UNIVERSITÉ LAVAL

parera
Food Risk Analysis and Regulatory Excellence Platform

Food Allergy Canada

ALLERGEN RISK MANAGEMENT

& Precautionary Allergen Labelling Guidelines

AGENDA

Why change is needed: multi-stakeholder perspectives to support moving forward

- **Food Allergy**
  - Consumer Perspective – Beatrice Povolo, Food Allergy Canada

Why now? What is underpinning the opportunity for change

- Update on international discussions and recommendations of the FAO/WHO Expert Working Group on Risk Assessment of Food Allergens - Dr. Samuel Godefroy, Université Laval

The Path Forward

- Introduction of the Allergen Management Guidelines – Dr. Silvia Dominguez, Université Laval

Q&A

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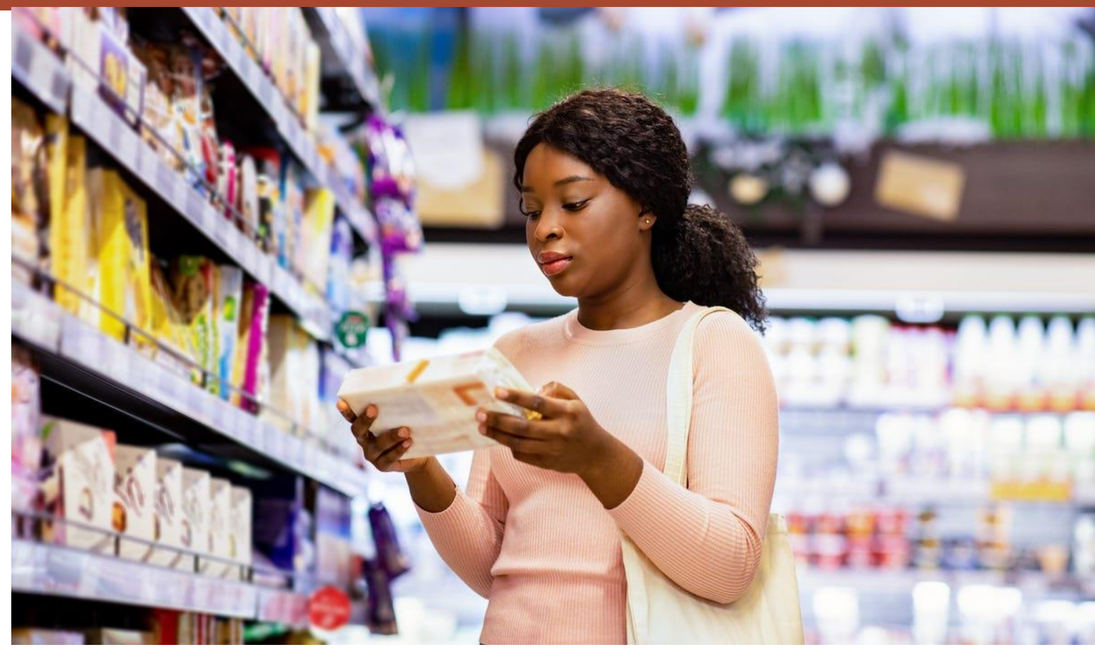
Canada

FOOD ALLERGY

CONSUMER REALITY

Current Reality

- There is no cure for food allergy
- Primary management is avoiding your allergen
- Need for vigilance in all settings – “need to know what is in your food”
- Accidents happen despite best efforts



Having access to complete and accurate ingredient information is key to making informed choices and staying safe

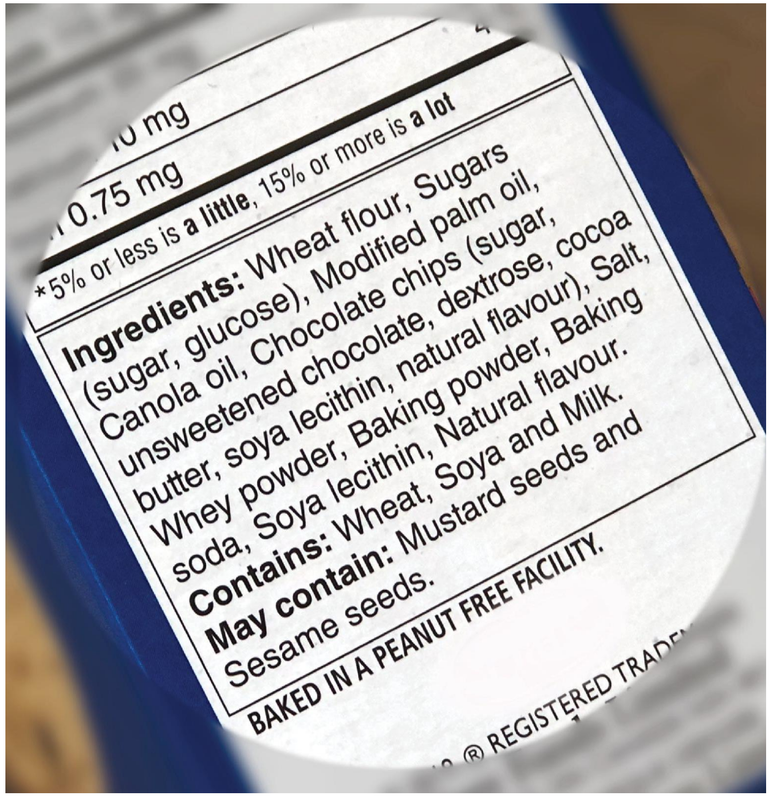
EX. REGULATORY FRAMEWORK: CANADA

Allergens declared in the ingredients list

- Mandatory
- Intentionally added ingredients

vs. Precautionary Allergen Labelling

- Voluntary
- Unintended presence allergens
- Must be truthful, clear, non-ambiguous and not a substitute for GMP
- To be used only after implementing all reasonable measures to avoid the allergen presence



Health Canada's two goals for PAL*:

1. to minimize risk for those with food allergies; and
2. to maximize choice of safe and nutritious foods for consumers with food allergies

**The Use Of Food Allergen Precautionary Statements On Prepackaged Foods 2012*

CONSUMER CHALLENGE

BLANKET STATEMENT

May contain *eggs, milk, fish, molluscs, crustaceans, mustard, peanuts, sesame, sulphites.*

OTHER FOOD OPTIONS

In-store/bulk departments

Restaurants

CONCERNING TRENDS

Tough New Labeling Law for Sesame Prompts Companies to Add It to Their Products

- US FASTER Act - Jan 1 ‘23
- Some manufacturers adding sesame as an ingredient to avoid PAL
- Reducing choices for consumers

INGREDIENTS

MADE FROM: ENRICHED WHEAT FLOUR (FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), WATER, SUGAR, YEAST, SOYBEAN OIL, WHEAT GLUTEN, CONTAINS 2% OR LESS OF: SALT, CALCIUM PROPIONATE AND SORBIC ACID TO EXTEND FRESHNESS, MONOGLYCERIDES, DATEM, MALTED BARLEY FLOUR, NONFAT MILK, SESAME SEEDS.
CONTAINS: WHEAT, MILK, SESAME SEEDS.

E- commerce Sales

- Lack of disclosure of ingredient /allergen information on online ordering platforms
- Common scenarios include:
  - ➢ No ingredient information provided
  - ➢ Inconsistent ingredient information provided online vs on the package
  - ➢ No information on precautionary allergen labelling statements (e.g., may contain)

Ingredients

DURUM WHEAT SEMOLINA, NIACIN, FOLIC ACID, FERROUS SULFATE, RIBOFLAVIN, THIAMINE MONONITRATE. ALLERGENS: CONTAINS WHEAT.

PAL on product; not listed online

VEGAN PRODUCTS

- Allergic consumers with milk and/or egg allergy view these products as ‘safe’

- CFIA Recalls for Milk – 2022
  - 47 milk related recalls
    - 22 in dark chocolate products
    - 50% have a Vegan claim

- Vegan claims can be interpreted and used on a company-by-company basis:
  - need for greater clarity and standards for managing allergens

“Vegan” and “plant-based” claims: risk implications for milk- and egg-allergic consumers in Canada

Silvia Dominguez[1*], Jérémie Théolier[1], Kamila Lizée[1], Beatrice Povolo[2], Jennifer Gerdts[2] and Samuel B. Godefroy[1]

https://link.springer.com/article/10.1186/s13223-023-00836-w

RESULTING BEHAVIOUR

- Consumers making their own risk assessment to ensure adequate food choice considering:
  - their perception of the allergen actually being in the product
  - not having any prior reactions to the product
  - the type of allergen(s)

- Purchasing more foods with PAL then previously
- Lack of confidence in the label results in QoL impacts

PATH FORWARD

- Improved allergen control plans for Canadian Food Manufacturers

- Risk-based approach to PAL

Accurate labelling that consumers can trust

CODEX & FAO/WHO EXPERT CONSULTATION ON ALLERGENS

Update on proceedings and recommendations

CODEX WORK ON FOOD ALLERGENS

The Codex Alimentarius Commission led the way in supporting Food Allergen Management

- **Labelling Rules** – Starting from the definition of Priority Food Allergens
- **Major Accomplishments in the 1990s**:
  - 1999 Codex Standard on Food Allergen Labelling
    - CCFL: Codex Committee on Food Labelling
    - CCFH: Codex Committee on Food Hygiene
  - Further interventions from 2018 onward

CODEX 60
CODEX ALIMENTARIUS 1963-2023

FAO/WHO EXPERT CONSULTATION ON RISK ASSESSMENT OF FOOD ALLERGENS

- Objectives

1. Validate and update the **list** of foods and ingredients in section 4.2.1.4 of the General Standard for the Labelling of Packaged Foods based on risk assessment
2. Establish **threshold** levels in foods of the priority allergens, and
3. Evaluate the evidence in support of **precautionary labelling**

- 3 meetings between 2020-2022

1. REVIEW & VALIDATION OF PRIORITY ALLERGENS LIST

- Only foods or ingredients that cause immune-mediated hypersensitivities should be included
- Criteria: prevalence, severity & potency

- Global priority allergens:
  - **Cereals containing gluten, crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts** – (not soy)
  - Other allergens **(i.e., celery, lupin, mustard)** not on global list due to lack of data or due to regional consumption

- Watch list: **pulses, insects and other foods (e.g., kiwi)**

2. THRESHOLD LEVELS OF PRIORITY ALLERGENS

- What are the **threshold levels** (of exposure) below which most allergic consumers would not suffer a severe reaction?
  - Based on ED05

	RfD Recommendation (mg total protein from the allergenic source)
Walnut (and Pecan*)	1.0
Cashew (and Pistachio*)	1.0
Almond**	1.0
Peanut	2.0
Egg	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Shrimp	200
Milk	2.0
Sesame	2.0

FAO/WHO (2021; 2022)

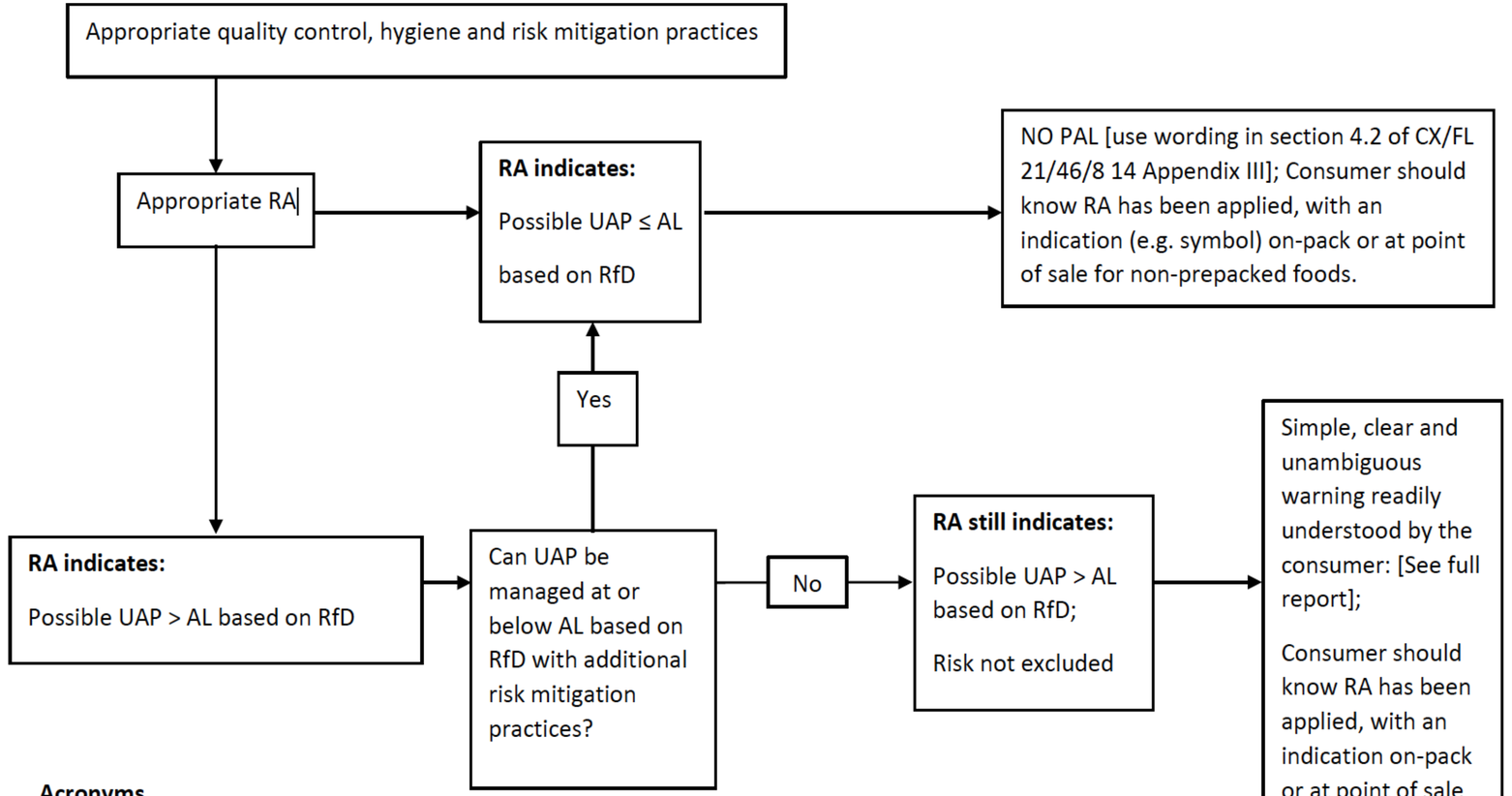
Analytical considerations:

- What are appropriate analytical methods for testing food and surfaces?
- What should be the minimum performance criteria for these analytical methods?

3. PRECAUTIONARY LABELLING OF PRIORITY ALLERGENS

- **PAL = effective** strategy to protect consumers from UAP when based on:
  - Comprehensive allergen risk management program
  - Single clear statement
  - Effective risk communication

- PAL decisions should be part of a **regulatory framework** (PAL when possible UAP > Action Level based on RfD)



Acronyms

RA: Risk Assessment

UAP: Unintended Allergen Presence

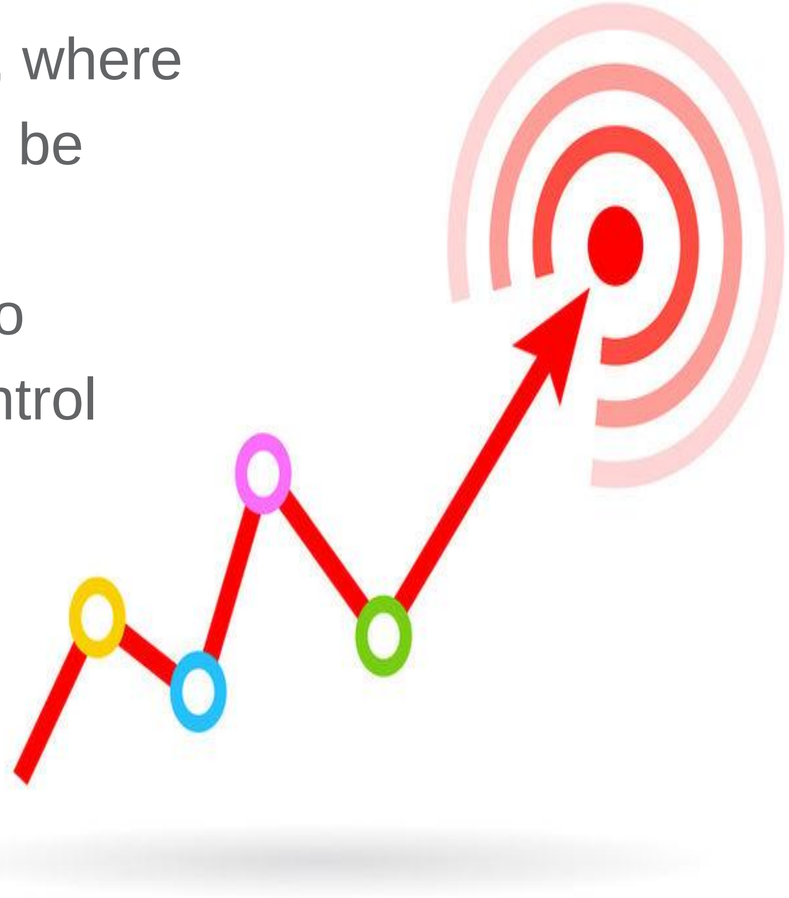
AL: Action Level

RfD: Reference Dose

NEXT STEPS

- Reliance on newly developed Guidance by Codex to develop updated allergen labelling standards
- Possible development of a Guidance on the use of PAL, where incorporation of risk assessment-based decisions would be advocated
- Consistent approach to inform consumers and be able to discriminate foods that were subject to food allergen control
- Continued activity for years to come

CCFL Meeting: October 2024



OVERVIEW

Allergen Management Guidelines
for Food Manufacturers

APPROACH

Available guidance

Summary of existing guidance

New data

Manufacturers survey

Validation

Review by all stakeholders

1 2 3 4 5 6

Stakeholders

Brainstorming sessions

Drafting & Reviewing

Drafting committee

Guidelines v1

- ✓ Allergen management best practices
  - Internationally recognized
  - Canadian manufacturers' input
- ✓ Structured risk assessment approach
  - Guide PAL decisions
  - Better meet needs of allergic consumers

CONTENT

Glossary

I. Foreword

II. Purpose

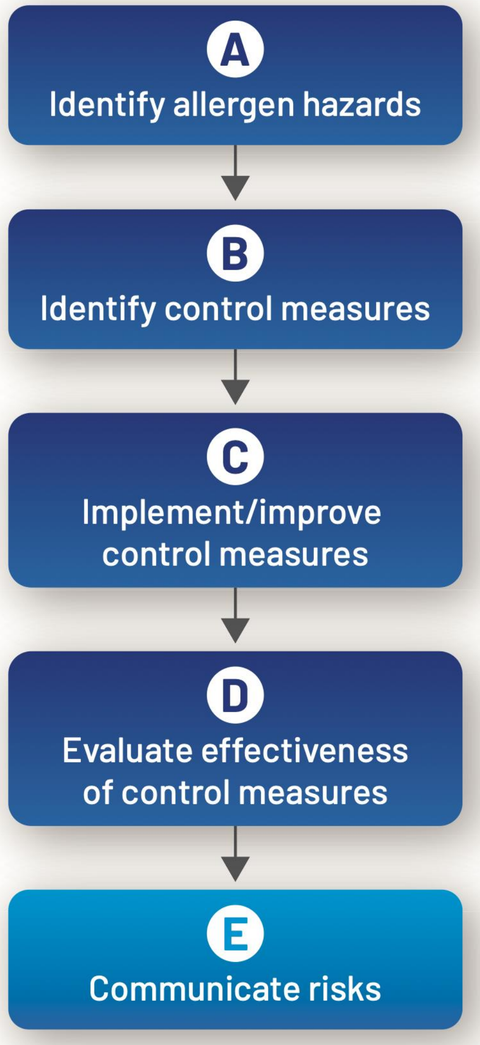
III. Food Allergy in Canada

IV. Regulatory Framework

V. Allergen Management in the Food Industry

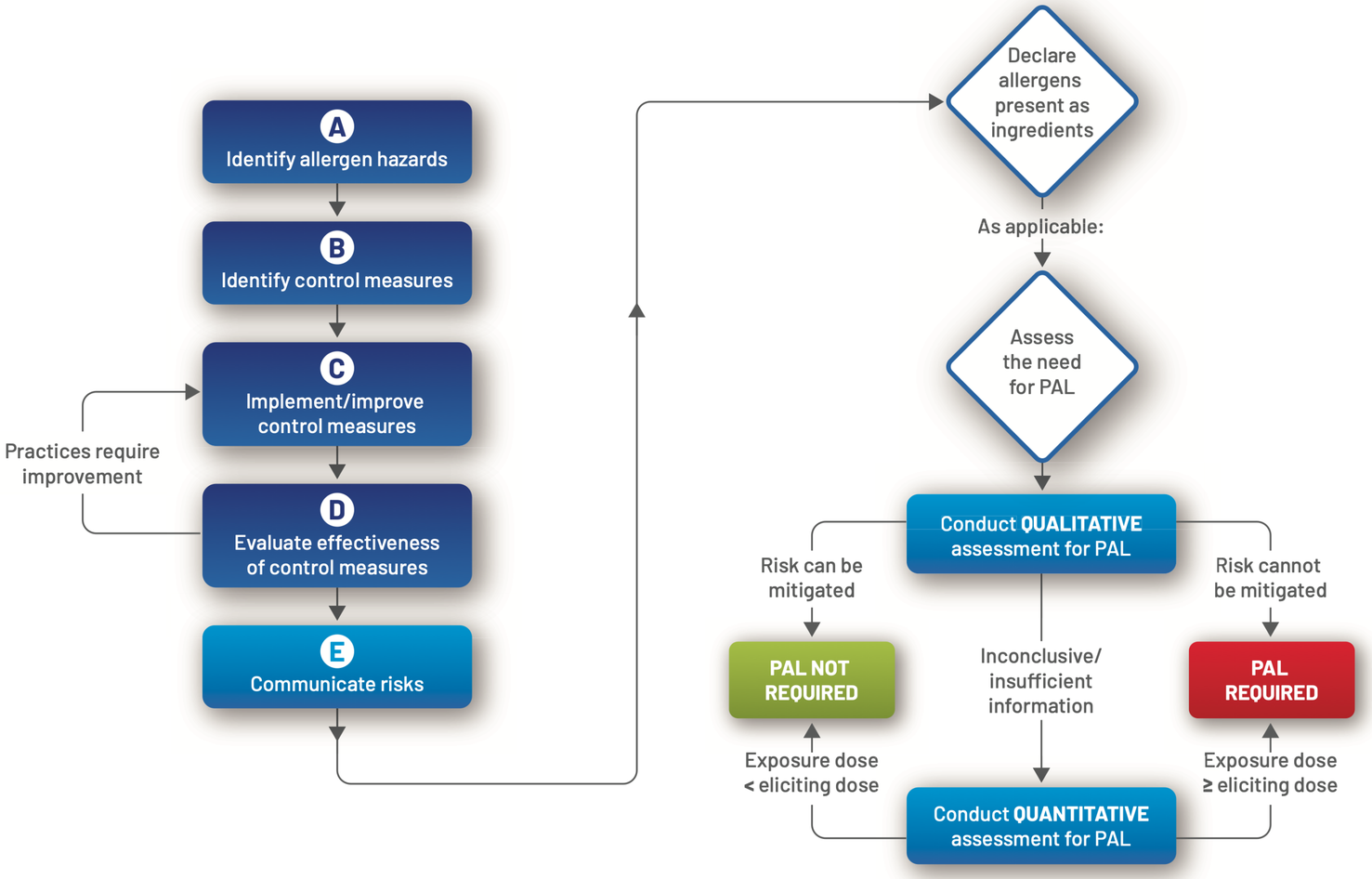
An **ACP** outlines:

- A facility's strategy to prevent introducing unintended allergens to a product
- How specific measures are to be implemented, monitored, and evaluated



E. COMMUNICATE RISKS

PAL DECISIONS



- 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**)

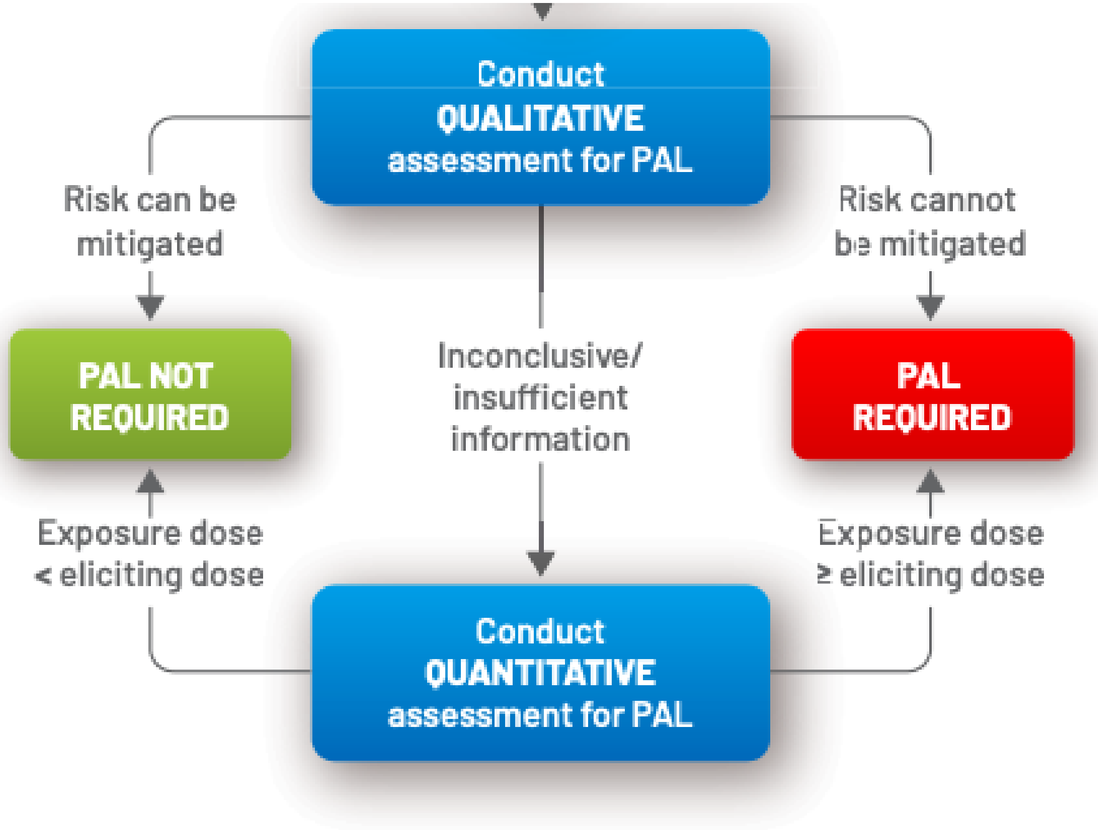
- **Qualitative assessment**
  - Weight of evidence

- **Quantitative assessment**
  - Reference dose

QUALITATIVE ASSESSMENT

- **Objective evidence** where control measures fail or pass; entire process

- **Weight of evidence** = some factors stronger / more direct effect on UAP than others
  - Influenced by the experience of the assessors
  - Multidisciplinary team, thorough knowledge of the operation



QUALITATIVE EX: COOKIES

Context

- Cookie (A) containing milk processed before cookie (B) not containing milk. Is PAL for milk needed?

Evidence

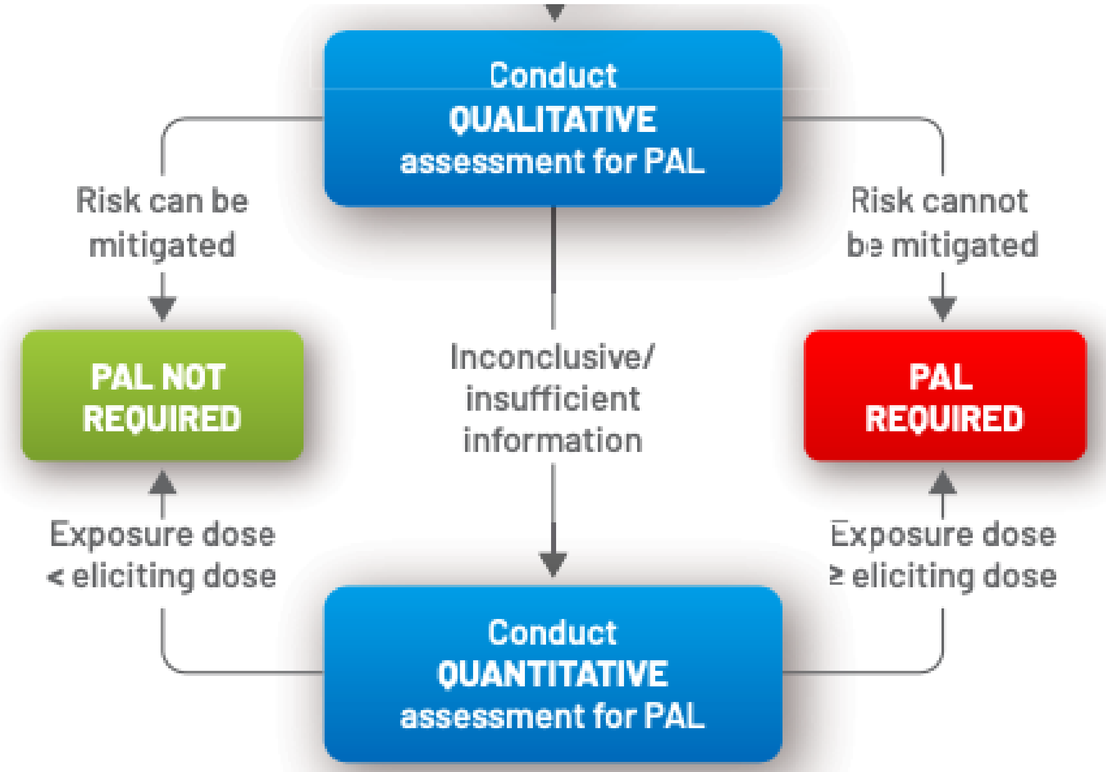
Production step	Control measures	Evidence	Weight
Raw materials	Ingredient containing milk: skim milk powder. Receiving procedures in place; personnel trained	Milk is clearly identified, handled and stored. **Cross-contact is unlikely** at this step	Weak
Design of premises and equipment	Equipment is recent and allows for proper cleaning	Equipment design does not hinder cleaning but **does not directly prevent cross-contact**	Weak
Production	Scheduling cannot be changed. Presence of milk in A is addressed in changeover procedures. Training of changeover personnel is adequate and conducted at the required frequency	Possibility of cross-contact is addressed in changeover procedures, but they **do not ensure absence of cross-contact**	Medium
Cleaning	Cleaning consistently 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, per SOPs. The validation study is robust and recent. Cleaning is verified per SOP, specifically targeting milk detection on surfaces.	**Cleaning assures no visible residue and analytical tests report undetectable milk proteins in B**	**Very strong**

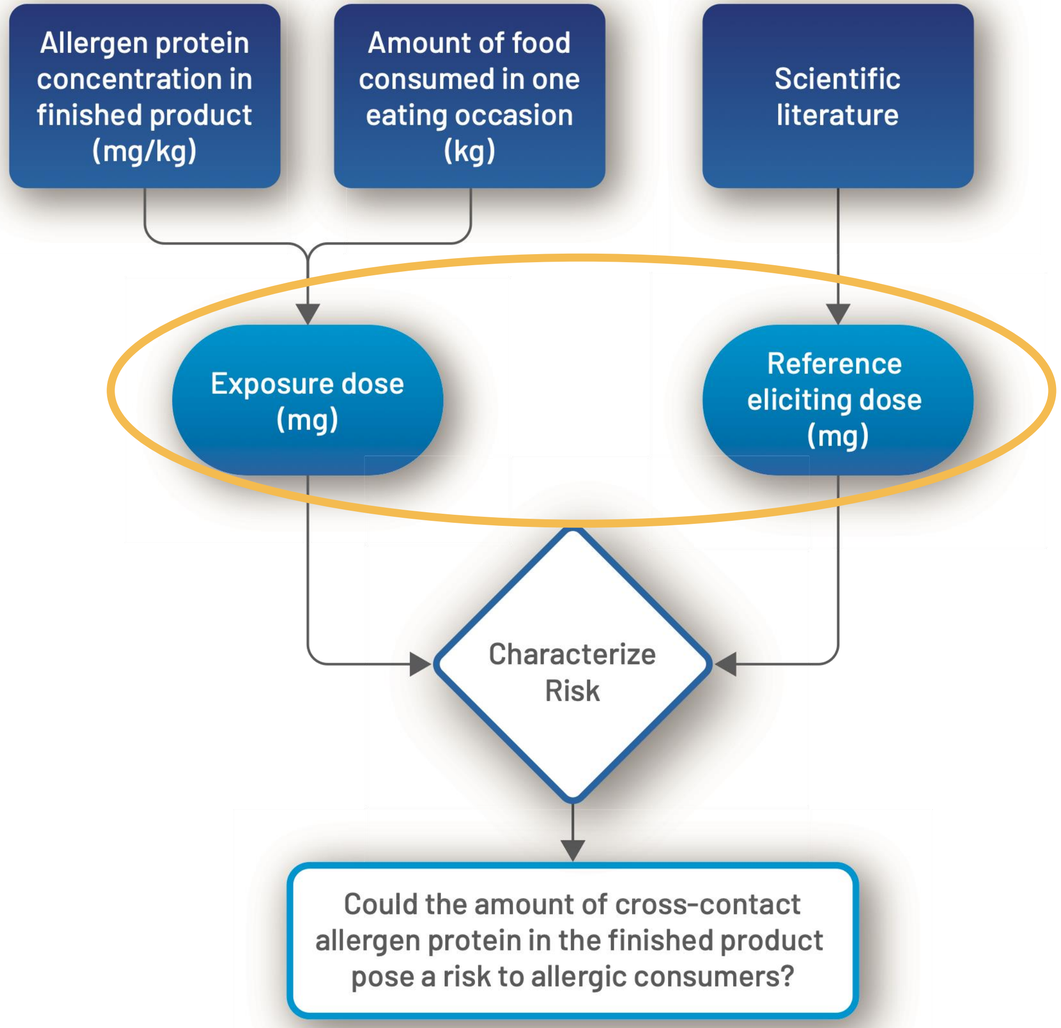
Conclusion

- Control measures can consistently prevent occurrence of milk in cookie B, when produced after A. PAL for milk not required.

QUANTITATIVE ASSESSMENT

- If qualitative assessment is inconclusive
- Worst-case scenarios





QUANTITATIVE EX: CHIPS

Context

- Chips manufacturer
- Ingredient = seasoning mix with PAL for soy
- Carry forward?

Reference ED

Food consumption

- CCHS 2015, savory snacks
- 2 bags of chips (56 g) > mean and P50

Allergen	Recommended reference dose (mg total protein from the allergenic source)		
	VITAL scientific expert panel (2019)		FAO/WHO expert consultation (21/22)*
	ED01	ED05	ED05
Soy	0.5	10.0	–

QUANTITATIVE EX: CHIPS

Allergen concentration in the finished product

Soy protein concentration in spice mix

Allergenic food	Protein content (%)
Whole soybean	40

total soy flour × protein fraction in soy flour

Soy protein = 15 × 0.40 = 6 mg soy protein per kg spice mix

For 100 kg of chips

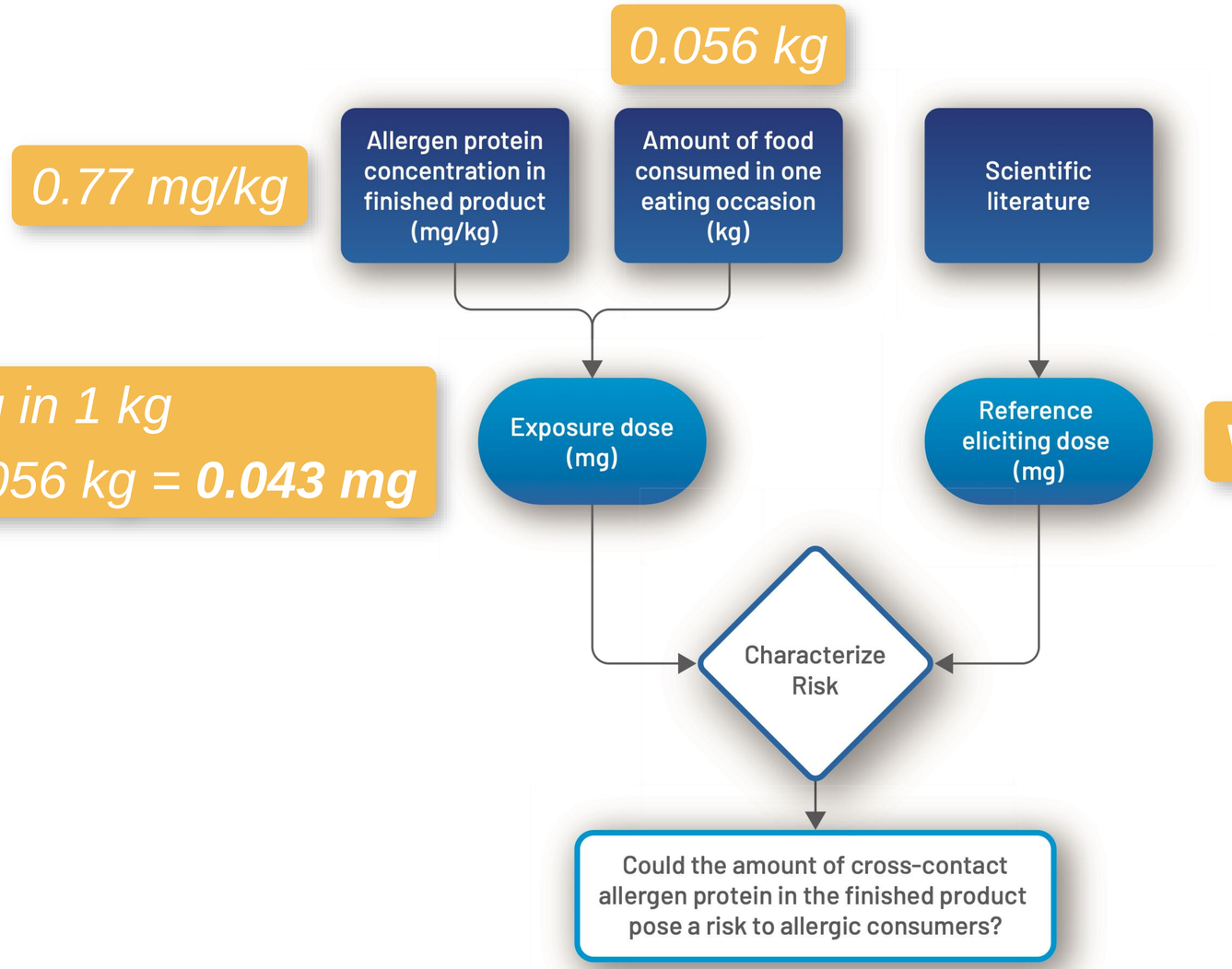
- 12 kg spice mix (per recipe), which contain 12 x 6 = 72 mg soy protein
- 6% weight loss during baking

  → after baking = 94 kg of chips

Soy protein concentration in chips:

72 mg / 94 kg = 0.77 mg soy protein per kg chips

QUANTITATIVE EX: CHIPS



0.77 mg in 1 kg
*→ in 0.056 kg = **0.043 mg***

VITAL ED01= 0.5 mg

0.043 mg < 0.5 mg
→ No PAL

KEY RECOMMENDATIONS

Robust allergen management implies

- Allergen hazard identification, including unintended allergens
- Risk-based control measures, based on recognized best practices
- ✓Result: accurate allergen declaration

PAL based on risk assessment

- Agreement with international guidance
- 1st allergen program + understanding of control measures efficacy, 2nd qualitative assessment, 3rd quantitative, if needed
- Standardized process = meaningful for manufacturers and consumers

ACTION

- Guidelines used as a resource to develop ACP’s
- Review / enhance existing plans
- Consult as ongoing resource

DOWNLOAD

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Q & A

Discussion