



UNIVERSITÉ  
**LAVAL**

Faculty of Agriculture  
and Food Sciences



**parera**

Food Risk Analysis and Regulatory  
Excellence Platform

# Food Allergen and Gluten Management

*Second Symposium of the Arab Section of  
AOAC International*

*08 May 2024 – Amman – Jordan*

*Approaches of Food Allergen Management  
Overall*

*Food Allergen Management Included in Food  
Safety Management Systems*

*Food Allergen and Gluten Testing*



## Food Allergy Incidents Are Preventable

*Avoidance Continue To Be The Most Effective Risk Management Approach For Food Allergic Consumers*

**Food Allergen Management is Witnessing Increased Interest Around the World – with a New Set of Work Items under Codex**



# The Issue: Celiac Disease

- ❑ Celiac disease is a lifelong medical condition observed in genetically susceptible individuals.
- ❑ Symptoms are related to the ingestion of the **gluten protein** found in **wheat and related grains**.
- ❑ Exposure to gluten can lead to a series of **immune-mediated adverse reactions**
- ❑ **Progressive deterioration** of the lining of the small intestine can also occur.
- ❑ Individuals with celiac disease have an increased risk of developing other diseases including
  - osteoporosis,
  - lymphoma and type I diabetes mellitus.
  - increased risk of reproductive problems.
  - growth failure and delayed puberty in Children
- ❑ **It is estimated that Celiac disease affects approximately 1% of the population worldwide**



# Interventions

- ❑ No cure possible to date to these conditions
- ❑ Avoidance of the Food where the Allergenic / Gluten Source Ingredient is Present, remains the main risk management strategy
- ❑ Preventive Controls and Accurate Information About Food Allergen Composition Are the Cornerstone of Food Allergen Risk Management Interventions



## Objectives

- ❑ Promote Trust in Information Available on Food Labels:
  - Label supports avoidance of inadvertent consumption of foods containing the "culprit ingredient" :
    - Accurate (complete, no hidden sources of allergens)
    - Clear (Simple Language)
    - Reliable (No Doubt)
- ❑ Labelling is a **risk management measure that can be regulated**
- ❑ Most labeling regulatory requirements follow Codex Standard:
  - **Impose the declaration of food content on the label (list of ingredients)**



# Codex Standards on Food Allergens

**CCFL: Codex Committee on Food Labelling**

**CCFH: Codex Committee on Food Hygiene**



## Current Risk Management

- ❑ Use of precautionary statements (advisory statements) to alert to possible / “unavoidable” cross-contact or cross-contamination incidents

## Gaps that May Need to be Addressed

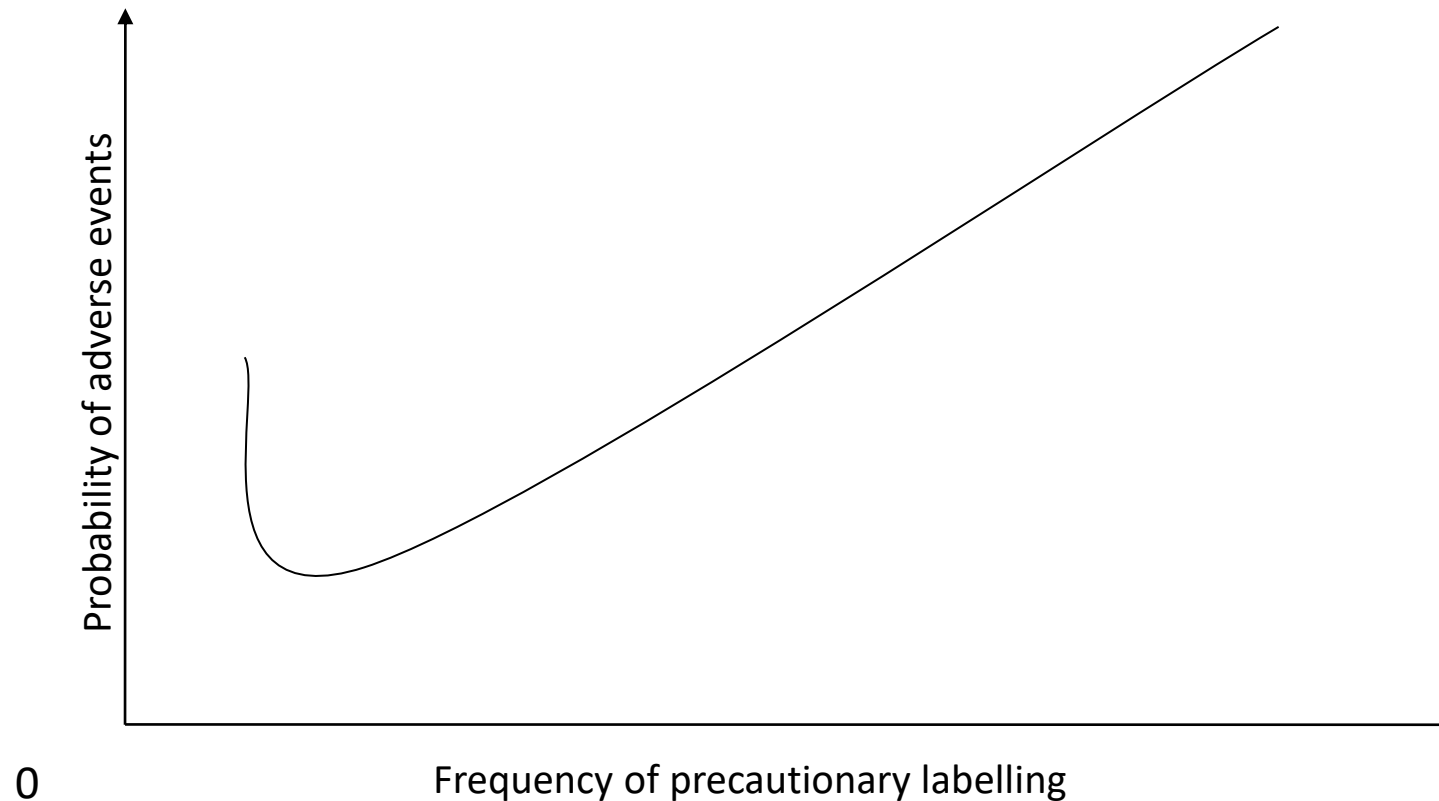
- ❑ Pervasiveness of precautionary statements : Question as to their effectiveness as a risk mitigation strategy (consumer perception/understanding)





# Precautionary Labelling

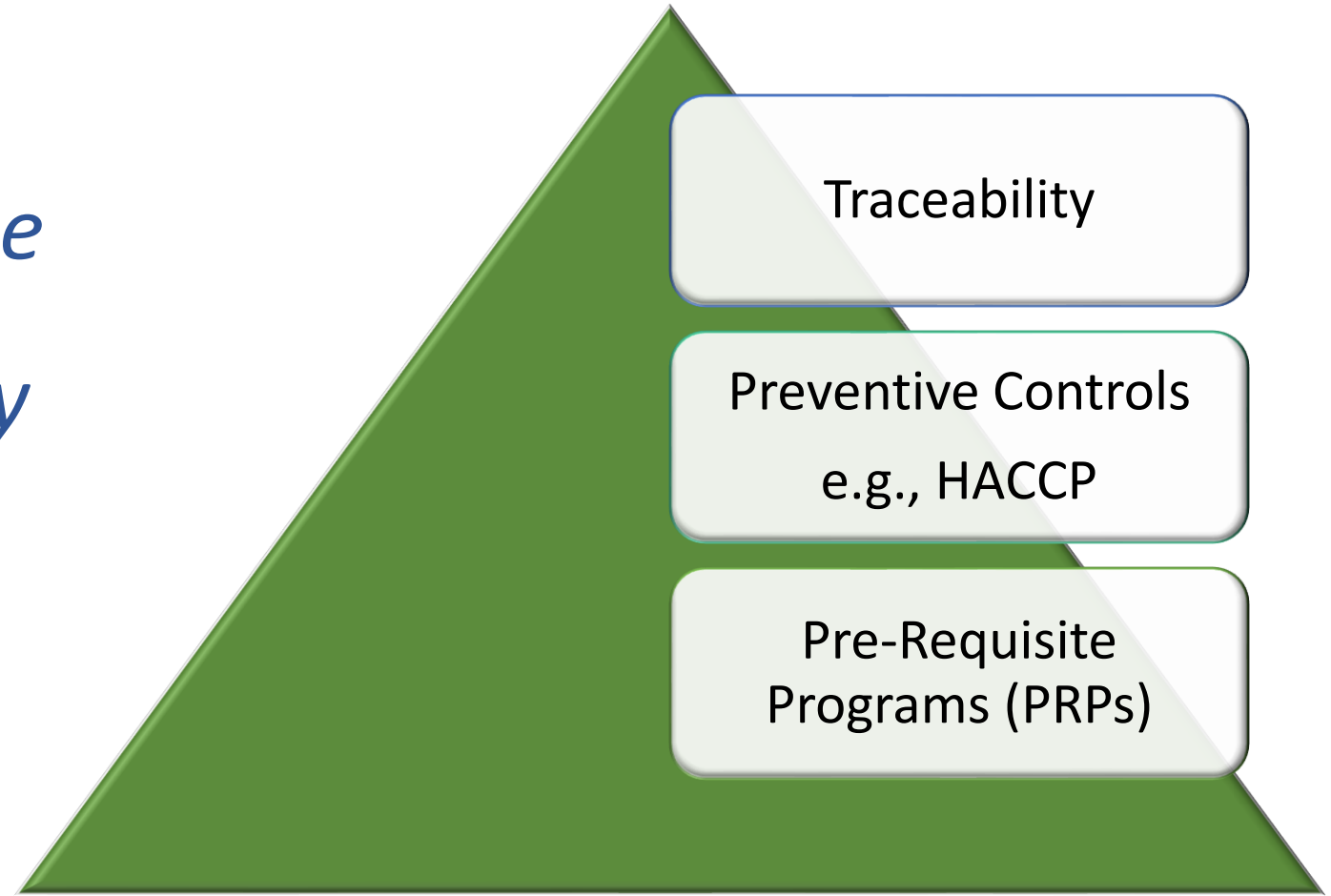
Illustration of the efficacy of precautionary labelling against frequency of use



From: Crevel RWR. Allergy management in the food industry. In: Mills C, Wichers H, Hoffman-Sommergruber K. Managing allergens in food. CRC Press, Woodhead Publishing Limited, Cambridge, England, 2007, pp 262-279.

## Preventive Approach

*Risk Management is to be  
Integrated in Food Safety  
Management Systems*



# Allergen Management - Part of the Organization's Food Safety Management System

- ❑ Developing, implementing and maintaining an Allergen Control Program (**ACP**) represents a significant company-wide, cross-functional effort.
  - Without a solid food safety foundation, isolated allergen control measures are **unlikely to succeed**.
- ❑ ACP should leverage a strong Food Safety Management System:
  - Education, management commitment, PRPs, preventive controls, record keeping

## □ Employee Education

- 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**),
  - Support and Adherence of Workforce is Required

## □ Management Commitment

- The commitment of the organization's upper management – not only of the employees directly working with allergens – is **essential**:
  - Set example and convey the importance of allergen control

## ❑ **Pre-requisite programs**

- Management of Premises & Equipment; Transportation, Receiving, Storage & Handling; Personnel Training ; Cleaning / Sanitation should consider Allergen Management as a Key Issue

## ❑ **Preventive control programs**

- HACCP: allergens considered as chemical hazards

## ❑ **Record Keeping:** aim to demonstrate products are safe and comply with regulations, and to facilitate traceability.

- Records should demonstrate allergen control measures were correctly implemented
- Records should also include information provided by suppliers

# Risk-Based Approach for Allergen Management

## Approach Based on Risk Analysis

*Strategies selected by food manufacturers to manage allergens will depend on the unique characteristics of their operations*



# Risk-Based Allergen Management Allows FBOs to:

- ❑ **Identify allergen hazards** in their facility and in their finished products
- ❑ **Assess the risk they 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
- ❑ **Reach and justify allergen labelling decisions**
  - E.g., use of PAL
- ❑ **Optimize risk communication with consumers**
- ❑ **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



# 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





# International Standards – Gluten Free

## STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN

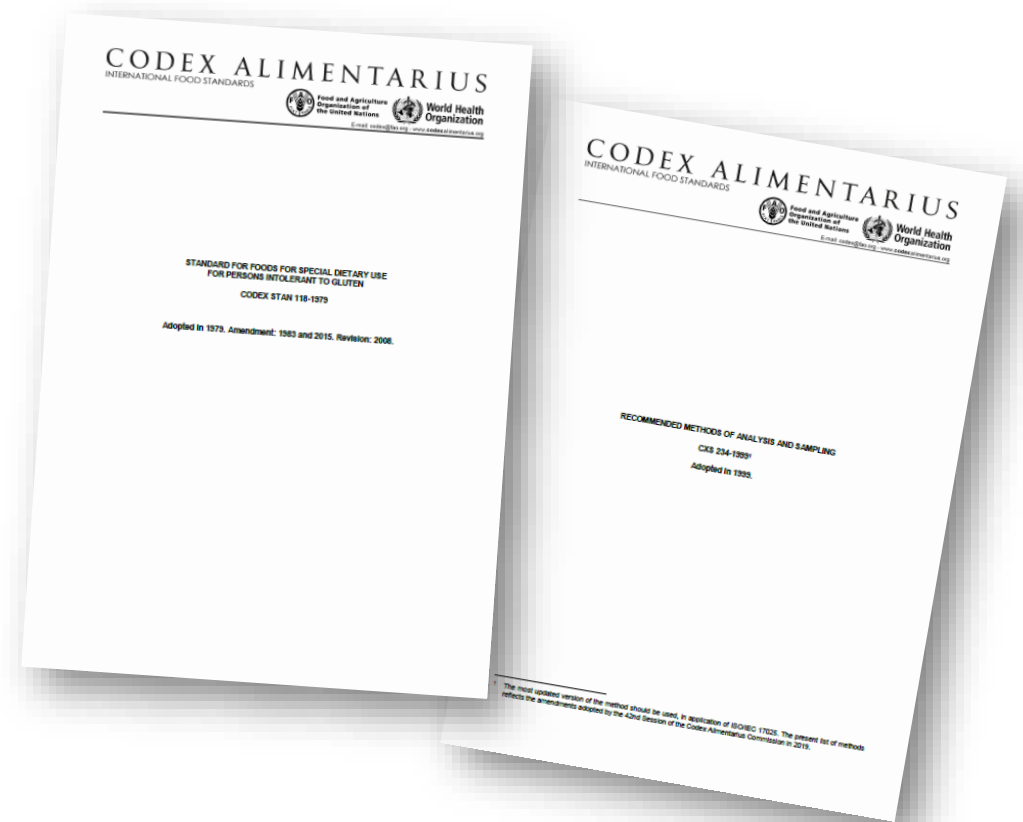
CODEX STAN 118-1979

Adopted in 1979. Amendment: 1983 and 2015. Revision: 2008.

## RECOMMENDED METHODS OF ANALYSIS AND SAMPLING

CXS 234-1999<sup>1</sup>

Adopted in 1999.



<sup>1</sup> The most updated version of the method should be used, in application of ISO/IEC 17025. The present list of methods reflects the amendments adopted by the 42nd Session of the Codex Alimentarius Commission in 2019.

# Codex Stan 118-1979

## 5.2 Method for determination of gluten

Enzyme-linked Immunoassay (ELISA) R5 Mendez Method.

## CSX 234-1999

### PART A – METHODS OF ANALYSIS BY COMMODITY CATEGORIES AND NAMES

Gluten-free foods	Gluten	Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method <i>Eur J Gastroenterol Hepatol</i> 2003; 15: 465-474	Immunoassay	I
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# FROM 2018 ... ONWARD

## Decision to Open the Allergen File with the Relevant Interventions:

*Guidance to Food Industry*

*Review of the Current Standards and Their Update*



**CODEX ALIMENTARIUS**



FAO/WHO Food Standards - Normes Alimentaires FAO/OMS - Normas Alimentarias FAO/OMS

# NEED GUIDANCE ON FOOD ALLERGEN MANAGEMENT

## New Codex Guidance Developed (2020)

REP20/FH – Appendix II

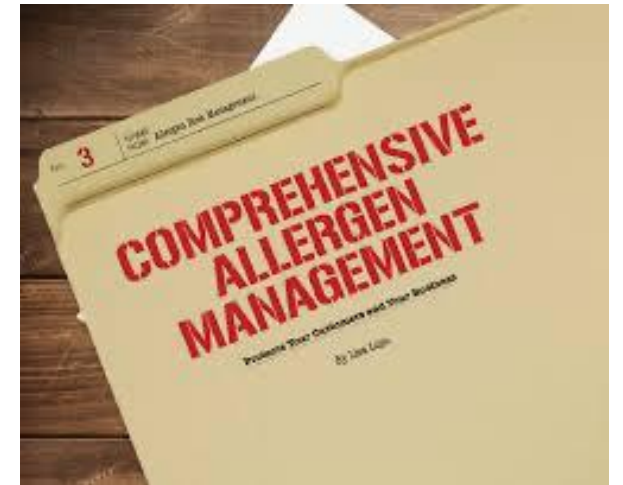
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**Appendix II**

**DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT  
FOR FOOD BUSINESS OPERATORS**

# HARMONIZED, PROACTIVE APPROACH

- ❑ **FBOs should develop policies and procedures to identify allergens and implement practices and controls addressing**
  - Cross-contact
  - Undeclared allergens
  - Labelling
  - Information for consumers
  
- ❑ **Control measures should be part of GHP/HACCP and based on risk assessment**
  
- ❑ **Effective, proactive allergen management = reduced risk for consumers**



Source : [qualityassurancemag.com](http://qualityassurancemag.com)

# CODEX PRINCIPLES: AREAS OF INTERVENTION

1. Primary Production

5. Personal hygiene

2. Design and Facilities

6. Transportation

3. Control of operation

7. Product Information  
and Consumer Awareness

4. Maintenance and  
Sanitation

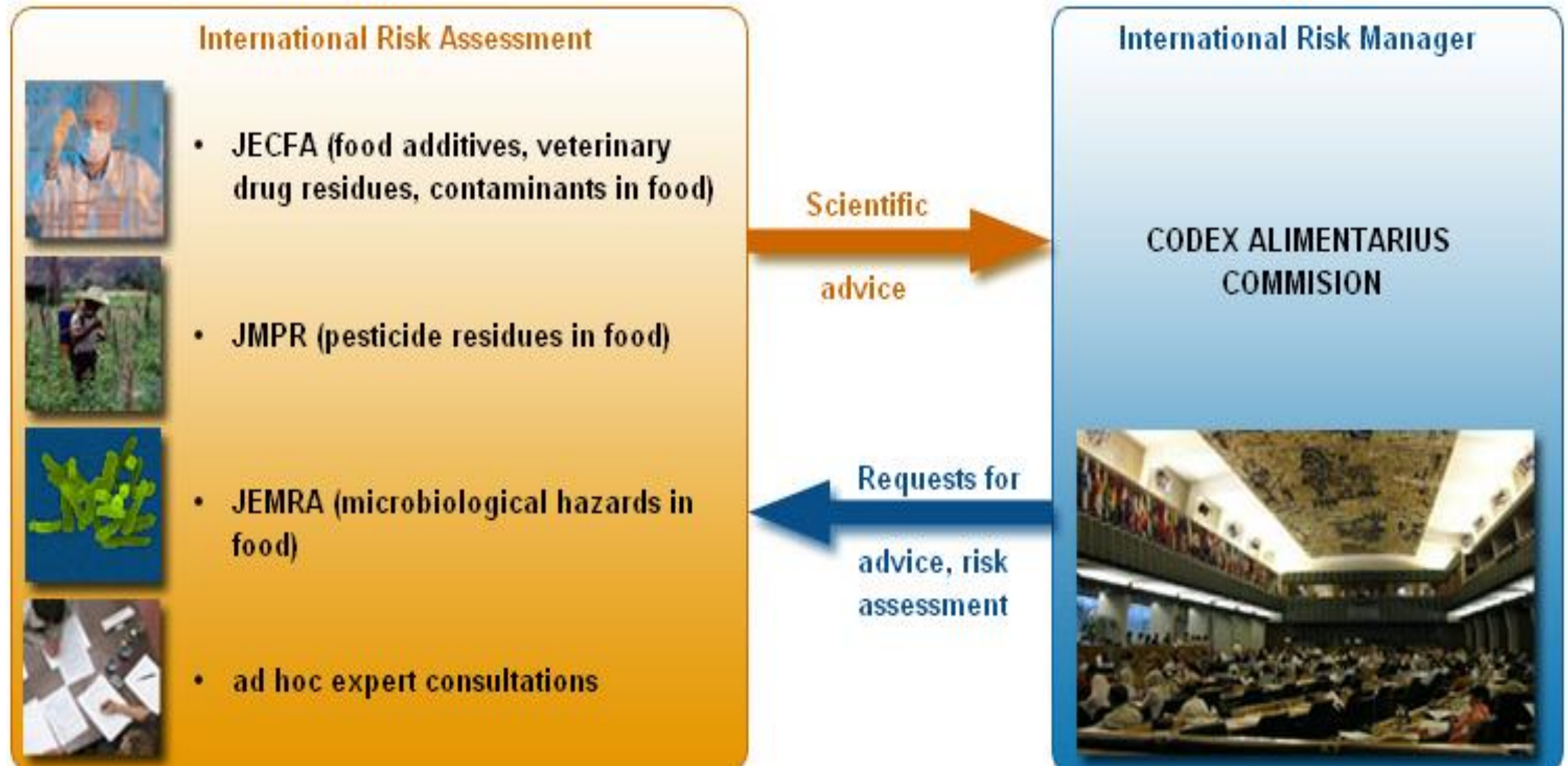
8. Training

## Focus:

- Prevent/minimize cross-contact
- Limit introduction of unintended/undeclared allergens
- Inform consumers

***BUT NO PRECISE GUIDANCE  
ON PRECAUTIONARY FOOD  
ALLERGEN LABELLING!!!***

# JOINT FAO/WHO FOOD STANDARDS PROGRAM



# NEED ADDITIONAL SCIENTIFIC ADVICE

**To Support Further Development of Standards,  
*Including the Review of Scientific Foundation for  
New Work***





# 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

Several meetings between 2020-2022



# REPORTS STEMMING FROM SCIENTIFIC ADVICE

- **The scientific advice requested was completed by an ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens, which was convened 4 times and issued full reports currently available:**
  - [Part 1: Review and validation of Codex priority allergen list through risk assessment](#)
  - [Part 2: Review and establish threshold levels in foods for the priority allergens](#)
  - [Part 3: Review and establish precautionary labelling in foods of the priority allergens – Summary and conclusions](#)
  - [Part 4: Review and establish exemptions for the food allergens – Summary and conclusions](#)



# 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:

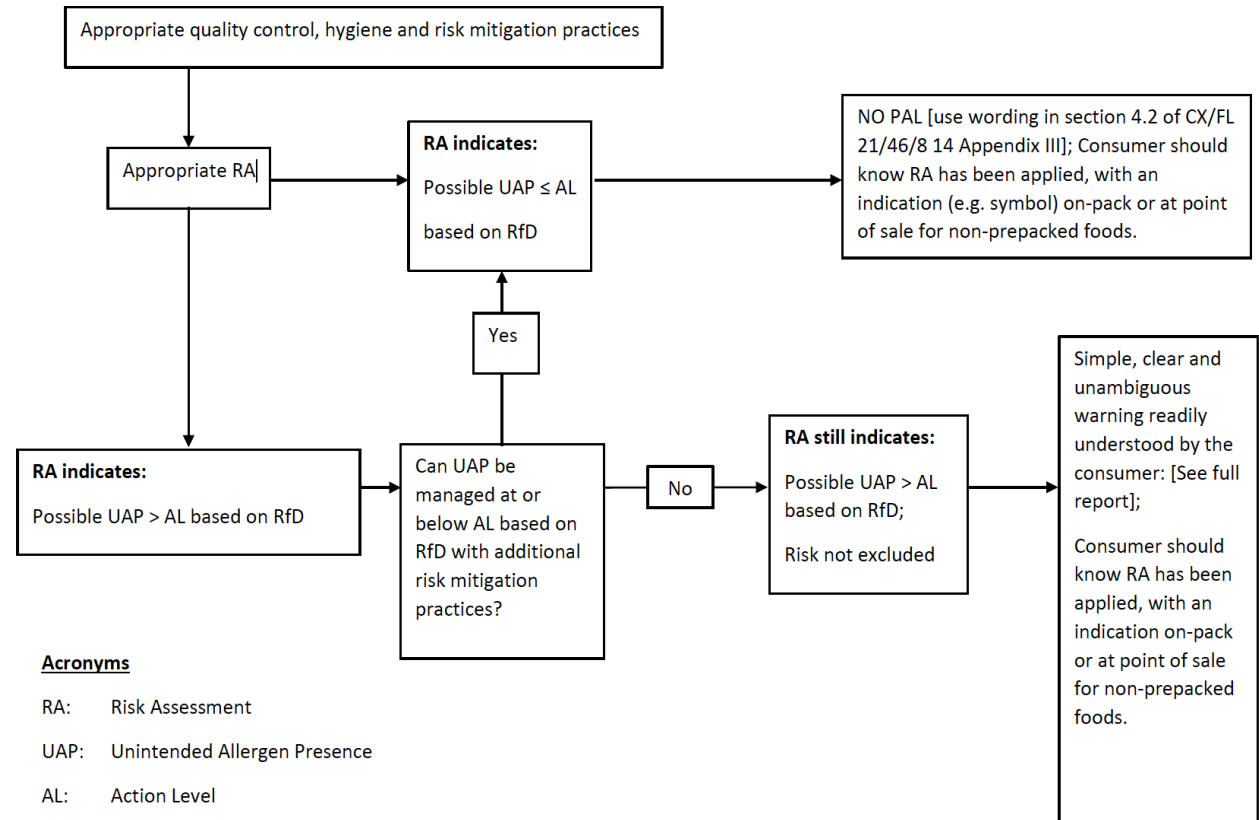
- What are appropriate analytical methods for testing food and surfaces?
- What should be the minimum performance criteria for these analytical methods?

# 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

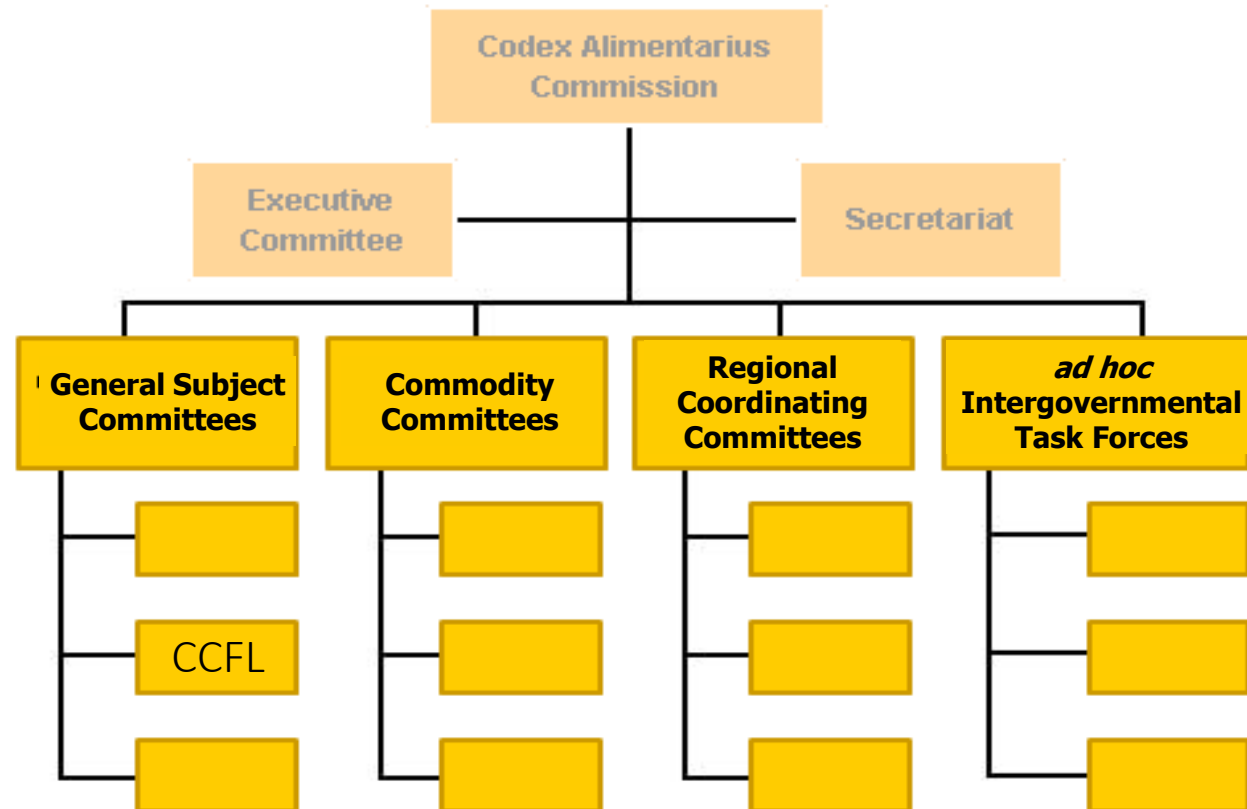
**PAL decisions should be part of a regulatory framework (PAL when possible UAP > Action Level based on RfD)**



# CCFL47

## Codex Committee on Food Labelling

*One of the General Standards Committees – Hosted by Canada*



# 1. UPDATE OF THE LIST OF WHAT IS KNOWN TO BE PRIORITY ALLERGENS

<b>FOODS AND INGREDIENTS</b>	<b>SPECIFIED NAME</b>
Cereals containing gluten <sup>2</sup> : <ul style="list-style-type: none"><li>– wheat and other <i>Triticum</i> species</li><li>– rye and other <i>Secale</i> species</li><li>– barley and other <i>Hordeum</i> species</li></ul> and products thereof	'wheat' 'rye' 'barley'
Crustacea and products thereof	'crustacea'
Eggs and products thereof	'egg'
Fish and products thereof	'fish'
Peanuts and products thereof	'peanut'
Milk and products thereof	'milk'
Sesame and products thereof	'sesame'
Specific tree nuts <ul style="list-style-type: none"><li>– Almond</li><li>– Cashew</li><li>– Hazelnut</li><li>– Pecan</li><li>– pistachio</li><li>– walnut</li></ul> and products thereof	'almond' 'cashew' 'hazelnut' 'pecan' 'pistachio' 'walnut'



# SECONDARY LIST

## FOODS AND INGREDIENTS

## SPECIFIED NAME

Buckwheat and products thereof

'buckwheat'

Celery and products thereof

'celery'

Oats and other *Avena* species (and their hybridized strains) and products thereof<sup>6</sup>

'oats'

Lupin and products thereof

'lupin'

Mustard and products thereof

'mustard'

Soybean and products thereof

'soy'

Specific tree nuts

'Brazil nut'

– Brazil nut

'macadamia'

– macadamia

– pine nut

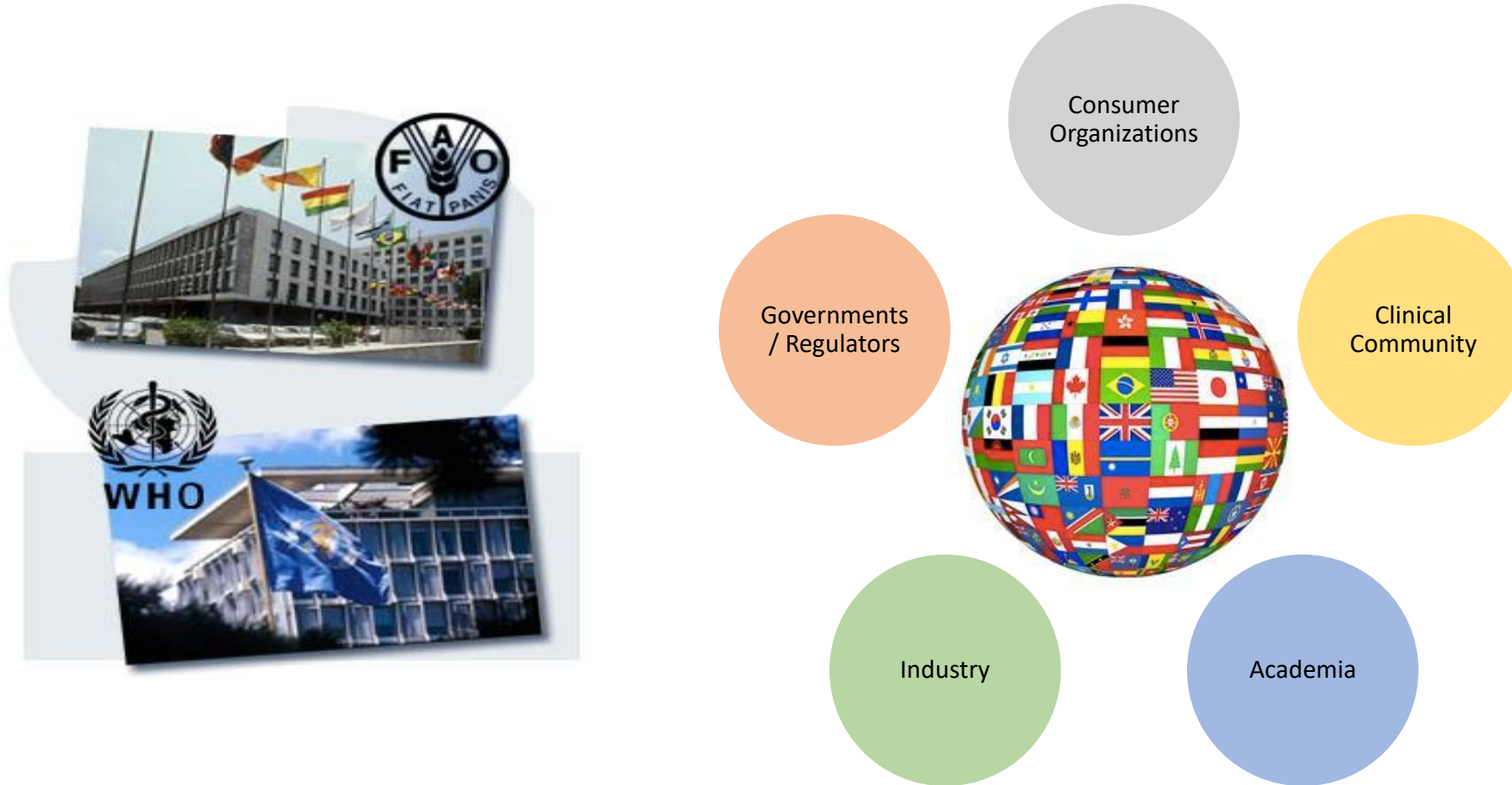
'pine nut'

and products thereof





## Confirmed Interest of International Organizations to Move Forward



- ❑ Leveraging AOAC Processes to Standardize Methods
- ❑ Support Availability of Reference Material and Testing Material
- ❑ Arab Data Base for Food Allergen and Gluten Methods Supporting
  - Clear and Predictable Food Regulatory Environment for Industry:
  - With Accessible and Effective Food Allergen Management Tools



