ALLERGEN MANAGEMENT IN THE FOOD INDUSTRY

Canada's multi-stakeholder approach

Silvia Dominguez, PhD - Université Laval

FOOD ALLERGY

- **Food allergy:** abnormal immune response to food, immune system mistakenly treats a food protein as harmful and causes an allergic reaction
- **Anaphylaxis:** serious allergic reaction, rapid onset, may cause death

- **Impact in Canada**:
  - >3 million (500,000 children)

food allergy ≠ food intolerance

CONSUMER REALITY

- There is no cure for food allergy
- Primary management is avoidance of allergens
  - *Crucial role: food manufacturers, food regulators*

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

CONSUMER CHALLENGE

CONCERNING LABELS

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

UNEXPECTED

ALLERGY WARNING: Contains Insects
People who are allergic to shellfish may also be allergic to insects
May contain soy

PAL BEYOND PACKAGING

Restaurants

In-store/bulk departments

CONSUMER BELIEFS & BEHAVIOURS

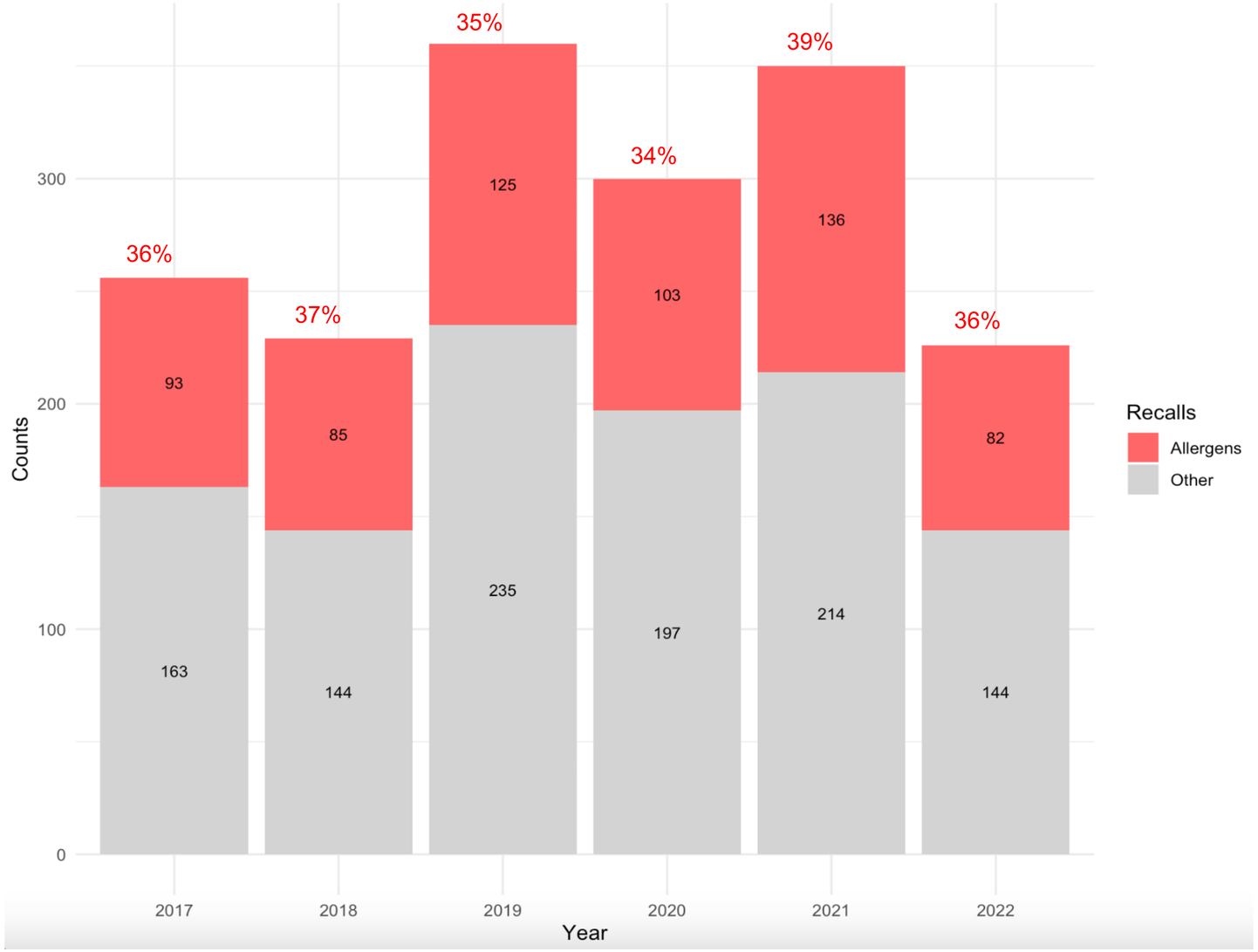
- Not overly confident in the accuracy of food labels
- No universal understanding of PAL
  - Find the concept useful but confusing
  - *What does it mean?*
- Limited safe food options
- Make their own risk assessments

Consumers need greater clarity and confidence in PAL

CFIA FOOD RECALLS

- Limitation: sampling bias
- Original recalls + updates counted separately

- Undeclared allergen recalls = trend continues



Source: inspection.canada.ca/food-recall-warnings-and-allergy-alerts/eng/1351519587174/1351519588221

THE NEED FOR CHANGE

Absence of mandatory requirements to use PAL:

- Unpredictable food regulatory environment
- Variety of criteria applied by manufacturers
- Inconsistent risk communication

Need for a consistent, harmonized approach to the effective use of PAL

Codex proposed *Guidelines on the use of PAL* (Annex to GSLPF)

- Use of PAL should be based on **hazard identification** and **risk characterization**, and adherence to *Code of Practice on Allergen Management for Food Business Operators* (**CXC 80-2020**)
- Quantitative risk assessment is preferred for PAL decisions, but other risk assessment approaches may be considered

FACILITATING ADOPTION

- Codex proposed PAL guidelines = **Improvement of the way food allergic consumers are informed and protected**

Success requires **adoption by food manufacturers**

- Foundation = stakeholders' buy-in and involvement
- Access to effective resources and step-by-step guidance
  - ✓Allergen management best-practices
  - ✓Quantitative risk assessment and use of reference doses
  - ✓Other risk assessment approaches (i.e., qualitative)

Example: Canadian initiative facilitating adoption of Codex recommendations

OVERVIEW

Allergen Management Guidelines for Food Manufacturers

PROJECT OVERVIEW

Objective

To develop consensus guidelines to advance industry practices in allergen risk management, including the use of PAL

Partnership

Food Allergy Canada

UNIVERSITÉ LAVAL

MAPLE LEAF

Canadian FBOs

Funding

PARTENARIAT CANADIEN pour l'AGRICULTURE | CANADIAN AGRICULTURAL PARTNERSHIP

Government of Canada | Gouvernement du Canada

APPROACH

Surveys:
Manufacturers
Consumers

Academia
Industry
Consumers
+ Allergists
+ Regulators
+ International experts

Available guidance

Summary of existing guidance

New data

Manufacturers survey

Validation

Review by all stakeholders

1 2 3 4 5 6

Stakeholders

Brainstorming sessions

Academia
Industry
Consumers

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

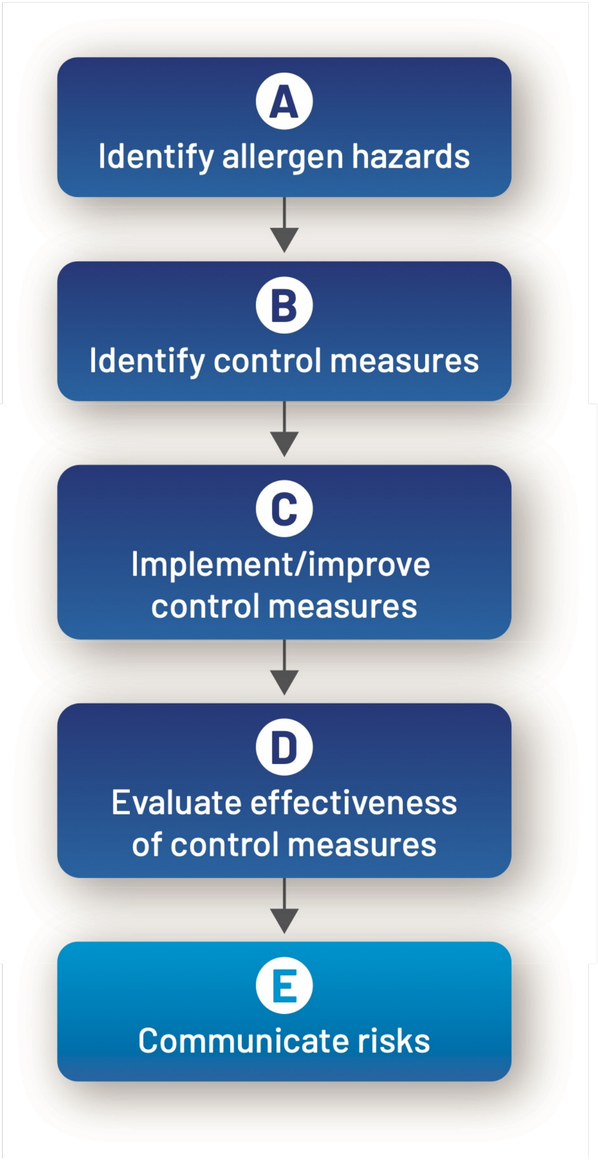
III. Food Allergy in Canada

IV. Regulatory Framework

V. Allergen Management in the Food Industry

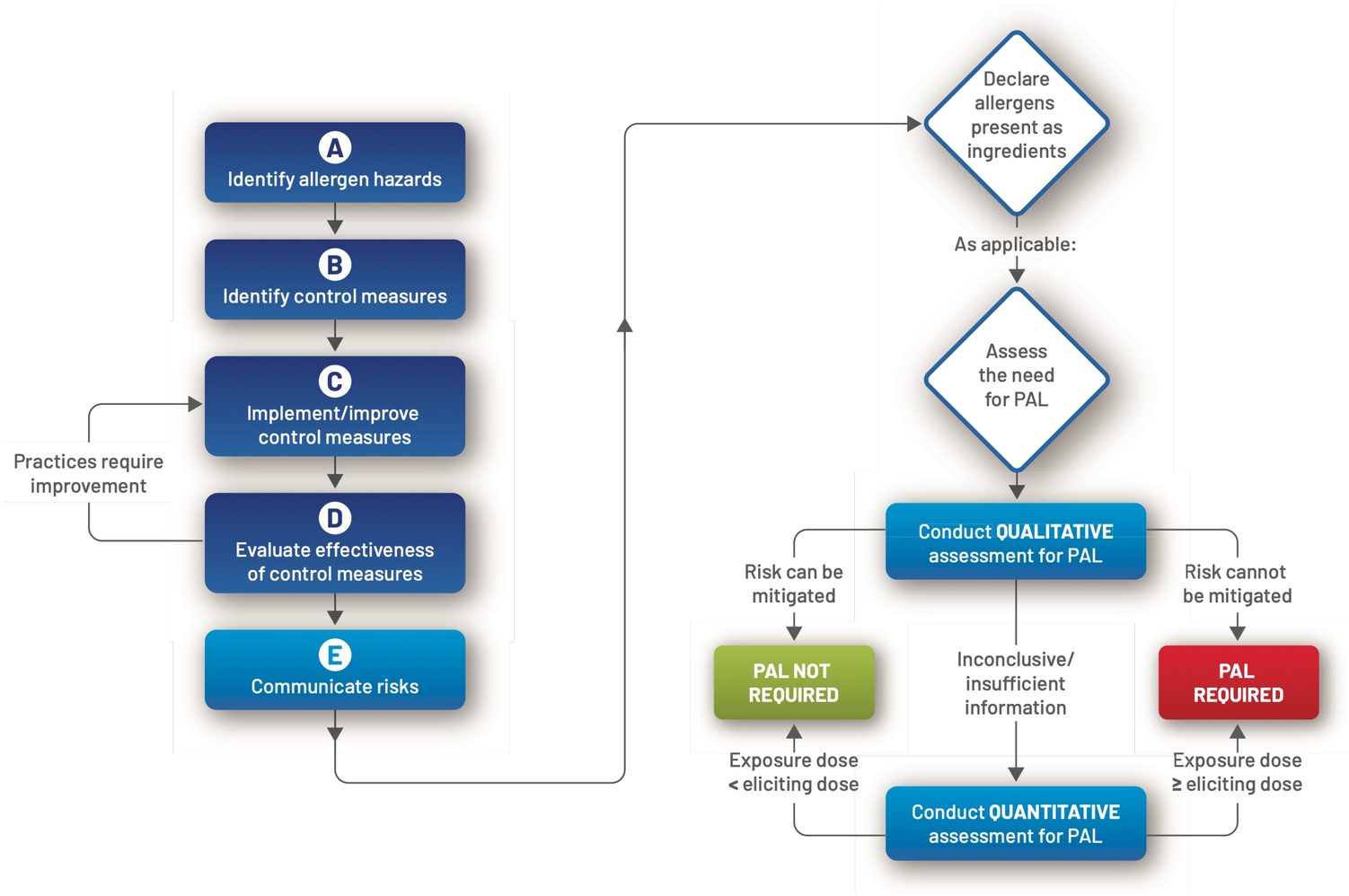
An **ACP** outlines:

- 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**)

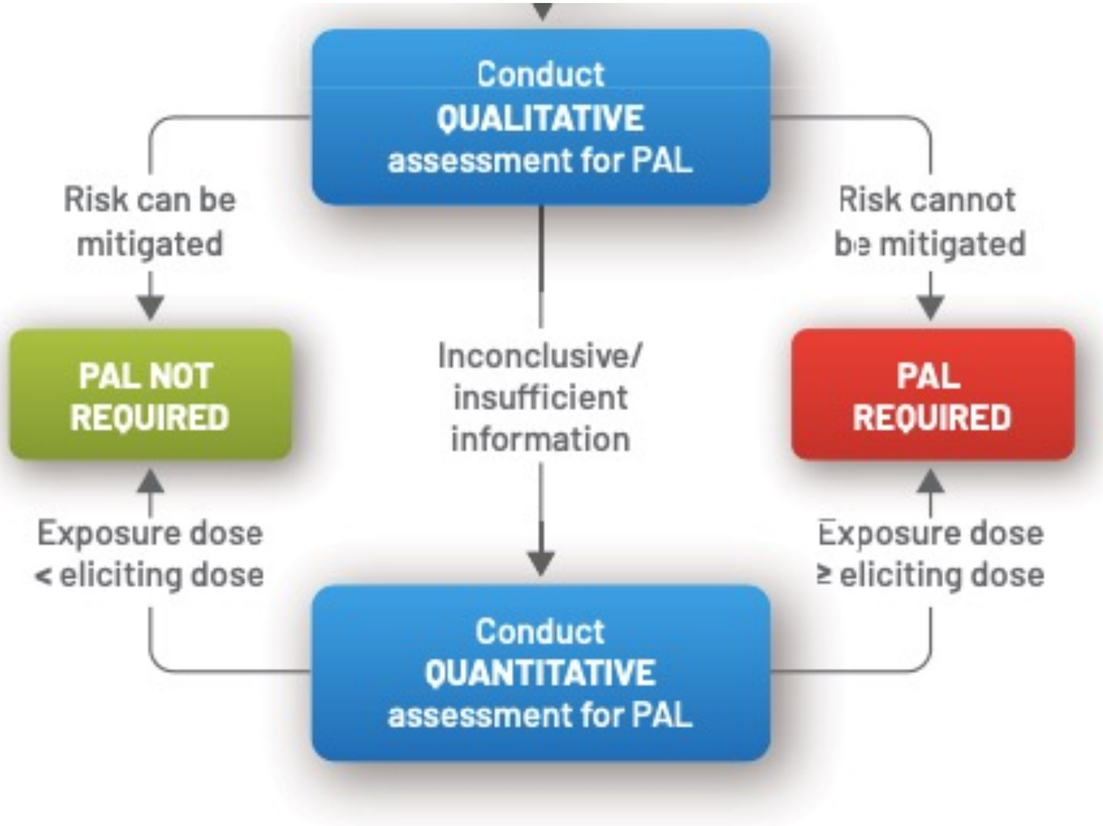
- **Qualitative assessment**
  - Weight of evidence

- **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

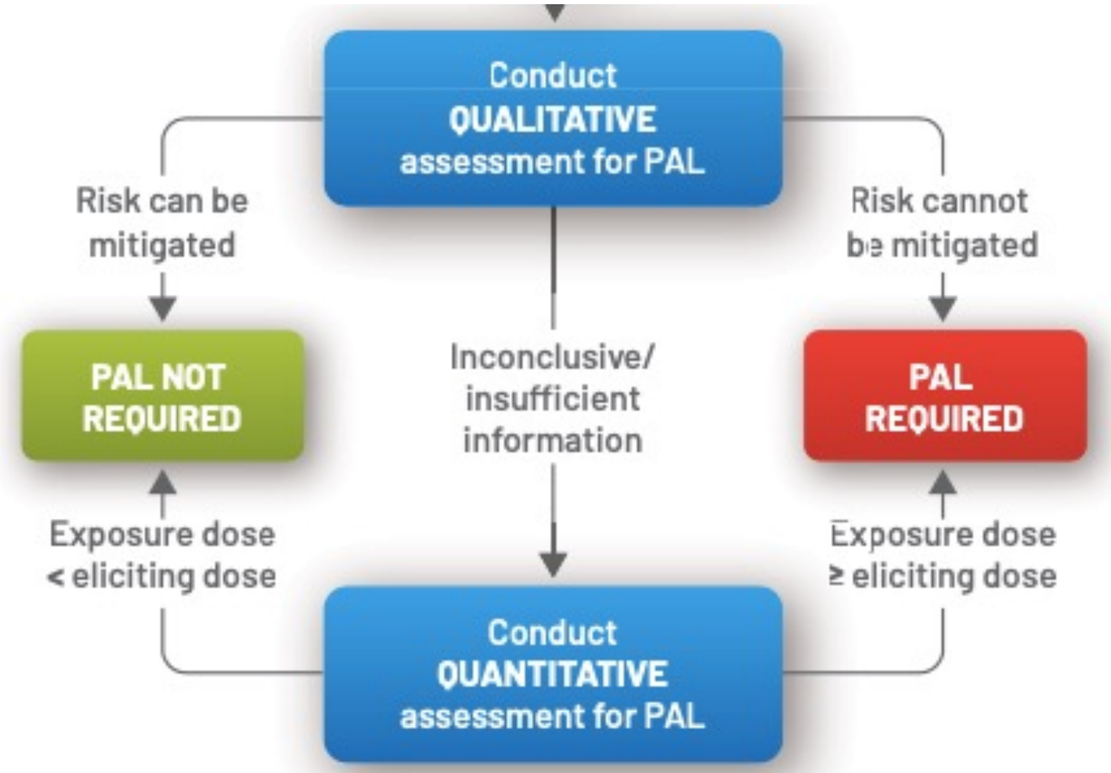
Conclusion

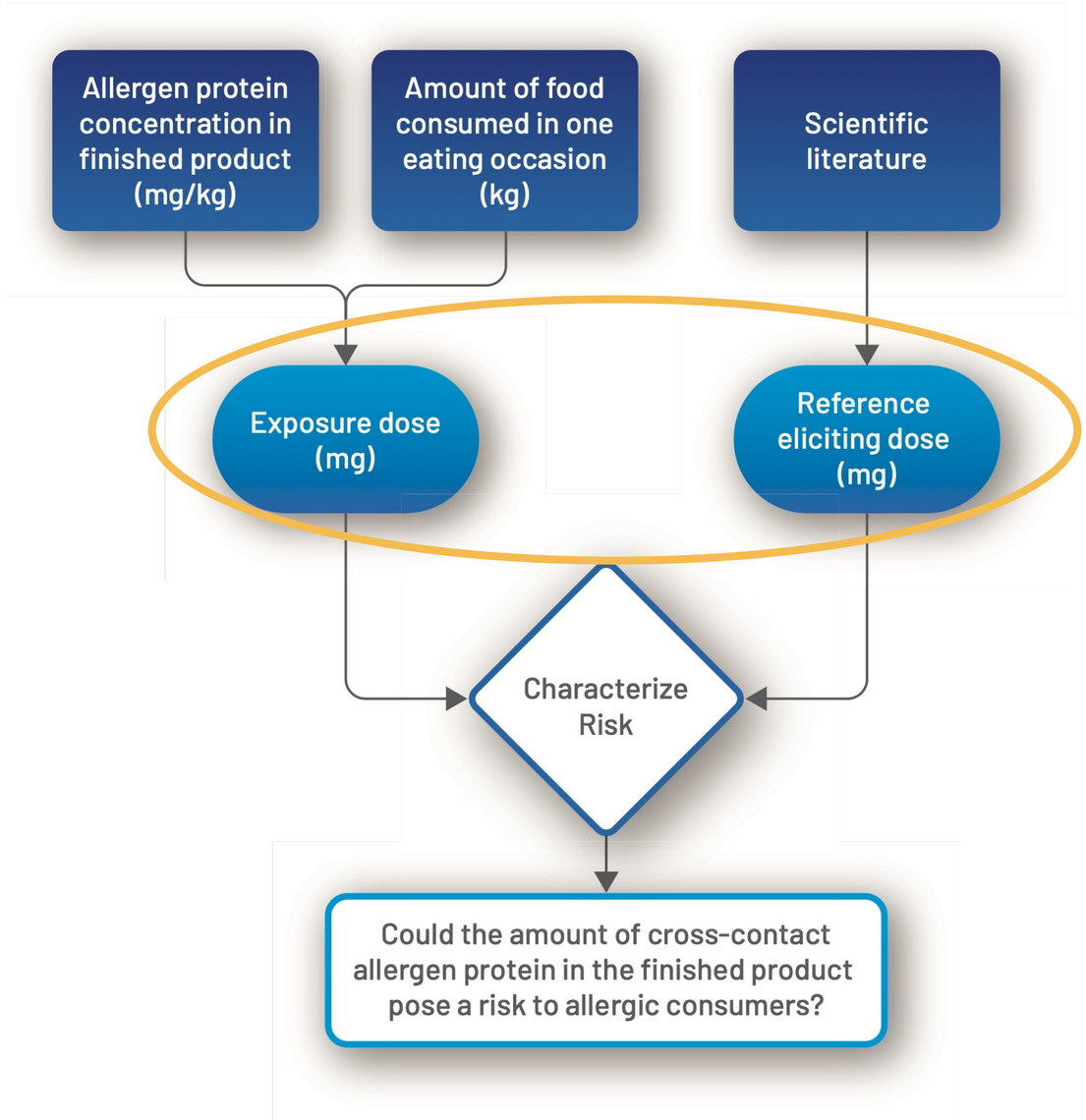
- Control measures can consistently prevent occurrence of milk in cookie B, when produced after A. PAL for milk not required.

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. Cleaning is verified per SOP, specifically targeting milk detection on surfaces. 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 assures no visible residue and analytical tests report undetectable milk proteins in B**	**Very strong**

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 = 15 ppm *soy flour*

Allergenic food	Protein content (%)
Whole soybean	40

total soy flour × protein fraction in soy flour

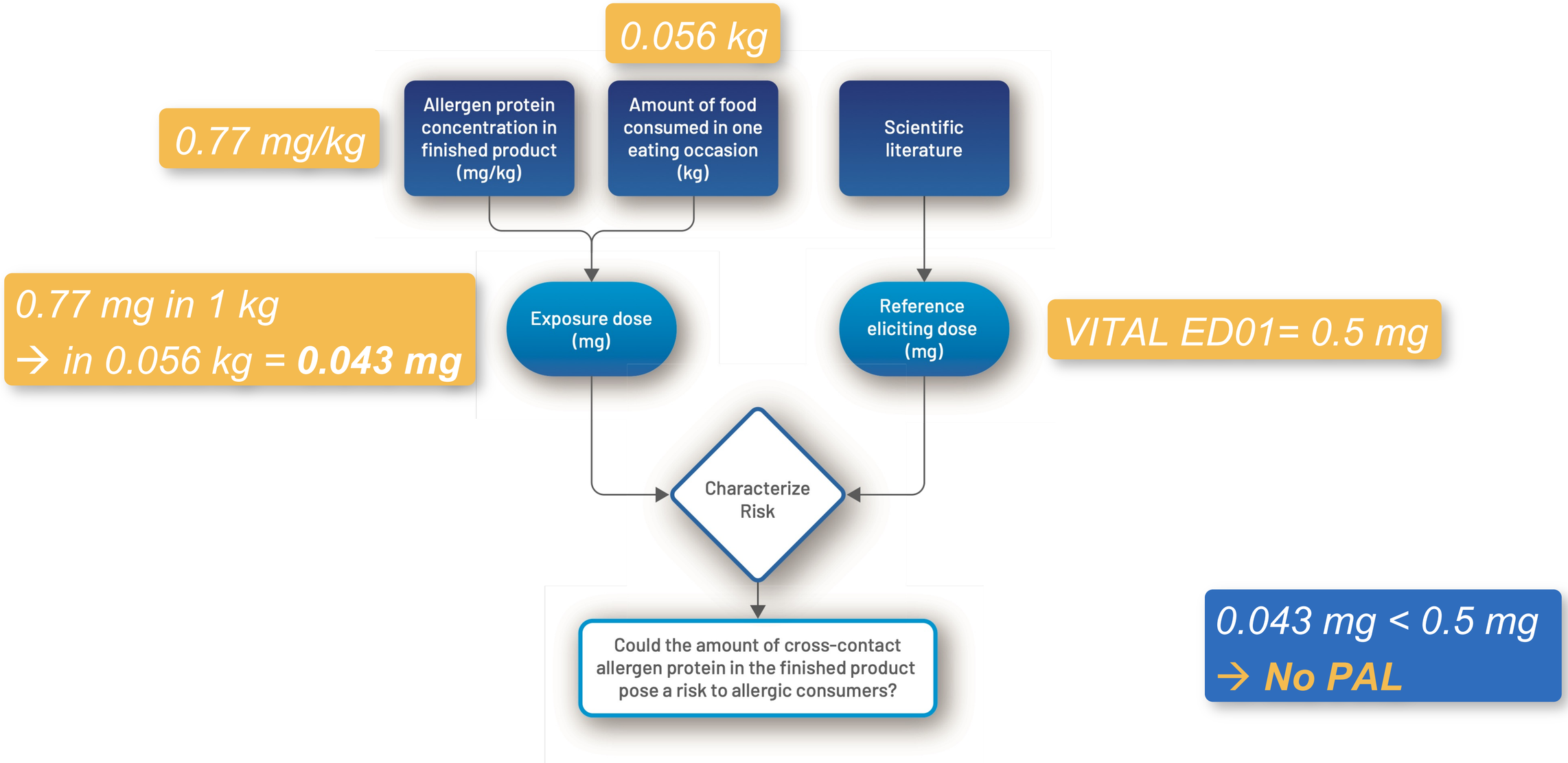
Soy protein = 15 × 0.40 = 6 mg soy protein per kg spice mix

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



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

RESOURCES

- Summary of international guidance and practices
- Allergen management guidelines for food manufacturers
- Training program (10 modules)
- User guide
- Self-assessment questionnaire
- Scientific publications

foodallergycanada.ca/AllergenGuidelines

Heliyon 8 (2022) e11302

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Research article

Allergen management under a voluntary PAL regulatory framework – A survey of Canadian food processors

Silvia Dominguez [a,*], Jérémie Théolier [a], Beatrice Povolo [b], Jennifer Gerdts [b], Samuel Benrejeb Godefroy [a]

[a] *Food Risk Analysis and Regulatory Excellence Platform (PARERA), Institute of Nutrition and Functional Foods and Department of Food Science, Université Laval, Quebec, Quebec, G1V 0A6, Canada*
[b] *Food Allergy Canada, 505 Consumers Drive, Suite 507, Toronto, Ontario, M2J 4A2, Canada*

THANK YOU

UNIVERSITÉ LAVAL

parera
Food Risk Analysis and Regulatory Excellence Platform

Food Allergy Canada