree nuts, shellfish, fish, cow's milk and eggs.

A food allergy differs from a food intolerance in that an intolerance does not involve the immune system – it typically involves the digestive system causing an individual to experience difficulty digesting a particular food (e.g. lactose) leading to discomfort, but it is not life threatening. Consumers managing food intolerances, like those with food allergy, depend on having clear and accurate ingredient information to ensure they can make safe, informed choices.

[3] Burks et al., 2012
[4] Asai et al., 2014

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What is celiac disease?

Celiac disease is a disorder of the immune system that is triggered by eating gluten, a protein found in wheat, barley, rye and triticale.

This disease causes damage to the small intestine and interferes with the absorption of nutrients from food. Undiagnosed or untreated, it can lead to other serious, long-term health conditions. Having access to clear, accurate labelling is important for individuals living with celiac disease so they can avoid products containing gluten. It is important to note that celiac disease is not the same as a wheat allergy and consumers with this allergy must be extra vigilant when purchasing products with 'gluten-free' claims as those products may not be safe for them. Health Canada has specific regulations for the labelling of 'gluten-free' products, with an established threshold of 20 ppm, unlike 'free-from' claims for food allergens, which are not currently specifically regulated by Health Canada and do not have established allergen thresholds.

For more information on labelling for gluten-free products, visit Health Canada.

For consumer resources, visit the Canadian Celiac Association and Cœliaque Québec.

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Impact on daily life

Food allergy, in any range of severity, impacts an individual's quality of life.[5] Eating can be complicated for individuals with food allergy as they must navigate the complexities of making safe food choices daily. They must fully understand what ingredients the food contains — reading labels and asking questions of those who prepare the food — to make safe and informed choices. These consumers rely on the accuracy of labels on prepackaged foods. Fortunately, identifying priority allergens in these foods has been made easier thanks to the updated Enhanced Allergen Labelling Regulations of 2011, requiring that these allergens be listed in plain, simple language.[6]

Despite this progress, however, a recent survey of Canadian consumers managing food allergy indicates that only 2 out of 10 feel very confident about the accuracy of the ingredient information provided, with more than 50% indicating that they have had to contact manufacturers to have them clarify ingredient information (Food Allergy Canada, Consumer Survey 2022 – in preparation). One particular labelling issue which poses a significant challenge to consumers is the lack of clarity on **Precautionary Allergen Labelling (PAL)** or *"may contain"* statements. With the significant proliferation of PAL statements over the past decade, consumers with food allergy have fewer safe food options.

They must attempt to assess the risks of consuming products with PAL statements — with more than 50% of them choosing to purchase products with PAL for their allergen(s) (Food Allergy Canada, Consumer Survey 2022 – in preparation). Recent studies have also shown that in some cases where PAL is used, there is no detectable level of the allergen, while in others, the amount of an allergen found was at levels that exceeded incidental cross-contact.[7] Based on these findings, some consumers may be unnecessarily limiting food choices while others may take risks that could lead to potentially harmful consequences.

Overall, consumers support the use of PAL but indicate that it is not specific enough, and some consider it to be a legal statement designed to protect manufacturers more than consumers. There is significant confusion around the use of PAL, which highlights the need to build confidence and trust in manufacturers' allergen management practices and food ingredient statements. The *"may contain"* statement must be more meaningful to allow increased safe food options for consumers.

[5] Turner et al., 2016
[6] Health Canada, 2021a
[7] Manny, La Vieille, Barrere, Théolier, et al., 2021; Manny, La Vieille, Barrere, Théolier, et al., 2021; Touma et al., 2021

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	Scenarios for the presence or absence of PAL	
	Product without PAL	**Product with PAL**
Helpful to allergic consumers	**1. Product without PAL with low or no risk of inducing an allergic reaction, i.e. is safe.** • Proper risk assessment by the food manufacturer. • Conclusion that the allergen is not present in the product at a level that is likely to cause an allergic reaction.	**2. Product with PAL with a real risk of inducing an allergic reaction, i.e. unsafe to consume.** • Proper risk assessment by the food manufacturer. • Conclusion that the allergen may be present in the product despite allergen management and GMP (good manufacturing practice).
Not helpful to allergic consumers	**3. Product without PAL with unknown risk of inducing an allergic reaction, i.e. may be safe or unsafe to consume.** • No proper risk assessment by food manufacturer resulting in possible allergen presence without being mentioned on the label. • No conclusion can be drawn about the presence of the allergen.	**4a. Product with PAL with unknown risk of inducing an allergic reaction, i.e. may be safe or unsafe to consume** • No proper risk assessment and allergen management to reduce the risk of unintended presence by manufacturer • No conclusion can be drawn about the presence of the allergen **4b. Product with PAL with unquantifiable, possibly high risk of inducing an allergic reaction.** • Risk assessment by manufacturer for some but not all allergens • Misleading PAL: incomplete list of allergens in the PAL statement/ some allergens are present but not mentioned on the label. • No conclusion can be drawn about the presence of the allergens not mentioned. **5. Product with PAL with low or no risk of inducing an allergic reaction** • Proper risk assessment by manufacturer • Decision to use PAL nevertheless by risk-adverse manufacturer

Source: DunnGalvin et al., 2015

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Food allergy: a food safety priority

Managing allergens within the food industry is a food safety priority, not a means to achieve a competitive advantage in the marketplace. Having robust and effective food allergen management is essential for all food operators and an important foundation for establishing consumer trust in food labelling. This requirement is reinforced within the current regulatory environment. Considered to be a chemical hazard, allergens must be effectively managed through the manufacturing process. As such, the Safe Food for Canadians Act requires that preventive controls be put in place to manage allergens and ensure that they do not appear in products in which they are not intended. However, even with these requirements in place, a gap still exists in relation to the use of PAL which is not addressed by the current food allergen labelling regulations.

Food industry response – recognizing the need for change

Many in the food industry recognize the need for effective allergen management to help mitigate risks to consumers — in the same way they manage other food safety hazards — and have integrated its management into their overall food safety program. However, without defined industry or government guidance, each manufacturer is left to determine their own best practices. As a result of these varying approaches to managing allergen risk, for some manufacturers, allergen risk management can be overwhelming and further complicated by the lack of guidance and absence of specific regulations on the use of PAL — beyond the requirement in subsection 5(1) of the Food and Drugs Act for information to be "truthful and not misleading".[8] These circumstances have led to the permissive overuse of PAL, impacting the overall marketplace by making *"may contain"* confusing for consumers and challenging to manage for the food industry.

[8] Food and Drugs Act, 1985

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Allergen recalls – costly for industry

Allergen recalls – costly for industry

In Canada, since 1999, when an allergen or gluten source is detected in a food product and it is not indicated on the label, it is subject to investigation, including a risk assessment by Health Canada. A food recall is issued when the food item is deemed to represent a health risk to consumers. Since 2017, undeclared food allergens have been the main cause of food recalls in Canada, representing more than 30% of the total number of recalls per year (Table 1). The most frequently affected food categories are bakery products, ready-to-eat meals, confectionery products (including chocolate), and salty or other snacks (crackers, sauces, baking mixes, etc.). Beyond the significant financial losses caused by these recalls, affected food manufacturers have often seen brand reputation negatively impacted over the long term and in some cases, even permanently. It is therefore important to recognize that, while establishing an allergen risk management approach may seem complicated, it can be very costly not to have one in place or to manage one improperly.

Table 1: Annual number of food recalls and food recalls due to undeclared allergens in Canada (2017 – 2021)

Year	Total number of food recalls	Food recalls due to undeclared allergens
2021	256	93 (36%)
2020	229	85 (37%)
2019	360	125 (35%)
2018	300	103 (34%)
2017	350	136 (39%)

Source: CFIA Food recall warnings and allergy alerts (Canadian Food Inspection Agency, 2019b).

Regulatory framework

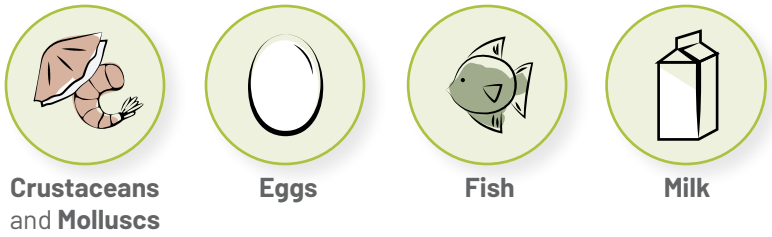
Priority food allergens in Canada

Precautionary Allergen Labelling (PAL)

Regulatory framework

Priority allergens were added to the Canada Food and Drug Regulations in 1999, under the authority of the Food and Drugs Act.[1] The original list of priority allergens (eggs, milk, peanuts, crustaceans and molluscs, fish, sesame seeds, soy, tree nuts, wheat and triticale, and sulphites) was expanded in 2011 to include mustard. Currently, Canadian authorities require identification of priority allergens, added sulphites and gluten sources on labels of prepacked food products sold in Canada.

The priority food allergens in Canada[2] are:



Crustaceans and **Molluscs**

Eggs

Fish

Milk

Mustard

Peanuts

Sesame

Soy

Sulphites (food additive)

Wheat and **Triticale**

Tree Nuts*

*(almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts and walnuts)

The gluten sources are:

Barley

Oats

Rye

Triticale

Wheat

[1] Food and Drug Regulations, 2022; Food and Drugs Act, 1985
[2] Food and Drug Regulations, 2022

Regulatory framework

Priority food allergens in Canada

Precautionary Allergen Labelling (PAL)

The Canada Food and Drug Regulations (Section B.01.010.1) require that if any of these allergens, sulphites and/or gluten sources are present in a prepackaged food product as an ingredient or as part of an ingredient, this presence shall be identified on the product label.[3] A food manufacturer that fails to declare the presence of priority allergens, sulphites* and/or gluten sources on the label of a prepackaged food product is in violation of Canadian food legislation.

The requirement for priority food allergens and gluten declarations apply to all generations of ingredients (i.e. ingredients of ingredients or subcomponents).[4] For example, allergens present in the third or fourth generation of ingredients must be declared in the list of ingredients on the product label or in a "contains" statement immediately following the list of ingredients.

* For sulphites, the manufacturer must declare the presence of added sulphites if the final concentration in the food as sold is equal to or exceeds 10 mg/kg.

[3] Food and Drug Regulations, 2022
[4] Canadian Food Inspection Agency, 2021b

Note:
Ingredients that are derived from a food allergen, but which have been processed in a way that removes the protein are not themselves considered to be food allergens. Certain highly refined oils (like most soybean or fish oils) derived from priority allergen sources contain levels of protein that are too low to pose a health risk, and are therefore exempt from enhanced allergen labelling regulations.[5] There is a separate regulation that requires peanut oil to always be declared even if it is highly refined.[5]

[5] Health Canada, 2013b

The list of priority allergens is not the same in all countries. These lists, including the Canadian list, are regularly reviewed by authorities and are subject to modification. Food exporters should be aware of, and comply with, allergen declaration requirements of the importing countries.

Regulatory framework

Priority food allergens in Canada

Precautionary Allergen Labelling (PAL)

Precautionary Allergen Labelling (PAL)

PAL is often used by food manufacturers to indicate the potential presence of unintentional allergens that are not part of the product's recipe. In Canada, PAL is not mandated but may be used by food manufacturers on a voluntary basis.[6]

Health Canada has recommended that only one statement be used by manufacturers – *"May contain"* – if used on a pre-packaged food product.[6] Guidance on labelling requirements and manner of declaration (e.g. placement, font, size, colour) was developed by CFIA and is accessible to food business operators (FBOs).[7]

PAL statements are to be used only when — after implementing all reasonable measures to limit or eliminate sources of unintentional allergen presence — the allergen may still be found in the final product in an amount representing risk to the allergic consumer. PAL statements, if used, are required by Health Canada to be truthful, clear and non-ambiguous, and are not a substitute for Good Manufacturing Practices.

[6] Canadian Food Inspection Agency, 2019c
[7] Canadian Food Inspection Agency, 2018b

In addition, the Food and Drugs Act and the Safe Food for Canadians Act prohibit labelling food in a manner that is misleading or deceptive; this prohibition applies to all food labels, including voluntary label elements, and the use of PAL can be questioned by the CFIA.[8]

[8] Canadian Food Inspection Agency, 2019a

Allergen management in the food industry

Allergen control plans explained

- A. Identify allergen hazards
- B. Identify allergen control measures
- C. Implement / improve control measures
- D. Evaluate effectiveness of control measures
- E. Communicate risks

Qualitative assessment

Examples of qualitative assessment for PAL

Quantitative assessment

- A. Allergen protein concentration in the finished product
- B. Amount of food consumed in one eating occasion
- C. Exposure dose
- D. Eliciting dose (ED)
- E. Risk characterization

Examples of quantitative assessment for PAL

Allergen management in the food industry

Allergens, considered to be a chemical hazard, must be **effectively managed** through the manufacturing process to ensure that they **do not appear in products** in which they are not intended. Allergens should be included as **chemical hazards** in the facility's Hazard Analysis Critical Control Point (HACCP) plan. Allergen control measures should be **implemented**, **monitored** and **documented** as part of the facility's HACCP plan requirements.

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Examples of quantitative assessment for PAL

The Safe Food for Canadians Regulations (SFCR) require food manufacturers to implement preventive controls to manage hazards in foods.[1] The CFIA has developed guidance to help food manufacturers comply with this requirement through the development and implementation of Preventive Control Plans (PCPs).[2] The Food Safety Enhancement Program is one example of a type of PCP, based on the **Hazard Analysis Critical Control Point (HACCP)** principles.[3] HACCP aims to identify hazards in a food manufacturing operation and to establish how they will be prevented or minimized.

[1] Safe Food for Canadians Regulations, 2018
[2] Canadian Food Inspection Agency, 2021a
[3] Canadian Food Inspection Agency, 2021c

To enhance allergen management, it is recommended that all food manufacturers develop an allergen-specific preventive control plan, commonly referred to as an **Allergen Control Plan (ACP)**. An **ACP** outlines a food manufacturing facility's strategy to prevent or minimize the risk of introducing unintended allergens to a product, including how specific measures are to be implemented and monitored, and how their effectiveness is to be determined. An ACP answers "where?", "when?" and "who?" types of questions for every allergen management element covered. General guidance on preventive controls for food allergens, gluten and added sulphites has been developed by the CFIA and is available to FBOs.[4]

Specific control measures targeting allergens should complement — or be incorporated within — the food safety and quality systems and procedures already in place at the facility. Control measures are usually outlined in **Pre-Requisite Programs (PRPs)** or procedures describing the operational requirements in a manufacturing facility, which provide the basis for the safe production of food. Properly documented, implemented, and maintained PRPs provide the foundations for effective preventive control programs.

[4] Canadian Food Inspection Agency, 2018a

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Quantitative assessment

A. Allergen protein concentration in the finished product

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C. Exposure dose

D. Eliciting dose (ED)

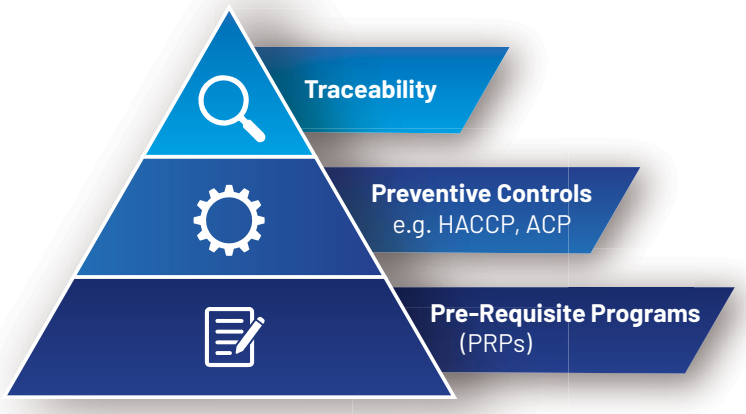
E. Risk characterization

Examples of quantitative assessment for PAL

Examples of PRPs, where allergen control measures could be incorporated, include **but are not limited to**:

- Good manufacturing practices (GMPs)
- Premises
- Equipment and utensils
- Transportation, receiving, storage and handling
- Personnel
- Cleaning/sanitation
- Pest control
- Operational PRPs

Figure 1: Example of the pyramidal structure for a food safety and quality management system:



While the specific strategies that each manufacturer selects to manage allergens may differ, a common structured approach to develop an ACP will make the process more efficient and consistent. Allergen management practices, when adapted to their specific operations, will allow food manufacturers to:

- Identify allergen hazards in their raw materials, ingredients, facility and in their finished products
- Assess the risk these hazards pose to allergic consumers (e.g. identify which hazards represent a higher/lower risk)
- Develop risk mitigation strategies for allergen hazards specific to their operations and finished products, and proportional to the level of risk they pose
- Justify allergen labelling decisions (e.g. use of PAL)
- Optimize risk communication with consumers (i.e. develop accurate, meaningful, and evidence-based risk communication strategies)
- Create a body of evidence on allergen management practices, supporting the requirements of quality certifications and regulatory inspections/investigations
- Enhance allergen recall, incident and/or deviation management procedures

Allergen management in the food industry

Allergen control plans explained

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- B. Identify allergen control measures
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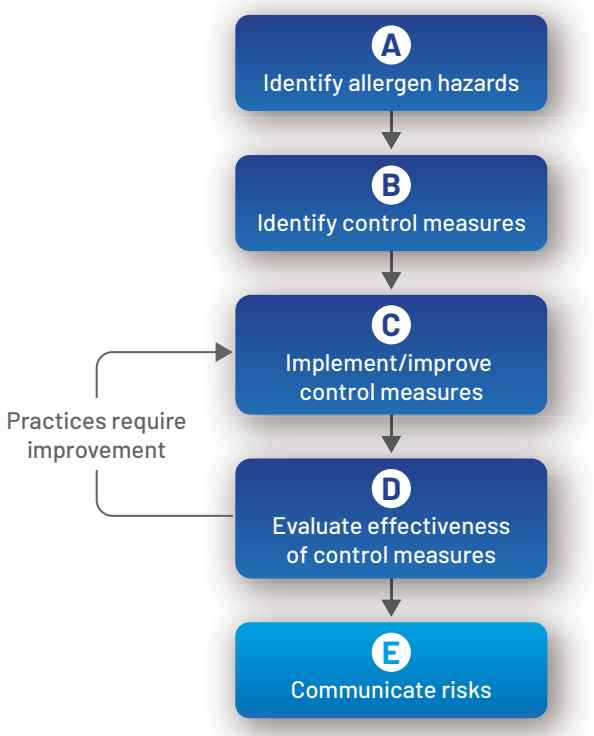
Examples of quantitative assessment for PAL

The structured approach to defining and implementing an ACP consists of the high-level steps represented in the process map in Figure 2 below:

Figure 2: Process map of an Allergen Control Plan:



Allergen control plans explained

A Identify allergen hazards

For complex food manufacturing operations, where several ingredients and manufacturing steps are involved, allergen hazard identification may be a time-consuming process requiring significant resources. Regardless of the level of complexity or size of the manufacturing operation, a systematic approach is necessary. It involves identifying all allergens that enter the facility, allergens added through raw materials or their components to the finished product, and allergens that may be unintentionally introduced into each finished product during receiving, handling, storage and processing.

The outputs of hazard identification should include, as a minimum, a facility allergen master list, and the following for each finished product:

- allergens intentionally added from raw materials
- unintentional allergens confirmed as potentially present in raw materials
- allergens potentially present from cross-contact during receiving, handling, storage and processing

Examples of hazard identification templates are provided in Annex 1.

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Quantitative assessment

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The facility's allergen master list must be updated when new ingredients (from existing or new suppliers) or new suppliers (of existing or new ingredients) are added. It is also important to verify if the information on the allergen master list remains accurate and updated during scheduled reviews of the facility's ACP at the frequency linked to the PCP.

Steps to identify allergen hazards:

1 Identify all allergens that enter the facility

- Conduct a thorough review of the specifications and/or information sheets of all raw materials used in the facility, such as ingredients (single and composite), processing aids, packaging materials and cleaning products. If the information provided in the specifications is incomplete or unclear, contact the supplier directly for clarification. To simplify the process in the future, it is important that this information be communicated through the company's Supplier Management Program. All raw materials and ingredients that are confirmed to be a source of allergen(s) are to be identified in a facility allergen master list alongside the supplier of each material.
- Request that suppliers indicate the source of any unintentional allergen presence in their raw materials (e.g. via cross-contact during their operation, via received materials earlier in their own supply chain), supported by evidence as to why the presence of unintentional allergen is being identified. Where possible, any such presence should be quantified (e.g. % or ppm of allergenic food, ppm of allergen protein) based on best-available validated methodologies.

Further considerations:

- Suppliers outside Canada may have different practices and be unaware of Canada's priority allergens. In different regions, priority allergens may differ from those declared in Canada (e.g., lupin is a priority allergen in Europe but not in Canada, mustard is a priority allergen in Canada but not in the United States), or there may be a lack of necessary allergen awareness and/or regulatory oversight to prevent unlabelled allergens or allergen cross contamination. It is critical to properly assess allergen contamination risks, ensure that foreign suppliers are aware of Canadian priority allergens (e.g. by including country-specific allergen requirements in the supplier agreement) and confirm that any presence or likelihood of presence are identified and declared with the documents that accompany the supplied raw materials (e.g. include the source of maltodextrin when originating from wheat).
- Be aware of unexpected allergens in foods

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- Commingled grains: post-harvest processes (e.g. cleaning, sorting, milling) may reduce the presence of commingled grains, but do not generally remove all traces.[5] For agricultural commodities (e.g. grains), allergens may be introduced as early as production in the fields and typical post-harvest practices. Any of these may result in commingling, including but not limited to:
  - crops grown adjacently
  - crops harvested with shared equipment
  - crops stored in the same containers or structures

Supplier agreements should outline the type of information to be requested with every shipment of the agricultural commodity. It is important to understand the likelihood of any unintentional allergen presence through typical agricultural practices and to consider the possibility during the risk assessment process. Additional information on allergen cross-contact due to agricultural commingling practices can be found at Allergen Bureau, 2021.

[5] Allergen Bureau, 2021

Note:

Allergens may be found in virtually any raw material. Consider unexpected allergens as part of the product development or innovation process. The following are some examples of possible sources that may not be clearly recognizable:

- in compound food ingredients that include allergenic sub-ingredients (e.g. spice mix containing mustard flour)
- in food additives (e.g. colour microencapsulated in fish-derived capsules or wheat-based anti-caking agents)
- in processing aids (e.g. release oil spray containing unrefined soy lecithin)
- in packaging materials (e.g. films coated with wheat starch, wheat-based biodegradable packaging, casein-based edible films)

Further examples of unexpected allergens in foods can be found at the Allergen Bureau's Unexpected Allergens in Food and information on component ingredient exemptions from Health Canada are listed at Manner of Declaring Ingredients & Food Allergens.[6]

[6] Allergen Bureau, 2021; Canadian Food Inspection Agency, 2021b

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Additionally, Health Canada has provided guidance regarding the presence of soy and wheat in cereal grains, and of mustard/canola in wheat that may be useful references to further understand the issues associated with commingling of grains:

- Important Information for Canadians with Wheat Allergies[7]
- Information for Canadians with Soy Allergy[7]
- Information for Canadians with Mustard Allergy[8]

[7] Health Canada, 2013a
[8] Health Canada, 2019

2 Identify all allergens that are directly added to each finished product from all raw materials

List all allergen inputs stemming from raw materials (including ingredients and processing aids) or a food contact material (if packaging).

Note:
To reduce the potential introduction of unintended allergens to a formula, use **the identical allergen profiles of all raw materials approved for use in that formula**. For example, a cheese powder ingredient that contains only milk allergen and that is used in a formula that only includes milk allergen, must not be substituted with a cheese powder that also contains egg. While the product prepared with the substitute cheese powder might look the same and taste the same as with another cheese powder, a new allergen is introduced with the egg component. This contradicts the objectives of avoiding any use of unnecessary allergens and reducing the complexity of allergen control. Moreover, consistency in product composition and labelling should be the priority to ensure the safety of all consumers.

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3 Identify all allergens that may be indirectly added to each finished product as unintentional components of raw materials

While allergens present in raw materials and directly added to the product are easily identified, some raw materials may also carry precautionary allergen labelling if there is a potential for unintentional allergen(s). For example, an ingredient supplier's label may include a precautionary allergen statement, or a supplier's accompanying documentation (ingredient specification) may include a list of allergens used in the same supplier production line. Identify these cases, noting how the unintentional allergens are declared by the supplier (e.g. PAL on a supplier's label, or mention of supplier processing conditions in accompanying documentation).

To further support the hazard identification process, it is beneficial to understand the supplier's HACCP plan and their manufacturing process of the ingredient relative to allergen hazards, and to understand the rationale and basis for the supplier's inclusion of a PAL statement.

4 Identify all allergens that may be unintentionally introduced into each finished product during receiving, handling, storage, and processing

Unintentional introduction of allergens that are not part of a finished product's recipe should be eliminated or mitigated through allergen controls. Key strategies used to manage this type of risk are:

- the thorough knowledge of the manufacturing operation
- the identification of critical control points targeting prevention of allergen cross-contact in the HACCP plan(s)
- the implementation of a robust ACP

When sporadic cross contact may still occur despite the most rigorous application of these strategies, the impact of the presence of such an unintentional allergen must be assessed.

Identification of instances that may lead to unintentional allergen presence in a food manufacturing operation can be achieved through a cross-contact assessment — a process that requires significant effort to identify potential risks and mitigation steps. With the assistance of a cross-functional team — ideally the facility allergen management team — conduct a review of the production floor plans and simulate the entire process flow (from raw material receiving to finished product release and transportation) to identify and track steps that could lead to unintentional allergen presence. This part of the assessment is known as "allergen mapping" and is specific to each facility. Figure 3 on the next page is an example of a factory map exercise from Allergen Bureau.[9]

[9] Allergen Bureau, n.d.

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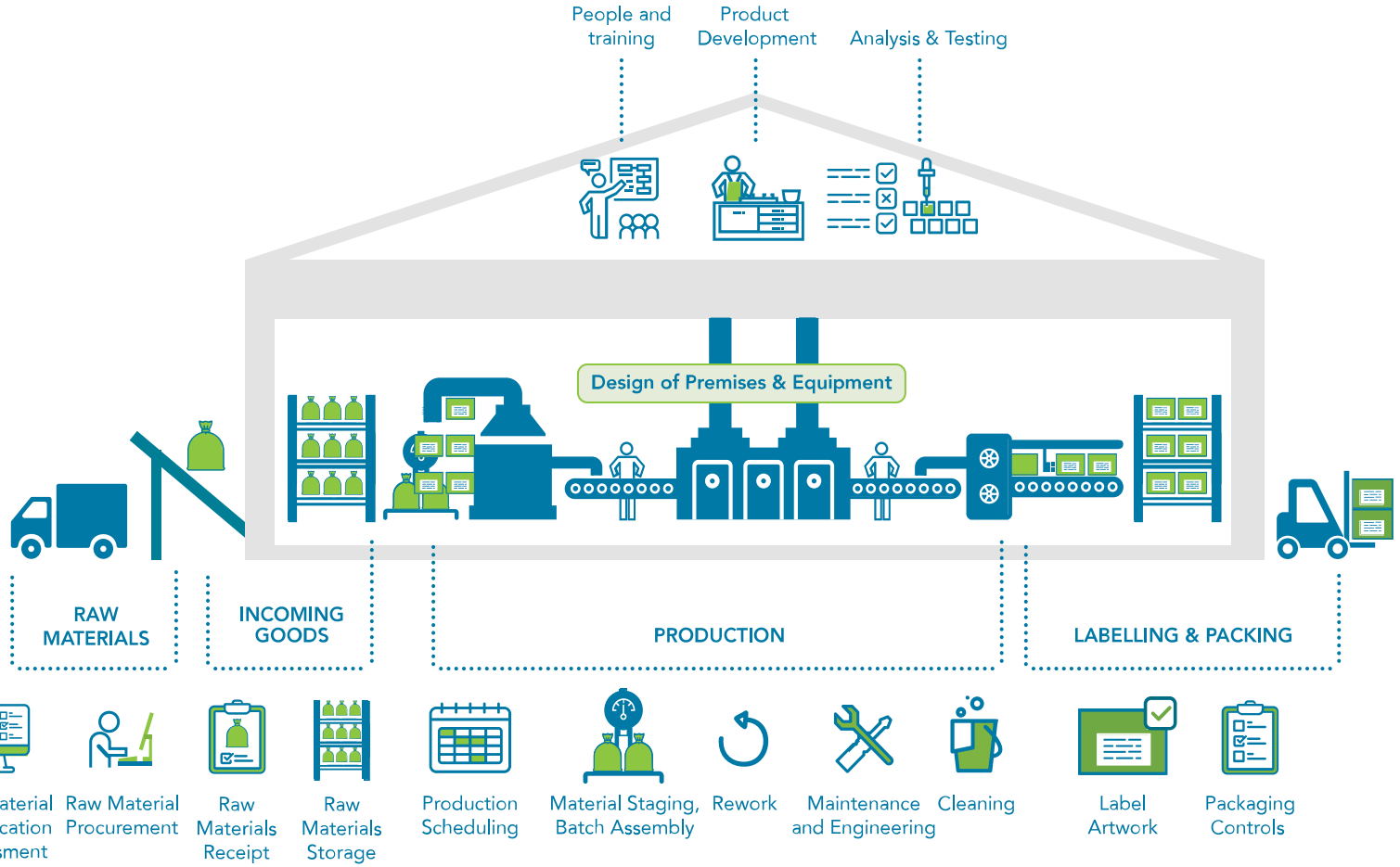
Figure 3: Example of a Factory Map from Allergen Bureau:



Source: Allergen Bureau, n.d.

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Table 2 provides examples of factors to consider when identifying allergen hazards that may be unintentionally introduced into finished products as a result of cross-contact within the facility.

Table 2: Identification of cross-contact allergen hazards within the manufacturing facility

People	
Employees or visitors that may act as sources of allergen cross-contact (e.g. employees who work in multiple areas with unique allergens during a shift, maintenance personnel who are not assigned to specific processes)	
Operations	
Receiving and storage	Errors in the identification (e.g. verification of allergen information upon receipt, colour coding) and/or segregation of allergenic raw materials
Raw materials handling and staging	Errors/mishandling when: • Selecting ingredients and/or packaging for a recipe • Handling of open packages of raw materials containing allergens • Weighing/mixing raw materials containing allergens • Staging multiple packaging items for more efficient changeovers close to the production line (i.e. risk of selecting an incorrect package)
Scheduling	• Allergen and allergen-free productions that occur at the same time in adjacent lines, or in the same line at different times • Sudden changes to the scheduling sequence for rushed orders
In-process	• Lack of segregation (e.g. crossover points, lines in close proximity) • Reusing ingredients that may have been in contact with allergens (e.g. cooking oil) • Improper identification or placement of rework containing allergens • Storing and reusing rework containing allergens throughout the process • Traffic patterns that may cross areas where allergens are processed and areas where they are not
Cleaning	• Cleaning procedures that may spread allergens (e.g. pressurized air) • Equipment or lines that are not easily accessible for cleaning or inspection or that contain "dead" spots where allergens can accumulate • Improper validation of the cleaning procedure
Non-food materials	
• Non-food materials that may act as sources of allergen cross-contact (e.g. carts, pallets, boxes, utensils, maintenance tools, surfaces, equipment)	
Environment	
• Lack of separate air handling systems and or barriers in areas where the process involves dust/airborne particulate • Air flow patterns that may introduce or spread allergens, if the level of airborne allergens may present a risk (e.g. if length of product exposure results in significant transfer)	

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The facility allergen management team can then walk the production lines — under all production settings and scheduling combinations — to validate any previously identified instances that may result in allergen cross-contact, and actively try to identify new occurrences. Consider the use of a schematic plan or floor map with allergen risks identified to help verify the actual process.

It is important to encourage feedback from line employees and be open to their recommendations as they are often the most familiar with actual practices on the production floor. This direct interaction with employees provides important insight into their level of understanding and commitment to allergen management.

This process can confirm the effectiveness of the ACP and will often identify practices that can be improved upon, modified or readily incorporated to enhance allergen control. Upon completion, update the ACP accordingly.

Document the results of the cross-contact assessment, including implementation of ACP updates.

B Identify allergen control measures

This step includes an overall assessment of the food manufacturing process and aims to identify risks associated with the possible introduction of an allergen hazard, at any point of the food production. Where required, this preliminary assessment will support the enhancement of existing preventive control measures and risk mitigation strategies to address any additional risks. The need for reliance on a precautionary allergen statement on food labels may require further assessment by conducting a qualitative or quantitative risk assessment to address additional risks due to the unintentional presence of allergens.

Additional or enhanced allergen control measures, identified after a thorough review of the manufacturing process, will take into consideration the following factors:

- Amount of allergen protein in a given amount of allergenic material
- Allergen's 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, carry-over, accumulation in equipment)
- Cross-contact distribution in the food (e.g. in clusters, homogeneous)

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Although a comprehensive allergen management approach encompassing the entire manufacturing operation is always necessary (i.e. an ACP), an understanding of the nature of the unintentional allergen risk informs the identification of critical control measures (i.e. critical control points in a HACCP plan). The identified risk mitigation strategies are then implemented as part of the PCPs and/or ACP.

The following simplified examples illustrate how various factors can be considered to assess the risks associated with allergens in food processing, which will inform the need for additional allergen-related risk mitigation strategies, to strengthen the preventive control plan:

- A Food Business Operator (FBO) processes cold-pressed soybean oil (liquid, low level of allergenic proteins) before a product (in a paste form) that does not contain soy as an ingredient. It is possible that a small amount of oil would be transferred to the following product. If cross-contamination occurs, it is expected to be homogeneously distributed. The FBO evaluates the production process and identifies critical risk mitigation strategies, either modifying the production schedule to ensure that soybean oil is not processed prior to products without soy, or implementing a cleaning process to eliminate or reduce the amount of soy residues to a level that does not pose a risk to consumers.

Consider these factors in an integrated manner when assessing allergen risk.

*For example, a cross-contact allergen in a powder form (e.g. **wheat flour**) is likely to be homogeneously distributed in a food matrix if introduced at a mixing step, whereas a particulate (e.g. a hazelnut piece) would not. The particulate would only contaminate a small percentage of units, however, the affected units would contain a higher level of allergen. The powder may contaminate an entire batch but at a relatively low proportion. Also, allergen dust or powder that can be suspended in the air may spread throughout a large processing area, however, the actual transfer to products may be minimal and require evaluation to determine if it represents a risk to allergic consumers.*

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- A FBO purchases liquid BBQ flavours from three different suppliers. The flavours are very similar in name and appearance, but they each have a slightly different allergen profile. The BBQ flavours are used in different finished products, each with different allergen declarations. It is possible that the BBQ flavours may be incorrectly identified upon receiving, during storage or during staging. If this type of error occurs, the final product would carry an inaccurate allergen declaration. The FBO determines that raw material receiving and storage procedures, and staging procedures are critical to properly identify the allergen hazards, prevent cross-contact and prevent mislabelling. Control measures may include verification that the company's system highlights the different versions of the BBQ flavours, by:
  - assigning a different code to each and properly listing the allergens present
  - verifying that current raw material receiving and storage procedures prevent misidentification
  - enhancing the existing staging procedures for recipes that use these BBQ flavours (e.g. adding details on the corresponding BBQ flavour code, location in the storage room, external and internal packaging appearance).

- A small baker manufactures a product containing wheat flour adjacent to (i.e. in an adjacent line) and simultaneously with a product that does not contain wheat flour as an ingredient. Production scheduling or equipment location cannot be altered at this time. It is clear that when flour is added during the mixing step, flour particles are suspended in the air. Flour dust may reach the adjacent line and may contaminate the product. The FBO has not determined whether the contamination level would pose a risk to allergic consumers but will apply mitigation measures to prevent the risk. The most important strategy to limit this cross-contact event is segregation before, during and after flour is processed. Procedures for transporting the flour from the storage to the production areas will include direction on how to prevent flour powder/dust release in other areas. Mechanical measures (e.g. separation barriers, air flow control) will be implemented in the production. Wet cleaning will be applied at the end of production. Control of personnel traffic and having dedicated staff working on the allergen line will also be implemented.

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C Implement / improve control measures

The purpose of managing allergens is to avoid or eliminate their unintentional presence in products, and to ensure products are appropriately labelled. This section provides general guidance on the elements that need to be addressed in an ACP, and further developed by the manufacturer to reflect the needs of their operation.

The recommendations provided in this document are aligned with those currently proposed by the CFIA and Codex Alimentarius Commission for FBOs,[10] as well as with industry best practices (e.g. (Australian Food and Grocery Council & Allergen Bureau, 2019; Food Allergy Research & Resource Program & University of Nebraska Lincoln, n.d.; Food Standards Agency, 2006; FoodDrink Europe, 2022).

[10] (Canadian Food Inspection Agency, 2018a, Codex Alimentarius, 2020)

1 Human resources

Allergen management must be seen as a priority for all staff. The employees' role in allergen management is critical to the success of any allergen control program. Employees from all departments and functions (e.g. those who buy ingredients, engage with suppliers through research & development, develop products, engage with consumers through response lines) must understand why an ACP is necessary and why specific control measures are being implemented. Allergen control measures often represent additional work for employees (e.g. increased document and procedure verification activities, increased restrictions when handling allergens, additional coding systems), and without their commitment and agreement on the importance of these measures, adherence may be challenging.

i Management commitment

The implication and commitment of the organization's senior management team — not only of the employees directly working with allergens — is essential to set a positive example and to demonstrate the importance of an ACP as a priority for their business. Active participation of management representatives in key roles (e.g. as members of the allergen management team) and activities (e.g. awareness activities) is needed to ensure the success of an ACP. In addition, the senior management team's commitment to securing financial resources and funding costs related to allergen management programs is essential.

ii Allergen management team

Allergen management in a food manufacturing facility, led by a dedicated, cross-functional team is critical for success. This team includes upper management representatives as well as members of the food quality and safety, production, research & development, purchasing, and marketing departments. In smaller or less complex facilities, a smaller team may suffice.

The team oversees the development of the ACP and its implementation, and conducts audits, reviews and updates, as needed. Each team member brings their expertise which allows them to become fully engaged in the ACP development process and to take ownership for the plan from the initial stages.

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A high level of engagement from each team member is key to the development and successful implementation of the ACP.

(iii) Training

Schedule training for all facility employees, including top management, on food allergens and allergen management in food manufacturing. The scope and level of detail of the allergen training provided will depend on the employee's role in the organization. At a minimum, this training should include:

- Basic food allergen concepts (e.g. what is food allergy and why is it important?)
- Priority allergens
- Health consequences of allergic reactions
- Implications for consumers and food manufacturers
- Allergens used in the facility
- Regulatory framework
- Labelling requirements
- Cross contact as a source of unintentional allergens
- Allergen risk analysis

Basic food allergen training will help raise employees' understanding of:

- the risks allergens pose to allergic consumers
- how these risks can impact the organization
- factory-wide allergen control measures (e.g. colour coding, traffic flow, GMPs targeting allergens)

Function-specific food allergen training will address:

- how certain roles or tasks fit within the facility's allergen management strategy
- which risks to prevent or minimize by each role
- procedures for implementing tasks correctly
- procedures for managing deviations

Employees are encouraged to report incidents that may compromise allergen control (e.g. potential undeclared allergens, labelling errors) and take action.

The content, dates and attendance of each training session must be documented and kept on file. Conduct allergen training with all new hires, annually as a refresher, and after any significant changes in the operation or process/policy related to allergens.

Inform ALL visitors and service providers of the facility's ACP, with an emphasis on measures related to allergen management (i.e. consequences of introduction of allergens in the facility, cross contact prevention).

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2 Supply Chain

i Understanding allergen risks in the supply chain

To understand and control the allergens that enter a food manufacturing facility, the capacity to trace back raw materials is essential. Given the complexity of modern food supply chains, it is optimal to trace raw materials not only one step back but as far back as possible (e.g. primary production). Understanding where and when an allergen enters the food supply chain provides valuable information for risk assessment.

Food manufacturers must also have the means to trace their finished products within their operation (including work-in-process and rework), and forward up to the consumer.

In the context of allergen management and considering the acute nature of allergic reactions, having the ability to recall non-compliant products as quickly and efficiently as possible can help to prevent serious public health events. Therefore, the entire supply chain, not only the steps immediately before or after food manufacturing, must be considered for effective allergen management.

If applicable, incorporate raw material and finished product allergen information into digital end-to-end supply chain processes (procurement, inventory management, production, distribution, audits, etc.).

ii Suppliers (including suppliers of ingredients, packaging materials and processing aids)

- Establish requirements for the review and approval of raw materials and the suppliers — considering the robustness of their allergen control measures including, as a minimum:
  - Active ACP
  - Trace-back / Trace-forward capabilities
  - Allergen information (normally provided with raw materials supplied)
  - Knowledge of allergen sources (intentional and unintentional) in the raw materials supplied
  - Compliance history
- Conduct a thorough audit of potential new suppliers' allergen management programs, ideally including documentation and on-site reviews
  - If the company's policy is to conduct global supplier audits, incorporating all their food safety programs, include a dedicated section on allergen management

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- Conduct regular audits of approved suppliers' allergen management programs (e.g. once yearly or whenever any significant changes to the operation occur)
  - Establish a procedure for suppliers to communicate any change to their process that may affect the allergens present in the raw materials supplied, as soon as it occurs. For example, establish a company ingredient specification that is signed by the supplier, and include a section in the ingredient specification that any allergen changes made by the supplier must be communicated.
- Establish allergen information requirements to be provided with every shipment of raw materials supplied, including:
  - Raw material traceability information (name, code, production date, quantity supplied, carrier, etc.)
- Establish allergen information requirements to be provided when approving raw materials, and to be updated periodically, including:
  - Allergens intentionally added (directly, or as subcomponents of ingredients) and their proportion of the total weight/volume, and/or a specific concentration in the supplied raw material
  - Unintentional allergens and their source (e.g. cross-contact during manufacturing, carry forward from ingredients). Whenever possible, provide a range of unintentional allergen concentration.
  - Allergens (intentionally or unintentionally added) physical form: liquid, powder, particulates, paste, etc.
  - Any additional information regarding allergens used in the supplier's manufacturing facility, allergens processed in the same production line as the raw material supplied, validate allergen clean procedure (if applicable), etc.
- Include requirements in supplier contracts and internal receiving procedures that any raw materials with new or changed or unexpected allergen profiles will not be accepted

Note:
Require commodity ingredient suppliers (e.g. grains, seeds, pulses) to provide information on potential agricultural commingling during primary production and post-harvest (e.g. crops grown in the same field, harvested with shared equipment, transported in the same trucks, stored in the same facilities). In a situation where information on the possible agricultural commingling is provided by suppliers, the supplier must implement and document mitigation measures in an effort to limit the occurrence of allergen cross-contact during these steps. This information gathering by the ingredient supplier is encouraged to limit the prevalence of PAL in agricultural commodities only in instances where unintentional allergen presence cannot be avoided, as opposed to implementing the use of PAL by default.

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Note:
Examples of questions to consider when developing an allergen information form for suppliers are provided in Annex 2. Additional guidance on how to obtain the required information from suppliers may be found at Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment, 2022.

iii Transportation

Despite the complexity or simplicity of the distribution channel, and the level of reliance on technology, fully document the carrier's activity for all materials (e.g. type of material transported in previous load, cleaning dates). Records should be completed consistently and made available to facilitate traceability and incident management. This data includes but is not limited to:

- Types of foods/materials transported
- Segregation procedures
- Cleaning procedures and wash records
- Incident reports (to be completed and transmitted to all involved parties without delay)

For allergen management, it is important to ensure that the selected Carrier has received allergen training and has procedures in place to prevent allergen cross-contact. For example:

- Proper identification and segregation
- Include food safety and allergen training requirements for Carriers in the supplier expectation manual
- Add training requirements in the Carrier's contract or the third- or fourth-party logistics contract

iv Recall plan

All food manufacturers are expected to have a Recall Plan in place to remove non-compliant products rapidly and efficiently from the market (Canadian Food Inspection Agency, 2018c). The evaluation of the facility's Recall Plan should include mock recall exercises. A facility's recall plan should consider including food allergy consumer groups and other organizations representing vulnerable populations within their Recall Plan Notifications List to ensure concerned individuals are warned as quickly as possible (e.g. Food Allergy Canada, Allergy Quebec, Canadian Celiac Association; Coeliaque Québec)

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3 Purchasing

Purchasing (or sourcing & procurement) is one of the first steps in a food manufacturing operation that would allow or prevent the entrance of allergens into the facility. When purchasing raw materials (including ingredients, packaging materials and processing aids), it is critical to:

- Be aware of the allergens being used in the manufacturing facility
- Be aware of the allergens in the product(s) where each raw material will be used
- Understand the information provided by suppliers related to allergens and request clarification as needed
- Always request up-to-date allergen information from suppliers
- Establish fluid communication with suppliers and require immediate notification of any changes in the allergen profile of the raw materials supplied. Substitutions must not be accepted without previous written agreement and review
- Maintain a clear register of raw materials sourced, their allergen profiles and approved suppliers
- Maintain efficient communication channels with the research & development team and other internal stakeholders

In addition, purchasing of cleaning products may also be relevant for allergen management. Specifically, any procurement changes related to products or suppliers of products used in allergen cleaning procedures must be first validated with the relevant parties (e.g. Quality Assurance, Sanitation).

4 Product development and reformulation

Although the use of allergens or ingredients containing allergens in food products is not discouraged, food manufacturers need to understand that their use requires special considerations.

Development of new products that include introducing new allergens (not previously present in the facility) requires adjustments to the manufacturing operation. Certain adjustments would be required as early as the plant trial stages of product development. In addition, reformulation of existing products to include new allergens – or to remove existing allergens from the formulation – would require a reassessment of risk communication strategies (e.g. label update, development of digital communication strategies, involvement of consumer groups). This reassessment also applies for any samples used internally or in consumer trials.

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When allergens in raw ingredients do not play an important functional role, consider choosing existing ingredients within the facility that do not contain allergens or select new ingredients without allergens.

Research & development teams need to:

- Include an allergen profile as part of the new product development cycle to ensure changes are flagged, communicated and that the systems are updated
- Consider that different allergen profiles for similar products within the same brand portfolio may cause confusion for consumers (e.g. Company A Caesar salad dressing contains milk, but Company A Caesar light salad dressing does not contain milk)
- Be aware of potential sources of unintentional allergen cross-contact (e.g. through the manufacturing process, in raw materials, packaging materials, in processing aids) and how these may impact labelling
- Consider the implications of introducing ingredients that have a known cross-reactivity potential to priority allergens (e.g. highly refined concentrated plant-based ingredients, like pea or other legumes)
- Understand the allergen labelling requirements in the markets where the finished products will be commercialized

5 Raw materials receiving and storage

The most effective allergen risk management strategy to be applied during raw materials receiving and storage is **identification and segregation** (physical or in time). Within these categories, consider specific measures that include the following:

- Establish receiving procedures that minimize cross-contact (e.g. schedule the receiving of allergenic materials after the receiving of non-allergenic materials)
- Inspect the shipment before unloading from the carrier truck and identify any potential allergen cross-contact
- Verify the integrity of incoming packages
- Verify that the allergen declarations on the label of incoming materials match those in the specification sheet and reject non-compliant materials
- Verify allergen claim supporting documentation (e.g. allergen-free, gluten-free), when applicable
- Identify and code received raw materials that contain allergens according to the facility's procedures
- If necessary, establish a routine allergen testing program for incoming raw materials. Determine testing frequency and scope based on risk assessment. For example, annual sampling of ingredients ranked as "high risk" (per FBO's assessment), sampling of next incoming unused lot of ingredients involved in industry recalls related to allergen cross-contact.

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- Apply segregation when storing raw materials containing allergens
  - Do not store raw materials containing allergen(s) above or next to raw materials that do not contain the allergen(s)
  - Organize the storage area(s) such that employees do not need to cross from areas containing allergen-containing areas to areas that do not contain allergenic raw materials
  - Clearly identify shelves or areas dedicated to specific allergens (e.g. colour coding)
  - Keep raw materials packages and containers closed at all times during storage

6 Process design

Identification and segregation (physical or in time) strategies are also the basis of allergen risk management when designing a food production process. Depending on the process characteristics, specific measures may include the following:

- Using clearly identified dedicated lines, if feasible, to process products not containing allergens
- Minimizing the amount of allergen changeovers
- Scheduling production runs such that allergens are processed on separate dates or areas, or after products that do not contain allergens. If not feasible, schedule a full allergen clean following the processing of a product containing allergens on a given line. Clearly identify production runs that include allergenic raw materials on the schedule.
- Avoiding crossover points between allergen-containing lines and lines that do not contain allergens (e.g. conveyors transporting ingredients / products containing allergens running above production lines that do not contain these allergens)
- Using physical barriers to limit the area where allergens are present (e.g. doors to limit employee access to areas where allergens are being processed and to keep allergens within this area, panels between adjacent production lines where allergens are and are not being processed)
- Controlling the airflow to ensure that allergens that may be transported in the air (e.g. light flakes, flour) do not spread throughout the facility
- Establishing traffic flow patterns (in space and time) to avoid unintentional introduction of allergens via employees and vehicles (e.g. carts, trolleys, forklifts)
- Installing hygiene control stations (e.g. hand-washing stations, change stations for disposable gowns) as needed at the entrance and/or exit of areas where allergens are handled

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7 In-process

i Personnel working with allergens:

- Receive thorough function-specific allergen training
- Be identified during production (e.g. colour-coded coats)
- Limit their movements to the pre-established traffic patterns (e.g. assign dedicated employees to one process/area during a shift and avoid moving from allergenic lines to non-allergenic lines during the same production shift)
- Have access to the required supplies to adequately fulfill their tasks and avoid cross-contact (e.g. dedicated coats, head and foot covers, gloves, dedicated tools, supplies for identification of allergenic raw materials and equipment)
- Have access to allergen-related information directly on the production floor (e.g. production schedule, allergen factsheet, diagrams or photos of allergen control measures, allergen colour code sheet)
- When temporary or permanent role changes occur, require staff to review the new role's procedures before starting the role
- Avoid last-minute replacements or schedule changes

ii Staging

- Follow recipe verification protocols in detail
- Use clearly identified (e.g. colour-coded) dedicated equipment and tools to weigh, prepare and transport allergen-containing ingredients. If not feasible, apply allergen cleaning procedures to remove allergens after each use
- Handle open containers of allergenic ingredients with care to avoid spills, spread and cross-contact
- Keep containers of allergenic ingredients closed and tightly sealed when transported within the facility
- Label allergen-containing ingredients that have been weighed and prepared in advance of production (e.g. spice blends containing mustard) to ensure the presence of an allergen is clear until use

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iii Changeover

Changeover refers to the change between processing or packaging one food product, to processing or packaging a different food product. For example, when moving from a wheat allergen product to a product containing dairy.

- Outline changeover practices for each processing line in a dedicated standard operating procedure, including but not limited to:
  - removal of ingredients, products and packaging from the previous run (e.g. line clearance procedure)
  - cleaning procedures
  - verification that the correct ingredients and packaging are selected for this run
  - label verification
- Establish a program for new equipment to ensure proper access for cleaning and inspection prior to purchasing and installation
- Document all changeover procedures
- For operations where products containing allergens are run in the same line/equipment as products not containing allergens (or different allergens), follow changeover verification procedures in detail and regard as a critical control point
- Validate the changeover program at a determined frequency

Note:
Refer also to Section 11: Cleaning for additional information

iv Rework and work-in-process:

- Properly identify, noting all allergens present
- Handle and store following allergen risk management measures in place (e.g. colour-coded containers, tightly sealed, stored in segregated areas)
- Use only in batches of the same product (like-into-like)
- Trace their reuse or incorporation into other products

v Other considerations

- Assess all cooking media (e.g. frying oil) and other food-based materials directly in contact with a product containing allergens for suitability for re-use and designate accordingly (e.g. similar product use or discarded after use)

8 Maintenance

Prevent allergen cross-contact through maintenance personnel, tools and materials (e.g. lubricants, grease):

- Establish traffic flow patterns for maintenance activities
- Implement cleaning procedures for maintenance equipment and tools that are effective at removing food allergens
- Use maintenance materials (e.g. lubricants, shop soaps/ cleansers) that are free of allergens

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9 Labelling

Because allergic consumers rely on avoidance as a primary strategy to prevent adverse reactions, any failure to accurately declare allergens, whether intentionally added or unintentionally via cross-contact, represents a serious risk to their health. Furthermore, allergen labelling is regulated and enforced in Canada.[11]

Labelling errors can occur during the actual labelling step (i.e. when the right label is used but the information on the label is incorrect, or when the incorrect label is applied to a finished product). Labelling errors may originate during the following:

- early product or label design stages
- label printing
- receiving, storage, movement, or staging of packaging material
- improper 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
- when an incorrect ingredient is received

[11] Food and Drug Regulations, 2022

It is therefore critical to systematically review the entire label process flow, identifying practices or steps that, if not tightly controlled, can lead to labelling errors, and include a label verification control point.

The identification of potential labelling errors is specific to the manufacturing process being assessed. Generic examples of steps that may require special attention are presented in Table 3.

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Table 3: Prevention of labelling errors – examples*

Packaging material supplier

- Pre-printing label verification and approval by the food manufacturer
- Supplier's label production and packaging procedures address prevention of mixing errors (e.g. different labels not packed in the same case)

Regulatory / Quality assurance

- Verification of accuracy of allergen declaration and allergen-free claims
- Consistent information on front panel graphics and ingredient panel on reverse of product
- Graphic emphasis when new allergens are added to existing products, and when new products with allergens are added to existing product lines that did not previously contain these allergens
- Approval of label design and control of label information by Research & Development and Regulatory Affairs (i.e. lock out unauthorized changes to maintain integrity of label information)
- Verification of translation accuracy (e.g. English/French)

Product development

- Access to accurate and up-to-date allergen information from raw material suppliers
- Awareness of allergen declaration requirements in target market(s)
- Development of accurate allergen declarations
- Identification of new allergens added to existing products, and new products with allergens added to existing product lines that did not previously contain these allergens

Operations

- Establish a change management process for new and updated labels
- Verification of raw materials' allergen information upon receipt
- Handling of packaging material during receiving, storage and staging
- Clearance of labels in equipment from prior runs
- Incorporate technologies (e.g. digital scanning tools) to reduce occurrence of incorrect label and undeclared allergens
- Control parameters (e.g. temperature, type of label) that could impact legibility/readability of scanning capability
- Use of rework containing allergens
- Verification of finished products' inner and outer packaging accuracy (e.g. visual checks)
- Handling and storage of leftover packaging materials after production
- Disposal of inaccurate/obsolete labels

*The tasks listed in this table may be assigned to different functions/roles depending on the company's organizational structure

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Document the results of this process for each finished product:

- noting all processing steps or practices that may lead to labelling errors
- identifying the specific allergens concerned
- outlining the control measures in place

10 Other communication channels

Changes affecting the food product's label must also be reflected in other communication channels to avoid any inconsistencies that may confuse consumers. Consumer response lines, whether outsourced or in-house, must be kept up to date of any changes and know how (and to whom) to pass on inquiries. Other communication channels that require alignment with information provided on the product's label may include:

i E-commerce

While the food supply chain has grown in complexity in recent decades, simplified channels have also emerged. Notably, e-commerce — the buying and selling of products through online platforms (e.g. retailers' websites, social media, e-commerce applications) — has experienced significant growth.

Note:

"A transaction via e-commerce is the sale or purchase of prepackaged foods, conducted over computer networks, through web, extranet or electronic data interchange, by methods specifically designed for the purpose of receiving or placing of orders. The prepackaged foods are ordered by those methods, but the payment and the ultimate delivery of the food does not have to be conducted online."[12]

[12] Codex Alimentarius, 2021

In Canada, the same health and safety requirements apply to food products manufactured for online sales and those sold in retail stores. However, from a labelling perspective, there is currently a gap in terms of what manufacturers must provide at the point of sale for products sold online versus what is on the physical label of a pre-packaged food product.

It is essential that manufacturers and their online retailers always provide full and accurate ingredient information, including any allergen declarations and PAL, on the e-commerce platform along with the product's sales information. It is essential that consumers have all ingredient information at the point of sale to ensure they can make a safe, informed choice and do not purchase products that contain or may contain their allergen(s).

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ii Digital communication channels

Digital communication channels (e.g. websites, social media, applications, blogs managed by food manufacturers or consumer groups) are important marketing and information channels. It is critical that the information from these sources aligns with the product label (i.e. indicate any allergens in the products or the potential for unintentional allergen presence, claims involving allergens or gluten). Digital channels may be used by food manufacturers as part of a comprehensive risk communication strategy, for example to communicate changes in the allergen risk associated with their products (e.g. addition of new allergens to an existing product, extensions of an existing line of products but with new allergens).

Digital platforms may offer a solution to maintain information related to label variants resulting from changes in its formulation and make it accessible to consumers. Information about the various label variants associated with the relevant lot numbers must be maintained at least throughout the shelf life of the product and made accessible to consumers through such digital solutions.

iii Machine-readable optical labels

Machine-readable optical labels (e.g. barcodes, QR codes) may be used by FBOs to convey information to consumers, for example, by directing them to online resources related to their products. Machine-readable optical labels may be applied on a food product's primary, secondary and/or tertiary packaging. Manufacturers must ensure that optical labels direct consumers to the most up-to-date version of the shared resource, and that the information transmitted, including allergen information, is accurate and aligned with the product label.

iv Engagement with consumer associations

Reaching consumers who are directly impacted by allergen labelling issues or changes is important. Working with consumer associations to communicate ingredient changes, allergen alerts or recalls can be an effective method to be included as part of an overall risk communication plan.

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11 Cleaning

It is necessary for food manufacturers to develop and validate cleaning procedures targeting the removal/reduction of allergen residues that are specific to their operations. When designing an allergen clean procedure, the nature of the food residue, the characteristics of the equipment and food contact surfaces, and the type of cleaning (e.g. dry cleaning, wet cleaning) 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 any other materials exposed to allergens, as applicable.

Cleaning is a facility-specific process. Consider the following measures when designing a cleaning procedure:

- Establish a visually clean standard that is validated
- Consider using allergen swabs or kits to verify an effective cleaning
- Identify ingredients or products that are more difficult to clean or that require a unique step to avoid cross contact
- Identify high-risk areas that are commonly missed during cleaning or inspecting
- Validate the cleaning procedure at a determined frequency using ingredients or product mix that are more difficult to clean
- Disassemble equipment when possible, for more effective cleaning. If not feasible, this should be considered when assessing cross-contact allergen risks
- Include a documented cleaning verification step in the changeover procedures
- Prevent the spread of allergen residues during cleaning (i.e. wet cleaning should avoid using high-pressure water hoses, dry cleaning should avoid using compressed air)
- Conduct analytical testing for cleaning validation and/or verification purposes (e.g. detection and/or quantification of allergen residues on surfaces, product hang-up, CIP rinse solution, "push-through" material, finished product). This is not, however, a replacement for a visually clean standard or the adherence to a validated cleaning method. Analytical surface and wash samples are good indicators of cleaning efficiency but are not necessarily indicators of risk to an allergic consumer. **When deemed appropriate**, conduct analytical testing using *"fit-for-purpose"* tests (i.e. appropriate to the allergen, food matrix, and limit of detection required), combined with an adequate sampling plan (Annex 3). Seek technical advice (e.g. kit manufacturer) when selecting analytical methods for allergen testing. Validate optimal method(s) for each food product, manufacturing process and cleaning procedure under evaluation.

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Note:

Cleaning **validation** is the process of assuring that a cleaning procedure is effective at removing or reducing a specific allergen residue to a specified level considered acceptable to control allergen risk. "The validation process should be specific to the allergen, process and product matrix combination."[13]

Cleaning **verification** is the ongoing process demonstrating that previously validated cleaning procedures are effectively carried out each time. "Cleaning processes should be verified through visual observation and, where feasible and appropriate, through an analytical testing program."[13]

More information on food allergen cleaning validation and verification may be found at NEOGEN & Food Allergy Research & Resource Program, 2016.

[13] Codex Alimentarius, 2020

12 Deviation management

A facility's ACP must include procedures on how to address deviations (e.g. failures of specific allergen control measures, handling of products unintentionally contaminated with allergens not included in the recipe).

Implement and document corrective and preventive actions as part of this process.

Conduct a root-cause analysis to assess where and why control was lost, and how to prevent this type of incident from occurring in the future. An example of an Allergen Incident Form may be found at Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment, 2022.

13 Record keeping

Most food manufacturers maintain records documenting how foods and raw materials are handled in their operations to (a) demonstrate that their products are safe and comply with regulations and (b) to facilitate traceability. Both elements are critical for allergen management. For example, records demonstrating that allergen control measures were correctly implemented are essential for establishing the level of control achieved. Documentation provided by suppliers may be considered as supporting evidence for risk assessment and for certain control measures. Traceability-related records are also critical for tracking products affected by recalls. Therefore, a strong record keeping culture is necessary to support allergen management.

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D Evaluate effectiveness of control measures

In addition to monitoring activities, regularly evaluate the facility's ACP to confirm it continues to be effective at controlling allergen hazards. At a minimum, schedule an annual review or audit (e.g. as part of the annual HACCP validation).

Re-evaluate the ACP outside of scheduled review when there are changes for example:

- Before any changes are implemented in the operation (e.g. changes in the process / facility / equipment design, changes in standard operating procedures)
- When new allergens are or may be introduced (e.g. new raw materials, new suppliers, new finished product recipes, changes in handling practices)
- When its efficacy is questioned (e.g. reports of allergic reactions, recalls, unsatisfactory external audits)

Include the following elements in the ACP's evaluation:

- Direct observation of in-plant practices
- Assessment of control measures in place
- Review of records and supporting documentation
- Trends of deviations and similar root causes

Outline which measures are in place to control which hazards, how they are to be implemented, and official records (signed and dated) demonstrating that these control measures were carried out as part of the ACP documentation.

Supporting documentation may include risk assessments, validation of cleaning procedures, supplier letters of guarantee regarding the allergen status of raw materials, training records, and testing results.

Audit and assess the entirety of this body of evidence during the ACP's evaluation, and document this complete audit and assessment.

If deficiencies in current practices are noted, control measures must be updated and documented in a revised version of the ACP.

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E Communicate risks

Allergens that are part of a finished product's recipe must be declared as ingredients. Risks that cannot be avoided (i.e. allergens present, allergens that may be present) must be communicated to consumers to allow them to make informed and safe choices. Risks must also be accurately communicated to other manufacturers and clients (e.g. foodservice, caterers), if applicable, to make them aware of the allergens entering their facilities. Accurate business-to-business communication is essential to ensure information can reach the final consumer.

1 Required labelling

The food product label is the most important means of communicating allergen risk to consumers. In Canada, regulations regarding the declaration of intentional allergen presence are standardized and require consistency across the food supply to ensure consumer understanding. For instance, priority allergens added as ingredients (e.g. "peanuts") or as part of an ingredient (e.g. "peanut butter [peanuts, vegetable oil, salt]) must be identified on the label of the prepacked food product in the ingredient list or in the "Contains" statement, if one is used (e.g. Contains: peanut). If a "Contains" statement is used, it must include all priority allergens even if they are already included in the list of ingredients.[14]

[14] Food and Drug Regulations, 2022

2 Assessing the need for PAL

Allergens that are part of a finished product's recipe must be declared as ingredients. Any of the same allergens unintentionally present (in raw materials, or from cross-contact during receiving, handling, storage and processing), and that are not subject to exemptions, need no further assessment for PAL as their presence is already declared. For example, a cookie batch may unintentionally contain milk from a product previously run in the same line; however, if milk is already part of the cookie's recipe, it will be declared on the label as an ingredient, and no further assessment of the unintentional milk presence would be required.

Communicating the risk of **unintentional allergen** presence through PAL is not specifically regulated. This is a regulatory gap which presents a challenge to both food manufacturers and consumers. PAL remains a valuable tool to communicate the risk of unintentional allergen presence, but PAL must be consistently applied and be based on sound risk assessment to be meaningful to allergic consumers. Allergic consumers need to be able to rely on product labels to understand which carry a real risk of allergen cross contact.

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Note:
PAL should be a clear statement with a single meaning that is easy to translate into other languages when/where necessary. The only precautionary statement recommended by Health Canada and the CFIA is *"may contain [X]"*, where X is the name by which the allergen is commonly known (Health Canada, 2012). All other qualifying statements (e.g. "made in a facility which also handles peanuts", or *"[X] may be present"*) are strongly discouraged by the regulators, as they do not provide relevant information to allergic consumers and their caregivers regarding the safety and suitability of the product.

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 (as determined by a risk assessment).

PAL is not a substitute for GMPs,[15] and the use of PAL does not eliminate the need to apply and follow GMPs, allergen preventive controls and any other measures used to mitigate allergen cross contact.[16]

[15] Health Canada, 2012
[16] Canadian Food Inspection Agency, 2018a

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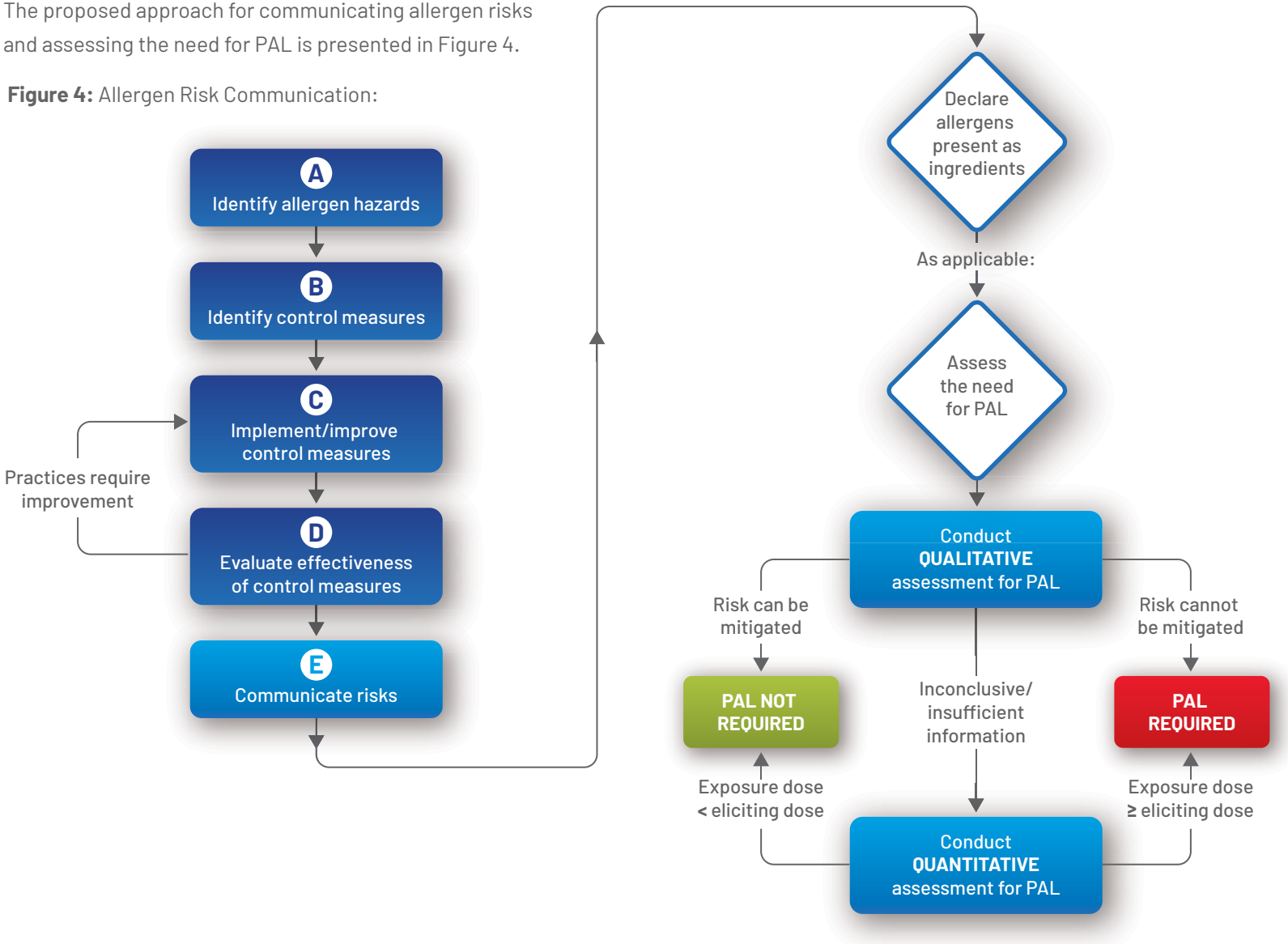
The proposed approach for communicating allergen risks and assessing the need for PAL is presented in Figure 4.

Figure 4: Allergen Risk Communication:



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- B. Amount of food consumed in one eating occasion
- C. Exposure dose
- D. Eliciting dose (ED)
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Examples of quantitative assessment for PAL

As described in Figure 4, base the decision to use or not use PAL on a risk assessment (quantitative or qualitative) and ensure it is consistent with the level of control the ACP can assure with respect to unintentional allergen presence. Use PAL only when all of the following four criteria are met (adapted from Grocery Manufacturers Association, 2009):

1. Where a food allergen in the manufacturing facility constitutes a risk of *presence* in products where such presence is unintended
2. 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
3. Where the food allergen is likely to be present in some, but not all, of the food product where its presence is unintended
4. 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).

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A qualitative assessment is based on the information and objective evidence that has indicated the potential presence of unintentional allergen, and 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. Objective evidence for assessing the risk mitigation effect of control measures include, for example, visual observation, analytical tests, validation studies, recognized cleaning standards, documented training records, scientific publications.

In a qualitative assessment for PAL, gather evidence from the entire manufacturing process (e.g. (Allergen Bureau, n.d.) factory map – see Figure 3). The following are examples of factors to consider, which must be adapted to a specific allergen, manufacturing process, facility and finished product.

Factors to consider:

1 Raw materials

Evidence related to raw material compliance with the manufacturers' requirements and the suppliers' level of allergen control, including:

- Only approved suppliers are used, and a supplier control program addressing allergen management practices is in place
- Certificates of analysis (CoA) are provided as required by the manufacturer
- Testing results of received lots that have not yet been used in the manufacturing process
- History of testing results on the occurrence of the unintentional allergen in the raw material, conducted by the food manufacturer or the supplier
- Acceptable audit of the supplier's ACP by the food manufacturer or a third party

Evidence of internal practices related to preventing the introduction of unexpected allergens or misidentification of allergens include:

- Personnel involved with purchasing raw materials has received adequate function-specific training on food allergens at the frequency established in the ACP
- Allergen information to be provided by suppliers when raw materials are approved and/or shipped are clearly established in official documentation
- Suppliers are required to communicate, formally and immediately, any allergen-related changes to the raw materials supplied

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2 Receiving and storage of raw materials

Evidence of internal practices related to preventing the introduction of unexpected allergens:

- Personnel involved with receiving and storing raw materials has received adequate function-specific training on food allergens (e.g. specification verification, label verification, transport verification, segregation/identification during storage) at the frequency established in the ACP
- Internal procedures reflect receiving and storage best practices for allergen management

3 Design of premises and equipment

Evidence that the design of the premises and the equipment allow for adequate cleaning:

- An assessment of equipment and infrastructure design is conducted, and any deficiencies are noted (e.g. equipment or infrastructure requiring replacement/modification to allow for adequate cleaning)

4 Production

Evidence on the manufacturing operation's ability to prevent or limit allergen cross-contact:

- Production scheduling does not introduce cross-contact allergens (e.g. analytical results of allergen detection/ quantification in finished products if relevant)
- Internal procedures reflect allergen management best practices on changeover, staging, rework identification, handling and storage, finished product identification and storage, employees' movements, etc.
- Any cross-contact allergens, potentially introduced during processing, are identified and characterized (e.g. allergen physical properties, distribution of unintentional allergen in the finished product, estimated or quantified amount of allergen in cross-contact material and/or in the finished product)

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5 Cleaning

Evidence of the cleaning procedures' ability to effectively remove allergenic proteins:

- Cleaning procedures address allergens and are consistently applied per standard operating procedure
- Cleaning validation studies (e.g. achieving a visually clean standard, analytical results of allergen detection/quantification in finished products) – Refer to Annex 3 for information on analytical testing
- History of cleaning verification results

Note:
Control measures aiming to prevent labelling errors are considered critical for all products containing or potentially containing allergens. If deficiencies are noted, update practices before continuing the assessment.

Depending on the characteristics of the manufacturing operation, some factors may have a stronger or a more direct effect on the occurrence of unintentional allergen presence than others. This can be incorporated in the assessment through a "weight of evidence" approach. Evidence is considered very strong when a direct link between the control measures and the occurrence or removal of unintentional allergen(s) can be clearly demonstrated. The proper amount of **evidence weight** needed to reach a PAL decision will vary for every assessment and will likely be influenced by the experience of the assessors. It is therefore crucial that a multidisciplinary, experienced team, with thorough knowledge of the manufacturing operation (i.e. the allergen management team), leads this type of assessment.

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A **qualitative assessment** may reach one of the following conclusions:

- 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

Any allergen hazard(s) for which a qualitative assessment is insufficient to reach PAL decisions should be further evaluated considering quantitative criteria to establish the risk for allergic consumers (i.e. allergen protein exposure and eliciting doses) – See Quantitative Assessment on page 61.

Note:
An assessment of the need for PAL is specific to the hazard, the manufacturing process, the facility, and the finished product. It is the responsibility of the manufacturer to fully document an evidence-based rationale for all allergen labelling decisions. It is also the manufacturer's responsibility to review the rationale behind a finished product's allergen declaration every time a new processing step is added and/or when changes that can potentially introduce allergens are considered.

Note:
Not all particulate allergens require PAL.
A case-specific assessment is possible and must be conducted to justify PAL decisions. Factors to consider include particle size, amount of allergen protein per particle and characteristics of the unintentional allergen introduction into the process (e.g. before/after a mixing step, through a hang-up point, maximum number of particles introduced). For further details on how to quantitatively assess unintentional particulate allergens please see Quantitative Assessment on page 61 and the International Life Science Institute (Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment, 2022).

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Examples of quantitative assessment for PAL

Examples of qualitative assessment for PAL

Note:

The examples provided in this document are simplified and must not be taken as conclusive recommendations. The scenarios described are hypothetical and focus exclusively on allergens. Potential issues related to other food safety hazards (i.e. microbiological, chemical, physical) are not considered. When assessing allergen hazards in a real food manufacturing setting, FBOs must consider the characteristics of their unique operation (e.g. raw materials, manufacturing process, hygiene practices, equipment).

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Example 1

A FBO slaughters and processes fowl. If eggs are found inside the birds at the time of slaughter, during the evisceration step of the manufacturing process they could spread to the surrounding carcasses. An assessment of the control measures in place provides the following evidence:

Example 1			
Production step	**Control measures**	**Evidence**	**Weight**
Raw materials	The supplier or the FBO cannot identify and segregate birds that carry eggs when they arrive at the facility.	Introduction of egg allergen in the facility cannot be prevented nor identified	Strong
Design of premises and equipment	The slaughter area and equipment do not allow for sufficient space to prevent spread of carcass contents. Modifications are not possible at the moment.	Cross-contact during slaughter cannot be prevented	Strong
Production	Since it is not possible to identify which birds carry eggs, production cannot be scheduled in such a way that those birds are processed separately. As a cross-contact allergen, eggs are characterized as a liquid allergen, with high protein content, likely to attach to poultry skin. Contaminated carcasses may have localized, high egg protein contamination. Contamination may spread during chilling (in water tanks).	Cross-contact is likely and could lead to highly contaminated products	Very strong
Cleaning	A thorough cleaning is conducted after every production shift but cannot control cross-contact during production	Products other than fowl are not likely to be contaminated with eggs, but they require their own, independent assessment.	N/A to this assessment

Conclusion: The evidence strongly indicates that the control measures in place cannot consistently prevent the occurrence of egg among adjacent carcasses when slaughtering fowl. All products containing fowl processed in this facility require PAL for egg.

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Example 2

A FBO produces baked goods. Production is scheduled in such a way that, on certain days, a type of cookie (A) containing milk is processed before another type of cookie (B) that does not contain milk. The FBO wants to determine if cookie B may contain milk. An assessment of the control measures in place provides the following evidence:

Example 2			
Production step	**Control measures**	**Evidence**	**Weight**
Raw materials	The ingredient containing milk is skim milk powder. The presence of milk allergen is evident. The supplier is approved and has a strong history of compliance. Receiving procedures are in place and personnel are trained. No incidences of milk allergen misidentification from this raw material and the supplier have been reported.	Introduction of milk allergen in the facility from this raw material is expected to be clearly identified, handled and stored upon receiving – but cannot be prevented at this step.	Weak
Design of premises and equipment	Equipment used in the production of A and B is recent and designed to allow for proper cleaning.	Equipment design does not hinder cleaning but does not directly prevent cross-contact	Weak
Production	Scheduling cannot be modified. However, the presence of allergen in A is addressed in changeover and cleaning procedures. Records on file indicate that training of specific personnel involved in this change over is adequate and is conducted at the required frequency, per ACP.	The possibility of cross-contact is likely and is addressed in changeover procedures. However, it is cleaning that will directly impact the occurrence/absence of cross-contact milk from A into B	Medium
Cleaning	Cleaning objectively meets a visually clean standard. A validation study analytically demonstrated that milk proteins are not detected in B, when cleaning is conducted after production of A, as established in the cleaning and changeover procedures. The validation study is robust (i.e. based on results from a sensitive, validated assay used for the form of milk in the matrix being tested) and recent. No changes in production or raw materials have occurred since. Cleaning is verified per standard procedures, specifically targeting milk detection in surfaces. No deviations have been documented.	Cleaning assures no visible residue and analytical tests report undetectable milk proteins in B	Very strong

Conclusion: The evidence strongly indicates that the control measures in place can consistently prevent the occurrence of milk in B, when produced after A. B does not require PAL for milk.

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Example 3

A FBO produces dry mixes. One of its ingredients contains PAL for mustard. The FBO wants to determine if a specific gravy mix, where this ingredient is used, may contain mustard. An assessment of the control measures in place provides the following evidence:

Example 3			
Production step	**Control measures**	**Evidence**	**Weight**
Raw materials	The ingredient containing mustard is a multi-component, dried flavouring preparation, not mustard-based. The presence of mustard is not evident. The supplier is approved and has a strong history of compliance. PAL for mustard was only recently added to this ingredient; there is no history of testing. This change was communicated by the supplier before shipment of the first lot, as stated in the purchasing agreement. The supplier has not been audited since this change was implemented. A targeted supplier questionnaire addressing this change indicates that cross-contact mustard may come from agricultural commingling, but no other information is available. The supplier cannot control this risk since it has not originated from within its facility.	Supplier control measures are robust but cannot prevent occurrence of cross-contact mustard in the raw material. The prevalence or concentration of mustard in this ingredient is unknown.	Medium
Design of premises and equipment	Design of premises and equipment does not affect introduction of allergens from ingredients	N/A	N/A
Production	Production practices do not affect introduction of allergens from ingredients	N/A	N/A
Cleaning	Cleaning does not affect introduction of allergens from ingredients	N/A	N/A

Conclusion: The evidence cannot conclude if control measures that are in place (in this case, focused on supplier control) can consistently prevent the occurrence of cross-contact mustard in this flavour. Based on the information available, a quantitative assessment is required to reach a decision on PAL for mustard in the finished product (i.e. gravy mix). Additional information will likely need to be collected (e.g. testing of ingredient for mustard, clarification on the origin of the unintentional allergen presence, supplier audit).

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Example 4

A small FBO produces baked goods. The facility is dated but complies with all food production requirements. One of their best-selling items is sesame bagels; they are produced every day. The FBO has found sesame seeds in certain areas and in pieces of equipment (i.e. staging area, oven trays and racks, ovens) and is concerned that they may contaminate products not intended to have sesame. An assessment of the control measures in place provides the following evidence:

Example 4			
Production step	**Control measures**	**Evidence**	**Weight**
Raw materials	Sesame seeds are received in 5 kg bags from an approved supplier. They are identified as allergens by receiving personnel and are placed on the bottom shelf of the storage room, sealed and segregated from other ingredients.	Introduction of sesame allergen in the facility from this raw material is expected to be clearly identified, handled and stored upon receiving. This step is not a likely source of sesame cross-contact.	Weak
Design of premises and equipment	Ingredients are staged in an area not physically separated from the production line. The facility's ovens are old and certain parts cannot be fully accessed during cleaning. Replacement or modifications are not possible at the moment.	Design of premises and equipment does not allow for adequate physical segregation and may hinder cleaning.	Strong
Production	Sesame bagels are processed during the first production run of the day. They are sold fresh, early every morning. Other products are also produced at the same time (i.e. bagels not containing sesame). Staging employees have received adequate allergen training. Sesame seeds are weighed separately, using dedicated tools. Opened bags are sealed before returning to the storage area. However, sesame seeds are sometimes found in scales and on the floor of the staging area. Bagels are sprinkled with sesame seeds on the trays in which they will be baked. Sesame seeds are often found on the production floor around this area. The volume of production requires that all ovens and oven racks are used when sesame bagels are processed. It is not possible to have only one oven dedicated to sesame bagels.	The possibility of cross-contact is likely and cannot be consistently prevented with the control measures in place.	Very strong

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Example 4			
Production step	**Control measures**	**Evidence**	**Weight**
Cleaning	The facility is cleaned every day at the end of production. Staging and production areas consistently meet visibly clean standards. However, sesame seeds are sometimes found in these areas at the start of the next day's production shift. Oven cleaning does not consistently meet a visually clean standard. Sesame seeds are sometimes found in oven areas that cannot be accessed during cleaning.	Sesame seeds are characterized as a particulate allergen, likely to spread, and difficult to remove from this facility's environment and equipment. Visibly clean standards cannot be consistently met.	Very strong

Conclusion: The evidence strongly indicates that the control measures in place cannot consistently prevent the occurrence of sesame in products not intended to have sesame in their recipe. Since sesame bagels are produced every day and a dedicated line cannot be implemented, the FBO has decided to use PAL for sesame in all the products made in this facility.

The qualitative assessment will often provide conclusive findings which will allow users to determine whether PAL is required or not. However, when it does not provide irrefutable information, a quantitative assessment may be required. This robust tool can be used intuitively and with ease by understanding the nuances between qualitative and quantitative processes, and by following the detailed information below.

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Quantitative assessment

When a qualitative assessment does not provide conclusive information on a requirement for PAL, a quantitative assessment may be considered. The main difference between qualitative and quantitative assessments is the nature of the input data (i.e. non-numerical versus numerical). As described earlier, a qualitative assessment considers where the allergen control measures fail or pass based on objective evidence such as visual observations. In contrast, in a quantitative allergen risk assessment, an estimated allergen protein exposure intake or dose, from consumption of a specific food product, is compared to an allergen protein dose predicted not to elicit an allergic reaction in most of the allergic population. Put simply, the risk may be estimated in this fashion: if the estimated exposure dose is higher than the eliciting dose, the food product may pose a risk to allergic consumers.

Quantitative risk assessments can be deterministic (based on fixed numerical data), probabilistic (based on probabilities and the likelihood of something occurring), or a combination of both. Generally, deterministic assessments are simple and provide sufficient information to guide risk management decisions in a food manufacturing context. Deterministic assessments considering "worst-case" scenarios, lead to conservative results, and offer a high degree of protection to an allergic consumer.

Note:
Probabilistic risk assessment in the context of food allergy requires access to specialist models and expert consultation and will not be covered further in these guidelines. Background information and examples of peer-reviewed probabilistic allergen risk assessments may be found here: Spanjersberg et al., 2007; Rimbaud et al., 2009; Rimbaud et al., 2013; Manny et al., 2021; Touma et al., 2021 (Manny, La Vieille, Dominguez, Kos, et al., 2021; Rimbaud et al., 2009, 2013; Spanjersberg et al., 2007; Touma et al., 2021).

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Input data

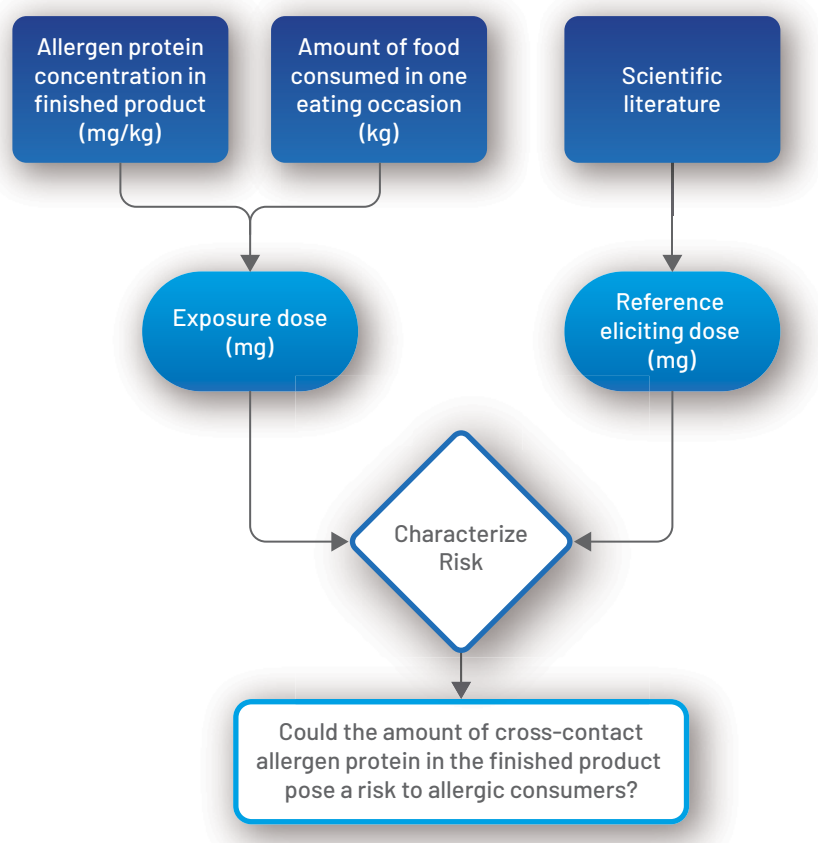
To conduct a quantitative allergen risk assessment in a food manufacturing context, the following values are needed (see Figure 5):

- allergen protein concentration in the finished product
- amount of food consumed in one eating occasion
- exposure dose — determined from allergen protein concentration in the finished product and amount of food consumed in one eating occasion
- eliciting dose

These values incorporate the concepts of hazard characterization (i.e. eliciting dose) and exposure assessment (i.e. food consumption), also applied in the qualitative assessment, but in a numerical form.

Note:
Values such as allergen reference doses are subject to review and update by the scientific community and competent authorities. It is therefore necessary to refer to the most up-to-date sources and to provide justification when using these values for risk assessment.

Figure 5: Quantitative Risk Assessment for PAL:



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A Allergen protein concentration in the finished product

When conducting a risk assessment for PAL, allergen protein concentration in finished products is **estimated** from in-process measurements and, if necessary, verified with analytical testing. In a preventive food safety approach, routine finished product testing is not recommended. Finished product testing, however, may be relevant in other situations, for example, when investigating allergen incidents or allergen control deviations.

The type of information needed to estimate allergen protein concentration in finished products depends on the nature of the cross-contact event (e.g. from carry-over material, from adjacent line). Examples are presented in Table 4 on page 64. Generally, a precautionary approach, considering worst-case yet realistic scenarios, is applied.

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Table 4: Information needed for estimating cross-contact allergen in finished products

Information	Options	Evidence
Cross-contact allergen matrix		
Physical form of the allergen or of the food matrix introducing the cross-contact allergen	Powder, liquid, paste, particulate, dust	Wheat flour (dust or powder), peanut or almond pieces (particulate), fish oil (liquid), peanut or almond butter (paste)
Details of the allergen derived material(s) introducing the cross-contact allergen and protein content of these	Variable depending upon allergen	Crude vegetable oils (e.g. soy) contain about 100-300 mg protein/kg, whereas fully refined oils contain at least 100-fold less
Frequency of cross-contact in the matrix introducing the allergen	Persistent (e.g. all units, always, all production runs) Sporadic (e.g. some units, some lots, some production runs)	Persistent = every run of product A results in hang-up material containing peanut Sporadic = sometimes, after processing product A, there is hang-up material containing peanut
Cross-contact allergen distribution in the matrix introducing the allergen	Homogeneous Heterogeneous	Homogeneous = peanut proteins are evenly distributed in hang-up material from product A Heterogeneous = sesame seeds are unevenly distributed in bagel dough hang-up material
Maximum level (concentration) of cross-contact allergen proteins in the matrix introducing the allergen	Concentration in mg total protein from the allergenic source/kg of food product	Samples of hang-up material from 10 different runs of product A are sent to an external lab and quantitatively analyzed for peanut proteins. The highest concentration detected is used for risk assessment as a worst-case.
Processing		
Point of introduction of cross-contact allergen into the process	Processing step	Considerations: Before or after a mixing step, affecting components of a product or the entire lot, before or after a baking step (potential final weight change due to water loss)
Maximum amount of material carrying cross-contact allergen that would be incorporated into the finished product	Mass in kg	Direct measurement or estimated from observations during processing

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Table 4: Information needed for estimating cross-contact allergen in finished products

Information	Options	Evidence
Finished product		
Cross-contact allergen distribution in the finished product	Homogeneous Heterogeneous	Homogeneous = Cross-contact soy in the form of oil is introduced before mixing and is homogeneously distributed into a salad dressing Heterogeneous = cross-contact almond pieces introduced intermittently from adjacent line immediately before packaging
Amount of finished product containing cross-contact allergen	Mass in kg	In a continuous process, cross-contact egg is "washed out" in the first X kg of product processed. Therefore, only the first X kg of product processed could contain cross-contact egg.

Analytical results

Quantitative assessments are only meaningful if the input data is accurate and representative. Samples must be collected following an adequate protocol and analyzed using fit-for-purpose tests in a qualified laboratory. Further guidance on allergen sampling and analysis may be found on Annex 3 and in (Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment, 2022).

Only analytical results that can be correlated with allergen concentration in finished product are suitable for risk assessment (e.g. allergen concentration in raw ingredients, in carry-over material). Currently, allergen tests that target non-food materials (e.g. surface swabs, rinse water) are difficult to correlate with allergen concentration in finished products, as it is unclear how much, if any, of the allergen would be transferred. Existing allergen tests for non-food materials are mainly used as indicators of the efficacy of control measures (e.g. cleaning); positive results suggest the need to review and enhance the control measures.

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Units

Usually, commercial analytical methods report allergen concentration results as the commodity source of the allergenic food (e.g. 5 ppm soy or soy flour; 5 ppm non-fat dry milk) or protein from the allergenic source (e.g. 1 ppm total soy protein; 1 ppm total milk protein). Further, some methods report in units of a specific protein within the allergenic source (e.g. 1 ppm beta-lactoglobulin or 1 ppm casein). These three ways of reporting are not equivalent. Establishing a clear dialogue with the method developer/supplier is essential to fully understand the meaning of the results of the analyses conducted.

Note:
"ppm" or "parts per million" is a common unit for reporting allergen concentration in food. "1 ppm" means there is 1 mg of the compound measured in 1 kg of the sample analyzed.

Example 1

A sample of ice cream is analyzed for peanuts. The laboratory report indicates, "2 ppm peanut". There are therefore 2 mg of peanut per kg of ice cream. The laboratory report needs to indicate what "peanut" refers to exactly (e.g. whole peanut, peanut flour) as a different conversion factor may be needed when calculating the amount of allergenic protein from the commodity source.

Example 2

A sample of crackers is analyzed for sesame. The laboratory report indicates, "0.7 ppm sesame protein". There is therefore 0.7 mg of sesame protein per kg of crackers. The laboratory report needs to indicate what "sesame" refers to exactly (e.g. roasted sesame seeds, sesame oil) as a different conversion factor may be needed when calculating the amount of allergenic protein from the commodity source.

For comparison against eliciting doses, the amount of total protein from the allergenic source in the food is needed. To convert analytical results expressed as allergen into allergen protein, the protein content of the allergenic food is required. This information can be obtained from:

- the testing laboratory
- scientific literature (e.g. Table 5 on page 67)
- food composition databases, such as the Canadian Nutrient File or the United States' FoodData Central.[17]
- data provided by supplier
- analytical methods (e.g. total protein analysis)

[17] Health Canada, 2021b; U.S. Department of Agriculture, n.d.

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Table 5: Total protein content of select allergenic foods

Allergenic food	Protein content (%)
Hazelnut flour	16
Whole peanuts	25
Crushed sesame seeds	17
Raw or cooked wheat flour	10
Dried whole egg	46
Non-fat dry milk	36
Whole soybean	40
Whole cooked shrimp	23
Mustard seed	26

Adapted from Holzhauser et al., 2020

Note:
Derivatives of the same allergenic food source may have different protein content. Notably, food processing can have a significant impact on protein content. For example, the soy content in soy lecithin is different than the soy content in tofu. It is therefore necessary to understand the characteristics of the allergen cross-contact sources and to assess whether available analytical methods are validated to quantify proteins from these sources.

Results expressed as the concentration of commodity units from the allergenic source can then be converted into the concentration of total protein from the allergenic source using the formula:

Total protein from the allergenic source =

commodity units of the allergenic source × *total protein fraction in the allergen*

e.g.: 10 ppm Non-fat dry milk × 36% protein in non-fat dry milk = 3.6 ppm total milk protein

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Simulated cross-contact scenario

In deterministic risk assessment, data is expressed as point values. These values may take the form of an average, a maximum, a minimum, or a given percentile from a set of measurements. For allergen risk assessment, given the acute nature of food allergy, **a conservative "worst case" scenario** is generally assumed.

Example 1

Supplier data shows that raw material may contain unintentional milk proteins (expressed as total protein from the allergenic source) at an average concentration of 0.5 ppm total milk protein, with a minimum of "not detected" and a maximum of 1 ppm total milk protein. The FBO decides to use the maximum concentration to estimate allergen concentration in finished products, to simulate the maximum allergen dose to which an allergic consumer may be exposed.

Example 2

A cross-contact event results in a variable number of contaminated finished product units, ranging from 3 to 90 units per production run. For risk assessment, however, the FBO assumes that all units contain cross-contact allergen, to simulate the event where an allergic consumer ingests a contaminated unit.

Example 3

Internal data shows that the amount of hang-up material that is carried over into a subsequent production run varies between 3 kg to 18 kg. For risk assessment, the FBO assumes that 18 kg of material is systematically carried over, to simulate a production run with the highest quantity of allergen proteins.

The nature of the cross-contact event and the robustness of the data will also influence the type of value to use. For example, an average value may be used if it originates from a very robust historical dataset, where isolated maximum values represent deviations that have been controlled. Or, for events where cross-contact is homogeneous (e.g. a liquid allergen evenly distributed in a liquid finished product), an average measure of allergen concentration may be representative. In all cases, it is necessary to justify the choice of input data.

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B Amount of food consumed in one eating occasion

For allergen risk assessment, food intake refers to the amount of food consumed in one eating occasion. This amount is not necessarily the same as the recommended portion size. Portion sizes are recommended intake values, proposed mainly for nutritional purposes, whereas food intake for risk assessment must be representative of the amount of food actually consumed. For example, the portion size of sliced bread established for nutritional purposes is 2 slices of bread per eating occasion, but dietary surveys indicate that more than 2 slices of bread are commonly consumed per eating occasion. In this example, the use of the portion size for risk assessment could potentially underestimate the exposure dose which could be twice as high.

Food intake data may be obtained from:

Food consumption surveys

Although not specifically developed to collect food intake data for risk assessment, data from nutrition-focused surveys may be useful.

The Food Consumption Table (FCT) provides daily food intake estimates from data gathered from the Canadian Community Health Survey (CCHS) — data that is representative of the Canadian population.[18] Food items are grouped in 10 categories, each including subcategories. The mean and percentiles (50th, 90th, 95th) of daily food intakes (in grams) are presented, for the entire group of respondents, and only for those that reported consuming the food (i.e. "eaters only"). For risk assessment, the food intake value of **eaters only** needs to be considered.

[18] Health Canada, 2017

Note:

The 50th percentile (P50) of the general population distribution of the intake of foods may be used as a Reference Amount in food allergen deterministic risk assessment.[19] If the P50 is not available, the mean would be a good alternative, as it is generally between the p50 and p65.[19]

[19] Blom et al., in preparation

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In nutrition surveys like CCHS, daily intakes include the total amount of a given food consumed throughout a day, but food-induced severe allergic reactions most often occur immediately after consumption of the allergenic food (i.e. due to allergen proteins ingested in one eating occasion, not from an aggregated consumption). For some foods, the daily food intake may be the same as the amount consumed in one eating occasion (e.g. breakfast cereals), but not for others (e.g. bread). Daily food intakes are useful for risk assessment, however, it is important to consider the common consumption pattern of the food being assessed.

If available, other types of food consumption surveys (e.g. product or population-specific) may provide more accurate data per eating occasion.

Although Canadian food intake data is preferred when assessing the risk posed by products consumed in Canada, international food consumption surveys may also be relevant examples (e.g. Birot et al., 2017). When Canadian intake data is not available for a specific food product, data from a foreign country may be used as a surrogate, acknowledging any assumptions and limitations.

Internal data

Some manufacturers collect or have access to consumption data specific to their food products. Depending on the characteristics of the data (e.g. representative, statistically robust), it may be considered adequate for risk assessment.

In addition, in some cases, the serving size of a product can be considered representative of one eating occasion (e.g. a pack of chips, a small container of yogurt, a burger), and manufacturers may use their internal finished product weight data to estimate consumption.

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C Exposure dose

Exposure dose refers to the amount of allergen protein expected to be in an amount of finished product representing an eating occasion. In a risk assessment simulation, the exposure dose is the allergen protein dose an allergic consumer would be exposed to when consuming the food product under assessment. Exposure dose is calculated from the allergen protein concentration and the amount of food consumed per eating occasion previously determined, as follows:

Exposure dose =		
total protein concentration from the allergenic source in food	×	*amount of food consumed in one eating occasion*

Units require special attention. An allergen protein concentration in mg/kg and an amount of food consumed in kg would result in an exposure dose in mg. An exposure dose expressed in mg can then be directly compared to an eliciting dose, usually also expressed in mg. Food intakes expressed in grams or ounces, for example, must be converted to match the units used to express the allergen protein concentration.

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D Eliciting dose (ED)

Eliciting dose refers to the total dose of protein from the allergenic source (expressed in mg) predicted to produce a response in a percentage of the allergic population.[20] For example, the ED05 is the mg dose of total protein from the allergenic source in question at which 5% of this allergic population would react with objective symptoms. Although extensive clinical data on eliciting doses is available in the scientific literature, allergen protein doses that can be considered safe for the entire allergic population have not been identified. Different allergen proteins have different eliciting doses,[21] however, they can each induce an equally severe reaction if ingested by an allergic individual. For example, at doses equal to or higher than the eliciting dose, milk proteins could result in an equally severe reaction in a milk-allergic individual, as peanut proteins in a peanut-allergic individual. Food allergy is a complex medical condition that varies considerably between affected individuals, making the establishment of universal threshold doses challenging.

[20] Allergen Bureau, 2019
[21] Houben et al., 2020

For application in food manufacturing, within a risk analysis framework, threshold eliciting doses or reference doses (RfD) for several allergenic foods (see Table 6) have been proposed by the VITAL Scientific Expert Panel (Allergen Bureau, 2019) and the FAO/WHO Expert Consultation on food allergen risk assessment (Food and Agriculture Organization of the United Nations & World Health Organization, 2021, p. 2) (Food and Agriculture Organization of the United Nations & World Health Organization, 2022) — the full report is not yet publicly available. VITAL recommends the adoption of ED01 values whereas FAO/WHO Expert Panel recommends ED05. Doses below the reference values are estimated to protect 99% (ED01) or 95% (ED05) of the allergic population, respectively.

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Table 6. Allergen reference doses (mg total protein from the allergenic source) recommended by international scientific committees

Allergen	Recommended reference dose (mg total protein from the allergenic source)		
	VITAL scientific expert panel (2019)		FAO/WHO expert consultation (2021, 2022)*
	ED01	ED05	ED05
Almond	—	—	1.0**
Cashew (and pistachio)	0.05	0.8	1.0
Celery	0.05	1.3	—
Egg	0.2	2.3	2.0
Fish	1.3	12.1***	5.0
Hazelnut	0.1	3.5	3.0
Lupin	2.6	15.3	—
Milk	0.2	2.4	2.0
Mustard	0.05	0.4	—
Peanut	0.2	2.1	2.0
Sesame	0.1	2.7	2.0
Shrimp	25	280.0	200.0
Soy	0.5	10.0	—
Walnut (and pecan)	0.03	0.8	1.0
Wheat	0.7	6.1	5.0

The RfDs presented in Table 6 may be incorporated into risk-based decision processes, acknowledging that they do not represent zero risk thresholds. The FBOs may select the level of protection of the allergic population they intend to achieve (i.e. 99%, 95%) when selecting reference doses for risk assessment.

* Summary reports: (Food and Agriculture Organization of the United Nations & World Health Organization, 2022) (Food and Agriculture Organization of the United Nations & World Health Organization, 2021, p. 2)
** Provisional
*** Finfish

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E Risk characterization

In quantitative risk assessment, the estimated allergen exposure dose (i.e. the amount of total protein from the allergenic source in the finished product under assessment) is compared against an allergen protein dose predicted not to elicit an objective reaction in most allergic consumers. The purpose of this comparison is to determine whether the allergen protein amount in the finished product could represent a risk to allergic consumers.

Eliciting doses may be used as **reference** values when characterizing cross-contact allergen risk and informing PAL decisions. E.g.:

- If the exposure dose is estimated to be **higher** than the eliciting dose, the risk would be considered important, and PAL is strongly recommended as a risk management decision
- If the exposure dose is estimated to be **lower** than the eliciting dose, PAL may not be needed based upon the overall risk assessment

Note:
Estimating exposure doses does not necessarily rely on finished product testing. Exposure doses can be estimated from measurements and other information collected earlier in the manufacturing process, as illustrated in examples 1-3 on subsequent pages.

Allergen eliciting doses provide valuable information for risk managers, making the PAL decision process more robust. However, reference eliciting doses do not represent zero-risk thresholds, and other factors (e.g. scope of product distribution, perception of the allergic individuals of the safety of the product, characteristics of the product's target population — notably, whether the product is geared towards children) need to be considered in the risk management decision process.

Incorporating eliciting doses into the PAL decision process may also facilitate risk communication with consumers. To help consumers make informed choices they should understand that PAL is used only in products:

- where unintentional allergens **may** be present despite thorough allergen risk mitigation measures
- that have been subject to a structured risk assessment process
- the risk assessment includes reference values based on clinical data estimated to protect most of the allergic population

For cases where a qualitative assessment does not provide conclusive information, and where a quantitative assessment cannot be conducted (e.g. insufficient data, inadequate data), the use of PAL may be considered as a conservative approach. The use of PAL in these cases should be considered temporary and should be reviewed as more information and/or more accurate data become available. The reasons why qualitative/quantitative assessments are inconclusive must be clearly documented.

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Note:
The examples provided in this document are simplified and must not be taken as conclusive recommendations. The scenarios described are hypothetical and focus exclusively on allergens. Potential issues related to other food safety hazards (i.e. microbiological, chemical, physical) are not considered. When assessing allergen hazards in a real food manufacturing setting, FBOs need to consider the characteristics of their unique operation (e.g. raw materials, manufacturing process, hygiene practices, equipment).

Examples

Example 1

Cross-contact allergen in raw material

The specification of seasoning mix "A", an ingredient in a recipe of chips, indicates it may contain soy. The FBO producing these chips conducted a qualitative risk assessment, but it was inconclusive (i.e. the supplier did not provide information on the occurrence of soy in seasoning mix "A"). The FBO decides to conduct a quantitative risk assessment to evaluate whether the *"may contain"* statement for soy should be carried forward onto the chips label. No other unintentional soy protein sources have been identified for these chips.

A Allergen concentration in finished product

Spice mix "A"'s specification did not contain cross-contact allergen details other than *"may contain: Soy"*. The supplier provides additional information per request:

- Soy cross-contact is sporadic, only some lots of spice mix "A" may be affected.
- The source of soy cross-contact is soy flour, used in several other products processed by the supplier.
- When cross-contact occurs, the allergen is not homogeneously distributed. Supplier's internal test results indicate that the level of soy flour varies greatly between samples.
- The maximum level of soy flour detected in spice mix "A" is 15 ppm, measured with an ELISA validated method by an external laboratory and reporting in units were soy = soy flour. However, these results originate from a limited number of samples selected randomly by the supplier.

Although the information provided by the supplier may not be fully representative, it is sufficient to develop a worst-case scenario of unintentional soy presence in spice mix A. For risk assessment, it could be assumed that all lots are contaminated at a level of 15 ppm soy flour.

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Table 7: Information collected to estimate the concentration of unintentional soy in potato chips

Information	Option	Source
Cross-contact allergen matrix		
Physical form of the allergen or of the food matrix introducing the cross-contact allergen	Powder (i.e. soy flour)	Ingredient specification
Frequency of cross-contact in the matrix introducing the allergen	Sporadic (i.e. some lots)	Supplier
Cross-contact allergen distribution in the matrix introducing the allergen	Heterogeneous (i.e. soy is unevenly distributed throughout the lot)	Supplier
Maximum level of cross-contact allergen proteins in the matrix introducing the allergen	15 ppm soy flour (maximum), which contains 40% soy protein	Supplier
Processing		
Point of introduction of cross-contact allergen into the process	Mixing step	Process specification
Maximum amount of material carrying cross-contact allergen that would be incorporated into the finished product	Spice mix "A" = 12% of recipe	Product recipe
Finished product		
Cross-contact allergen distribution in the finished product	Homogeneous	Spice mix "A" is added during a mixing step
Amount of finished product containing cross-contact allergen	Entire batch	Spice mix "A" is added during a batch mixing step

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The supplier provided allergen concentration expressed as "ppm soy", which means "mg soy/kg spice mix". The external laboratory confirmed that the ELISA reporting units were such that ppm soy refers to ppm of soy flour and that a conversion factor of 0.4 was recommended for converting the reporting units to ppm soy protein. This value could therefore be converted to "mg soy proteins/kg spice mix" using a conversion factor of 0.4 as follows:

Soy protein =		
total soy flour	×	*protein fraction in soy flour*
Soy protein = 15 × 0.40 = 6 mg soy protein per kg spice mix		

The potato chip recipe contains 12% of spice mix "A". The potato chips are produced in a batch process, and the spice mix is introduced during a mixing step. Any unintentional soy from the spice mix "A" is expected to be homogeneously distributed in each batch of potato chips. The potato chip-making process includes a baking step which is not expected to alter soy proteins. The baking step is known to slightly reduce water content (6% total weight loss), per product specification sheet.

The concentration of soy proteins in potato chips can be estimated considering a 100 kg batch of potato chips as follows:

- Amount of spice mix "A" added = 12 kg
- If 1 kg of spice mix "A" contains 6 mg soy protein, then 12 kg of spice mix "A" contain 12 × 6 = **72 mg soy protein**
- Considering water loss, the weight of the chips batch after baking is 100 × 0.94 = **94 kg**
- The concentration of soy protein in the finished product in a worst-case scenario is estimated to be 72/94 = **0.77 mg soy protein per kg of potato chips**

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B Food intake

According to CCHS-2015, the overall mean daily intake of savory snacks in Canada, as reported for "eaters only", is 42.5 g.[22] The P50 is 26.8 g and the P90 is 89.9 g. P75 is not available. The serving size on the potato chip label is 28 g. For risk assessment purposes, it has been decided that an eating occasion is to be considered as 2 bags of potato chips = **56 g**, or consumption between the mean and P90.

C Exposure dose

If there is **0.77 mg** of soy protein in one kg of potato chips, in one potato chip eating occasion (i.e. two packs = **0.056 kg**) there will be **0.043 mg of soy protein**.

D Risk characterization

The dose estimated to protect 95% of soy-allergic individuals is 10 mg soy protein, according to (Remington et al., 2020). A reference dose of 0.5 mg soy proteins (VITAL 3.0 reference dose) would protect 99% of soy-allergic individuals.[23]

Risk assessment results, considering the worst-case scenario, indicate that unintentional soy protein in potato chips (0.043 mg), if present, would be significantly below the reference dose protecting 99% of the allergic population (0.5 mg). Therefore, the FBO decides that PAL for soy does not need to be carried forward onto the potato chip label.

[22] Government of Canada, 2019
[23] Allergen Bureau, 2019

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Example 2

Cross-contact from carry-over material

A sausage manufacturer's changeover procedures do not fully eliminate residues from the previous run due to equipment design limitations. On some days, production runs are scheduled such that honey mustard sausage (HM) — a product containing mustard — is processed immediately before maple sausage (E) — a product that does not contain mustard. Scheduling cannot be altered at the moment. Qualitative risk assessment was inconclusive (i.e. mustard was likely to be found in carry-over material, but the amount of finished product affected could not be determined qualitatively). Therefore, a quantitative risk assessment is conducted to evaluate whether maple sausages need PAL for mustard. No other unintentional mustard sources have been identified for maple sausages.

A Allergen concentration in a finished product

Hang-up material from HM accumulates in the sausage filling equipment after every run. To determine the maximum accumulation (worst-case scenario), hang-up material after 10 runs of HM is weighed. The maximum amount weighed is 0.05 kg.

For the same 10 runs of HM, the subsequent runs of E are monitored to determine the production volume needed to "wash out" HM carry-over. Samples at different times since the start of production of E are tested for mustard (detection only, not quantification). The test used had been previously validated by the external laboratory for detection of proteins from mustard seed powder in this sausage matrix. The FBO establishes that the minimum (worst-case scenario) amount of E that needs to be processed before HM is "washed out" is 5 kg. Considering that E is produced in small volumes only, discarding initial product would be too costly.

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C. Exposure dose

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Table 8: Information collected to estimate the concentration of unintentional mustard in maple sausage

Information	Option	Source
Cross-contact allergen matrix		
Physical form of the allergen or of the food matrix introducing the cross-contact allergen	Powder (i.e. mustard seed powder)	Ingredient specification
Frequency of cross-contact in the matrix introducing the allergen	Persistent	Mustard is an ingredient of HM. Every run of HM sausage produces carry-over material with mustard
Cross-contact allergen distribution in the matrix introducing the allergen	Homogeneous	Carry-over material has been mixed in HM recipe
Maximum level of cross-contact allergen proteins in the matrix introducing the allergen	HM's recipe contains worst-case 0.6% mustard powder, which contains 26% mustard protein	HM product recipe
Processing		
Point of introduction of cross-contact allergen into the process	Sausage filling	HM material accumulates in sausage filling equipment
Maximum amount of material carrying cross-contact allergen that would be incorporated into the finished product	0.05 kg	Maximum weight of hang-up material weighed after 10 production runs of HM
Finished product		
Cross-contact allergen distribution in the finished product	Heterogeneous	Initial volume of E processed is likely to contain higher amounts of protein
Amount of finished product containing cross-contact allergen	5 kg (minimum)	Minimum amount of E needed to "wash out" mustard, measured from 10 runs of E

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Therefore, for risk assessment, it is assumed that 0.05 kg of HM material containing mustard will be incorporated into 5 kg of E. This represents the worst-case scenario, where the highest amount of mustard would be added into the smallest amount of E, resulting in the highest concentration of mustard in E.

HM's recipe contains 0.6% mustard, in the form of powder. Then, 0.05 kg of HM contains **0.0003 kg** of mustard powder.

$$\text{Mustard powder in 0.05 kg of HM} = \frac{0.05 \times 0.6}{100} = 0.0003 \text{ kg}$$

Using a conversion factor of 26% (Table 5), 0.0003 kg of mustard contains 0.000078 kg protein = 78 mg (approximated to **80 mg**).

$$\text{Mustard protein in 0.0003 kg mustard powder} = 0.0003 \times 0.26 = 0.000078 \text{ kg} = 78 \text{ mg} \approx 80 \text{ mg}$$

The concentration of mustard protein in the first 5 kg of E would then be **16 mg/kg**.

$$\text{Mustard protein in the first 5 kg of E} = \frac{80}{5} = 16 \text{ mg/kg}$$

B Food intake

The target weight of one E sausage is 75 g. For risk assessment, a high consumption (worst-case scenario) eating occasion including 3 sausages (0.225 kg) is assumed, based on internal data on consumption habits.

C Exposure dose

Since there were 16 mg mustard protein in 1 kg of E, there would be **3.6 mg** mustard protein in 0.225 kg of E (i.e. 3 sausages).

D Risk characterization

Eliciting doses for mustard have been proposed by the VITAL Scientific Expert Panel.[24] A dose of 0.4 mg mustard protein is estimated to protect 95% of the mustard-allergic population (ED05), and a dose of 0.05 mg mustard protein is estimated to protect 99% of the mustard-allergic population (ED01).[24]

Since the estimated exposure dose (3.6 mg) is above the ED05 (0.4 mg), the FBO decides to apply PAL for mustard in their maple sausages.

[24] Allergen Bureau, 2019

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C. Implement / improve control measures

D. Evaluate effectiveness of control measures

E. Communicate risks

Qualitative assessment

Examples of qualitative assessment for PAL

Quantitative assessment

A. Allergen protein concentration in the finished product

B. Amount of food consumed in one eating occasion

C. Exposure dose

D. Eliciting dose (ED)

E. Risk characterization

Examples of quantitative assessment for PAL

Example 3

Particulate cross-contact allergen, homogeneous distribution

The recipe for dessert topping "D" contains hazelnut pieces. The recipe for salad topping "S" does not. Both toppings are processed simultaneously in different but adjacent lines, separated with a physical barrier (i.e. plastic curtain). The FBO is concerned because some components of D are regularly found on the floor around the line processing S. The FBO cannot invest in enhancing physical separation at the moment. Since hazelnuts are used in all other toppings produced by the FBO, changing the production schedule would not reduce the cross-contact risk. D is the product manufactured in this facility that contains the highest percentage of hazelnuts in its recipe.

The qualitative risk assessment for hazelnut in S was inconclusive since the likelihood of occurrence of hazelnut in S could not be established. The FBO decides to conduct a quantitative risk assessment to evaluate the need for PAL for hazelnut in S.

A Allergen concentration in finished product

The FBO purchases only one type of hazelnuts (i.e. roasted, chopped hazelnuts) from two different suppliers. The specifications from both suppliers have the same particle size range: 2-4 mm.

The FBO verifies the chopped hazelnuts size by measuring 10 hazelnut pieces from 3 different lots per supplier. All measurements are within specification. For risk assessment, a maximum particle size of 4 mm is considered (worst-case scenario).

The FBO selects 10 hazelnut pieces measuring each 4 mm from the same 3 different lots per supplier to determine the weight. The maximum weight recorded is 15 mg (worst-case scenario).

The protein content in dry roasted hazelnuts is obtained from the Canadian Nutrient File (15.03%). Therefore, **one hazelnut particle** weighing 15 mg contains **2.25 mg protein**.

Hazelnut protein in a 15 mg particle = 15 × 0.1503 = 2.25 mg

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B. Identify allergen control measures

C. Implement / improve control measures

D. Evaluate effectiveness of control measures

E. Communicate risks

Qualitative assessment

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Quantitative assessment

A. Allergen protein concentration in the finished product

B. Amount of food consumed in one eating occasion

C. Exposure dose

D. Eliciting dose (ED)

E. Risk characterization

Examples of quantitative assessment for PAL

B Preliminary assessment

If cross-contact occurs, a minimum of one hazelnut particle would be found in a package of S. If a single hazelnut particle is sufficient to elicit an allergic reaction, PAL would be needed. Therefore, the FBO conducts this preliminary assessment.

The FAO/WHO Expert Panel (2021) proposes an ED05 of 3 mg hazelnut proteins.[25] Remington et al. (2020) proposes an ED05 of 3.5 mg hazelnut proteins, and VITAL 3.0, an ED01 of 0.1 mg hazelnut proteins.[26]

The estimated protein content in one particle of hazelnut (2.25 mg) is close but lower than both proposed ED05 (3 and 3.5 mg), and higher than ED01. Only slightly more than one hazelnut piece (1.2-1.4 pieces) or a piece weighing slightly more than the assumed maximum would be needed to reach the ED05. The FBO decides to continue the assessment as this information does not automatically suggest the need or not for PAL.

[25] Food and Agriculture Organization of the United Nations & World Health Organization, 2021, p. 2
[26] Remington et al., 2020

C Frequency of contamination

To estimate the number of cross-contact hazelnut particles that may be found in S, empty Petri dishes are placed immediately adjacent and at the height of line S during production. Petri dishes are placed at a fixed distance from each other (e.g. 0.5 m) such that the entire length of line S is covered. At the end of production, the hazelnut pieces collected on the Petri dishes are counted. One third of the Petri dishes contained hazelnuts, for a total of 160 hazelnut pieces. Considering that Petri dishes covered approximately half of the line, this value is multiplied by 2 (=320).

For risk assessment, it is assumed that 320 hazelnut pieces systematically fall directly on the processing line, during one production run of S, adjacent to D.

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E. Risk characterization

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D Food intake

S is produced in 10 g packages to be included in salad preparation kits. Each salad preparation kit contains four recommended salad servings. For risk assessment, however, it is assumed that an entire salad prepared from the kit – and therefore, an entire package of S – will be consumed in one single eating occasion, to simulate salad as a full meal (as opposed to a side dish).

All S components are mixed at a stage immediately before packaging. Therefore, it is assumed that cross-contact hazelnut would be homogeneously distributed in S.

S is processed in batches of 50 kg, resulting in 5 000 packages of 10 g. S is made of different ingredients (e.g. sunflower seeds, dried vegetables, seasonings, oil). Particulate ingredients (e.g. sunflower seeds, tortilla chip pieces, dried vegetables) account for 90% of the recipe. The average individual weight of the particulate ingredients is **estimated** as 30 mg, as determined from ingredient specifications. Therefore:

Based on these estimates, and given that cross-contact hazelnuts are expected to be homogeneously distributed in S:

- It is highly improbable that all cross-contact hazelnut pieces (320) will be in one package of S, which is made of approximately 300 particulates in total
- It is reasonable to assume that 320 cross-contact hazelnut pieces would be evenly distributed in 1 500 000 particulate ingredients (i.e. one batch of S), resulting in not more than 1 hazelnut piece per 10 g package

However, given that a very small variation in hazelnut piece weight, or if only 2 pieces happen to adhere to each other and contaminate one single package of S, this would be sufficient to reach the lowest ED05 (3 mg), the FBO therefore decides to apply PAL for hazelnuts in S.

$$\textit{Particulate ingredients total weight in one batch of S} = 50 \times 0.90 = 45 \text{ kg}$$

$$\textit{Estimated number of particulate ingredients in one batch of S} = \frac{45}{0.00003} = 1\,500\,000$$

$$\textit{Estimated number of particulate ingredients in a 10 g package of S} = \frac{1\,500\,000}{5000} = 300$$

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Annex 1: Allergen hazard identification template

Product name		**Product code**	

Raw materials				
Name	**Code**	**Amount in recipe (%)**	**Allergen(s)**	
			Directly added	**Unintentional**

Receiving, handling, storage, and processing		
Step	**Potential unintentional allergen(s)**	**Rationale**

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Annex 2: Information from suppliers – Supplier requirements checklist

To be completed by the **food manufacturer** for every ingredient/raw material under assessment.

This checklist is presented only as an example, to be modified/adapted by food manufacturers according to their supplier control program's requirements.

Ingredient: *(Name, code, package size)*		**Supplier:**	

Supplier contact information:	Does the supplier hold GFSI certification? ◯ Yes ◯ No

Documentation to be provided by the supplier	Received?	Notes
1. Food safety certificate from an accredited body (e.g. SQF, HACCP, AIB, ISO, BRC)	◯ Yes ◯ N/A	*(List certificates provided)*
2. Letter of guarantee for current year/Letter of continuing guarantee	◯ Yes ◯ N/A	
3. Ingredient specification sheet	◯ Yes ◯ N/A	
4. Nutrition information per 100 g	◯ Yes ◯ N/A	
5. Certifications for specific claims, as applicable (e.g. organic, kosher, vegan, gluten-free, [specific allergen]-free)	◯ Yes ◯ N/A	*(List certifications provided)*

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Documentation to be provided by the supplier	Received?	Notes
6. Allergen information (Completed form: Allergen report)	○ Yes ○ N/A	
7. HACCP flow diagram with Critical Control Points (CCPs)	○ Yes ○ N/A	
8. Regulatory requirements (per country of origin of ingredient)	○ Yes ○ N/A	*(List documents provided)*
9. Allergen-related Standard Operating Procedures (SOPs) (e.g. receiving, storage, changeover, cleaning, testing, training of personnel)	○ Yes ○ N/A	*(List SOPs provided)*
10. Other documentation	○ Yes ○ N/A	*(Specify additional documentation provided)*

Decision	○ **Supplier is APPROVED** ○ **Supplier is NOT APPROVED**
Justification (Describe the evidence and/or arguments supporting the decision to approve or not approve this supplier)	
Completed by	
Date	

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Example of an allergen report

To be completed by the **supplier** for every ingredient under assessment.

This report is presented only as an example, to be modified/adapted by food manufacturers according to their supplier control program's requirements.

Product (ingredient supplied): *(Name, code, package size)*		**Supplier:**	

Allergens/ other components	**Please indicate YES or NO**					
	Intentionally added to the finished product	**Raw materials indicate could be in the product** (e.g. raw materials in the ingredient formulation have precautionary allergen statements)	**Present in processing aids used in the product's manufacturing**	**Present in other products manufactured on the same line**	**Present in the same manufacturing facility**	**Tested for in final product**
Peanuts						
Tree nuts *(e.g. almond, Brazil nut, cashew, hazelnut [filbert], macadamia nut, pecan, pine nut, [pinyon, piñón], pistachio, walnut)*						
Sesame						
Milk *(e.g. butter, casein, buttermilk, cheese, cottage cheese, curds, whey, malted milk, lactoglobulin, lactose)*						
Egg *(e.g. albumen/egg white, egg yolk)*						

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	Please indicate YES or NO					
Allergens/ other components	**Intentionally added to the finished product**	**Raw materials indicate could be in the product** (e.g. raw materials in the ingredient formulation have precautionary allergen statements)	**Present in processing aids used in the product's manufacturing**	**Present in other products manufactured on the same line**	**Present in the same manufacturing facility**	**Tested for in final product**
Fish						
Crustacea *(e.g. shrimp, prawns, crab, lobster)*						
Mollusks *(e.g. abalone, snail, clam, oyster, mussel, scallop)*						
Soy products *(e.g. soy-derived vegetable protein, textured vegetable protein, miso, tofu, lecithin)*						
Wheat *(and related strains such as spelt, triticale, etc.)*						
Barley *(including malt and flavorings)*						
Rye *(including malt and flavorings)*						
Oats						
Sulphites *(at any level)*						
Mustard						
Other *(specify)*						

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Annex 3:
Analytical allergen testing and sampling

Testing for allergen presence or concentration can be an important part of allergen management and complement allergen control practices. Testing may reveal whether the preventive measures implemented to control allergen hazards are effective. However, the interpretation of a testing result is only meaningful if the method used is fit for purpose and if the sampling plan is adequate.

Sampling plans for food allergen testing are specific to the allergen, food matrix, and manufacturing operation, and need to consider the purpose of the testing and the acceptable or tolerable level of uncertainty. Due to these unique characteristics, sampling plans for food allergen hazards have not been proposed by standardization bodies. However, sampling is critical to obtain meaningful testing results and to correctly interpret them; and efforts to develop a robust sampling plan adapted to the testing goals are necessary. Consider the following factors when developing a testing program for allergen testing:

Establish the relevance of analytical testing

Analytical methods can provide valuable information for allergen control and risk management. Possible applications include cleaning validation, cleaning verification, allergen cross-contact quantification, and verification of raw materials' allergen profile. However, depending on the type of information needed and the characteristics of the allergen / food matrix, analytical methods may not be the best tool. For example, analytical testing, including surface swab testing, is of limited value for visible allergen "pieces" (e.g. particulates). Also, where heterogeneous contamination is likely to occur, a sampling plan could miss contaminated sites or items, and analytical results may lead to a false sense of security regarding the total volume processed during the production run. Heterogeneous contamination may be a result of cross-contact with nut chunks, sesame seeds or other particulate allergens, or of cross-contact occurring only at a specific point in the process (e.g. at a crossover point). This type of contamination would result in only a portion of the products being contaminated, potentially at high levels (as opposed to homogeneous, low-level contamination of an entire production batch). In these cases, food manufacturers may adopt a selective approach, and identify, based on a cross-contact assessment, specific sites that are likely to be cross-contaminated (e.g. difficult to clean areas of equipment that cannot be disassembled). These sites would then be subject to enhanced visual inspection (per visibly clean standards), as part of a cleaning verification procedure.

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Allergen testing methods

Consider the following factors when selecting the most suitable analytical method for the required application:

- food matrix
- allergen form (e.g. protein fraction, protein subject to processing, intact protein)
- type of measurement (i.e. qualitative, quantitative)
- type of sample (e.g. food contact surfaces, non-food contact surfaces, environment, in-process material, finished products, raw ingredients)
- limit of detection (e.g. sufficiently low to detect allergen presence to assure a defined level of consumer protection)
- potential cross-reactivity with other sample components (e.g. proteins of the same family as the target allergen)
- potential interference of other substances (e.g. disinfectants, detergents)
- how much the test results are expected to vary if the same sample is retested on another occasion

A given method may be suitable for an allergen in a particular food matrix, but not for the same allergen in a different matrix (e.g. a method for detecting almond in a granola bar type product may not be suitable for detecting almond in other nut/seed butter spreads). In addition, even for kits that measure/detect the same allergens, there are important differences between the different manufacturers and as such, each kit needs to be evaluated for the product/food matrix involved. Consultation with independent technical sales personnel and with analytical methods standardization organizations (e.g. AOAC International, n.d.) is essential. Currently, available methods for allergen detection and/or quantification, include ELISA, mass spectrometry and polymerase chain reaction, among others (Table 9). However, this information is subject to change as food allergen detection and quantification technologies and their functionalities are in constant development. If sending samples to a 3rd party laboratory, providing them with specific details of the product composition and of the composition of the product that may be contributing to the cross contact is critical so that they can evaluate interferences, false positives or negatives, etc. It is also important to include positive and negative controls in any testing to ensure performance of assay method and ability to detect the allergen of interest. Depending on the goals of the testing program or study, a combination of methods may be required (e.g. allergen-specific surface swabs and quantitative ELISA tests for in-process material).

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Determine what will be tested

Different testing programs will involve different types of samples. It is the food manufacturer's responsibility to establish their specific needs. Generic examples are provided in Table 9.

Table 9: Examples of food allergen testing samples

Sample*	Application	Analytical method(s)**	Considerations
Food contact surfaces	Monitor residual allergens	LFD	• Test immediately after cleaning or before process startup • Select sampling sites based on worst case (e.g. areas difficult to clean, areas where product buildup is likely)
In-process materials	Monitor residual allergens	LFD, ELISA, PCR, MS	• Test immediately after process startup and during the production run • Quantitative methods required if establishing the level of cross-contact allergens (e.g. verification of risk assessment estimates, PAL assessment)
Air samples	Monitor allergens transferred via aerosols and dust	Settle plates	• Test during production • Place settle plates in suspected areas
Rinse water	Validation or verification of wet cleaning / CIP systems	LFD, ELISA, PCR, MS	• Test final rinse water
Flushing materials	Validation or verification of cleaning systems that use flushing materials	LFD, ELISA, PCR, MS	• Test final flushing material
Finished product	Establish allergen status of finished products	LFD, ELISA, PCR, MS	• For non-compliance, test several samples from the same lot and establish the level of contamination • As part of cleaning validation or verification, test first finished products from line. Not recommended as the only sample type of an allergen cleaning or validation program
Ingredients	Establish compliance with allergen requirements	LFD, ELISA, PCR, MS	• Test ingredients based on risk assessment of potentially problematic ingredients and/or suppliers

* The presence of allergens in samples other than finished products and ingredients indicates that the cleaning protocol needs revision, but it does not necessarily mean that the finished product contains cross-contact allergens. From a risk assessment perspective, the crucial point is the transfer of allergens to the finished product. For example, it is possible that a surface swab tests positive, while the first product run through the line is within acceptable limits.

** Protein-specific or total protein lateral flow devices (LFD), Enzyme Linked ImmunoSorbent Assay (ELISA), Polymerase Chain Reaction (PCR), Mass Spectrometry (MS)

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Determine sampling plan and testing frequency

Cleaning validation

Unintended allergen occurrences in finished products may vary even within the same production run. Variations within a run or between runs could be the result of several factors, such as variable levels of unintended allergens in raw materials, heterogeneous allergen contamination, irregular efficiency of cleaning procedures, etc. To account for these variations, a minimum of 3 repetitions (i.e. 3 successful cleaning procedures) is usually considered for cleaning validation. Validation should be conducted whenever changes (in supplies, methods, equipment, etc.) are introduced. Even if the cleaning procedure remains the same as when it was initially validated, it is necessary to reassess its validity within a set frequency (e.g. once per year).

Finished products

Finished product testing on its own should not be the basis for allergen management decisions. The information collected from testing only this type of sample is likely to be inconclusive due to the variable nature of allergen cross-contact. In addition, a preventive rather than a reactive approach is regarded as the foundation of allergen management. Nevertheless, finished products may be tested as part of a comprehensive study including other types of samples (e.g. cleaning validation, root-cause analysis for non-compliance). Sample collection times and/or sites will depend on the type of process and from where cross-contact might be coming.

Raw material surveillance

Food manufacturers may choose to monitor the allergen status of raw materials to verify compliance, for example, as part of routine surveillance or non-compliance investigations. For routine surveillance, sampling frequency is based on risk assessment (i.e. considering the raw materials inherent characteristics and the supplier's history of compliance and other risk factors). For example, manufacturers may choose to test every shipment of high-risk raw materials from new suppliers, and not to test low-risk raw materials from suppliers who have a demonstrated history of compliance and who provide certificates of analysis with every shipment. When testing is relevant, food manufacturers may establish the sample size considering the volume of raw material received per delivery, the characteristics of the raw material (e.g. bulk, prepacked, liquid, grains), and the tolerated level of uncertainty.

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Agricultural commingling: Process through which an exchange occurs between different crops during cultivation, primary processing, storage and/or transportation.

Allergen control plan (ACP): Systematic method for identifying and controlling allergen hazards from the incoming ingredients to the final packaged product in any food processing plant.

Allergen management team: Cross-functional team responsible for assessing allergen risk and developing control measures to mitigate those risks.

Allergen master list: Document listing all raw materials used in a facility, identified by company codes, and clearly identifying all relevant allergens associated with those raw materials.

Anaphylaxis: Immediate hypersensitivity resulting in an acute, potentially life-threatening systemic reaction.

Celiac disease: Immune-mediated systemic disease triggered by the consumption of gluten. Although there may be common symptoms to allergic reactions, celiac disease does not cause acute reactions.

Chemical hazards: Chemical substances that can cause physical or health hazards. These substances may occur naturally or may be introduced during food processing.

Cleaning validation: Process that generates evidence demonstrating that a cleaning procedure can control a specific hazard.

Cleaning verification: Continuous process to determine if validated cleaning procedures are operating as intended.

Compliance history: Recorded history of a supplier's respect of product specifications and requirements.

Corrective actions: Actions taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product, if any, and prevent or minimize reoccurrence of the deviation (Codex Alimentarius, 2011).

Critical control point: Step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Codex Alimentarius, 1997).

Cross-contact assessment: Assessment conducted by a cross-functional team to identify receiving, handling, storage, and/or processing steps where there is unintentional transfer of allergens.

Eliciting dose (ED): Total dose of protein from an allergenic source (expressed in mg) predicted to produce an objective response in a percentage of an allergic population.

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Exposure dose: Quantity of protein from an allergenic source expected to be in an amount of finished product representing an eating occasion.

Food allergen: Otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food, capable of triggering a response in individuals who are sensitized to it (Codex Alimentarius, 2020).

Food risk analysis: Systematic disciplined approach to apply science-based analysis and take consistent solutions. Risk analysis consists of risk assessment, risk management and risk communication (World Health Organization & Food and Agriculture Organization of the United Nations, 2006).

Hazard analysis critical control points (HACCP): Systematic approach to identifying biological, chemical and physical hazards that present a risk of contamination in food products, and to determine the control measures needed to prevent, eliminate or reduce to an acceptable level the identified hazards (Canadian Food Inspection Agency, 2021c).

HACCP plan: Document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration (Codex Alimentarius, 1997).

Ingredient specification: Control document provided by a supplier with relevant ingredient information on quality, sensory, allergens, nutrition, labelling, certification, physical, chemical and microbiological attributes. The document also includes limits for critical attributes and any other stipulations or expectations agreed by both the supplier and customer.

PrecautionaryAllergen Labelling (PAL): Declaration on the label of a prepackaged food of the possible inadvertent presence of an allergen in the food (Health Canada, 2012).

Prerequisite programs: Programs that are in place to ensure that the general environment of future food transformation is appropriate for safe food production (Canadian Food Inspection Agency, 2021c).

Preventive control measures: Measures in place to prevent or mitigate risk of identified hazards and reduce them to an acceptable level.

Preventive control plan: Written document that demonstrates how hazards to the food being produced are identified and prevented, eliminated or reduced to an acceptable level (Government of Canada, 2018).

Qualitative risk assessment: Systematic approach to evaluate the risk of a particular situation using non-numerical terms (e.g. high, medium, low).

Quantitative risk assessment: Systematic approach to evaluate the risk of a particular situation using numerical values.

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Recall plan: Written and organized plan of the procedures to follow when there is a need to recall a food product (Canadian Food Inspection Agency, 2018c).

Reference dose: Food allergen eliciting dose that is used as a threshold or reference value for the implementation of further action, e.g. specific risk management and risk communication measures.

Risk assessment: Scientifically based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment, and risk characterization (Food and Agriculture Organization of the United Nations & World Health Organization, 1997).

Risk communication: Interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties (Food and Agriculture Organization of the United Nations & World Health Organization, 1997).

Risk management: Process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures (Food and Agriculture Organization of the United Nations & World Health Organization, 1997).

Supplier management program: The identification, assessment and approval of a new supplier, and the verification of the approved status of existing suppliers at a predetermined frequency.
The program involves — but is not limited to — the following steps:

- Identifying potential suppliers of an ingredient
- Assessing the food safety, quality, functionality, and the regulatory requirements of the ingredient
- Creating contracts, negotiating terms and reaching agreements
- Establishing key performance indicators (KPIs), monitoring performance and reporting on delivery

Traceability: The ability to track a given food or ingredient from its point of production (e.g. farm, abattoir, harvest at sea) through processing, manufacturing, and transportation to retail and sale to consumers (Institute of Food Technologists, n.d.).

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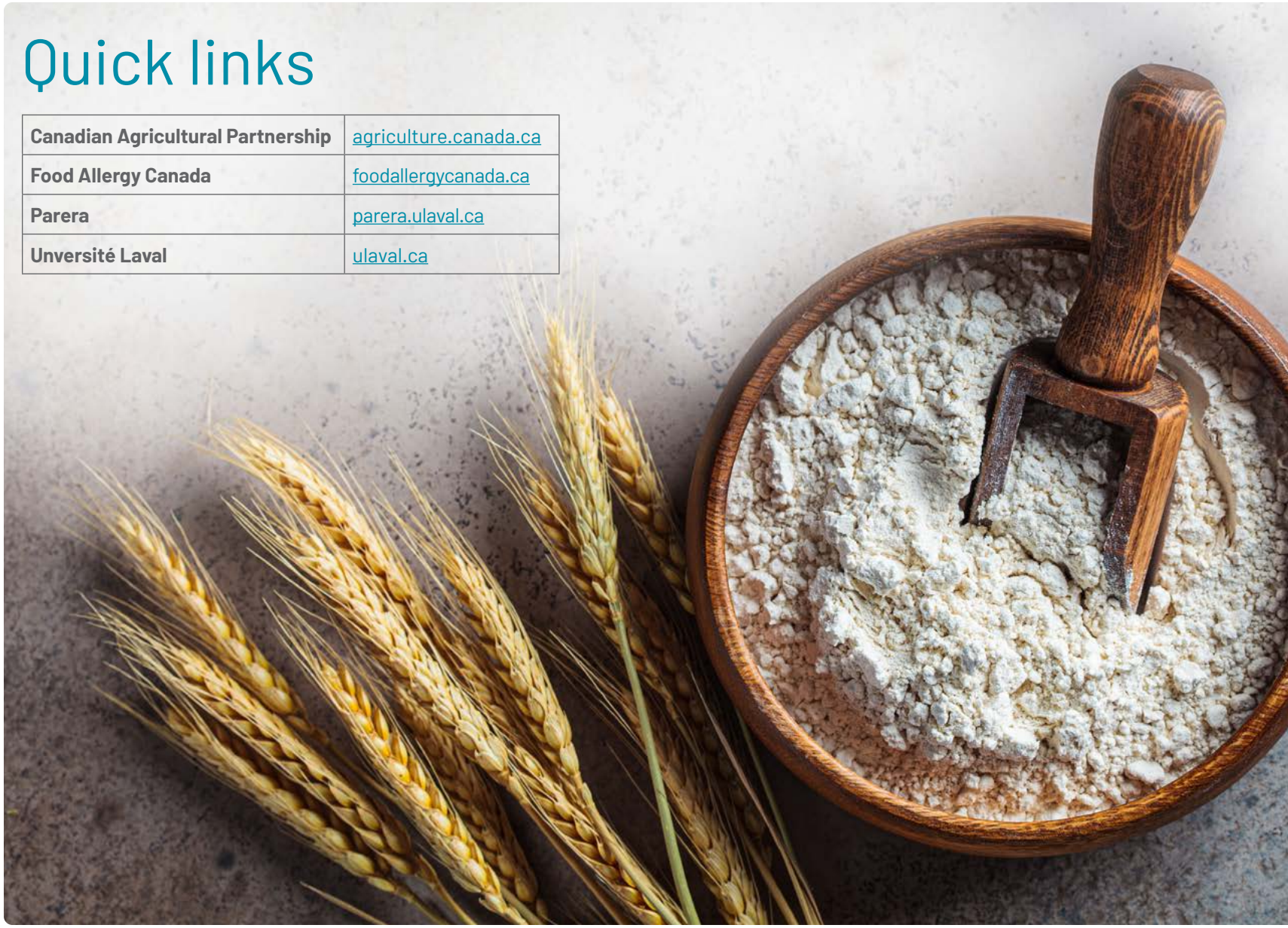

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