Recent Developments in Management of Food Allergens and Gluten Sources

Arab AOAC Session

Dubai International Food Safety Conference (DIFSC)

Third Global Food Regulatory Science Symposium

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Outline

Review of Current Status of Allergen-Related Guidance in Codex

Discussions Underway and Future Directions

Overall: Positioning the Challenge Globally

- 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**

Unknown Factors / Impacts

Interventions

- **A life-long gluten-free diet** is the only way to avoid the symptoms and the complications of celiac disease
- Individuals with celiac disease are advised to avoid the consumption of wheat, rye, barley, oats and triticale, as well as their hybridized strains.
- Gluten can be present in a food as a result of its manufacture using ingredients that **are gluten sources themselves**, such as wheat or barley.
- Gluten **can also be present in a food due to cross-contamination**
- Labelling Can be Used to Help **Celiac Individuals Identify Foods Suitable for Their Conditions**

Interventions - Allergens

- ❑No cure possible to date for food allergy conditions

- ❑Avoidance of the Food where the Allergenic Ingredient is Present, remains the main risk management strategy

- ❑Labelling of Prepackaged Foods and Accurate Information on menus remains the cornerstone of regulatory interventions guided by Codex…

Regulatory Policy : Focus on Labelling of Prepackaged Foods

- Consumers depend on the information provided on the label to avoid the food allergen, gluten sources and added sulphites in a prepackaged food

Labelling as a Risk Management Measure

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 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

CODEX
CODEX ALIMENTARIUS
1963-2023

Action Guided by Codex

*The **Presence** Of Priority (Allergenic) Food Should ALWAYS Be Subject To **Declaration In** **The List Of Ingredients** On A Food Label*

Example of Label Issues Addressed by Standards

Ingredients : Sugar, **Flour**, **Ovalbumin**, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

- ❑Flour can have various sources : priority allergens or not
- ❑Ovalbumin is a protein found in egg whites

Ingredients : Potatoes, sunflower oil, salt, **seasonings**

- ❑Multi-component Ingredients (e.g., Seasonings, spices ..) generally exempt from component declaration on food labels
- ❑Possible Presence of Allergens in Such Mixtures : Wheat, Milk, Mustard etc..

Gaps Addressed by Regulatory Requirements

Current Risk Management

- ❑General labelling conditions require that a complete and accurate list of ingredients appear on the label of most prepackaged foods

Gaps that may need to be addressed

- ❑Certain ingredients are exempt from component declaration.
- ❑Some prepackaged foods do not require a list of ingredients
- ❑Need to mention the food commodity: source of allergen (**in Plain language**)
- ❑Legibility of allergen declaration

Regulatory amendments to enhance the labelling requirements for allergens and gluten sources as **ingredients** addressed these gaps

Example of Label Changes – Cake Mix

❑Before

Ingredients : Sugar, **Flour**, **Ovalbumin**, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

❑After

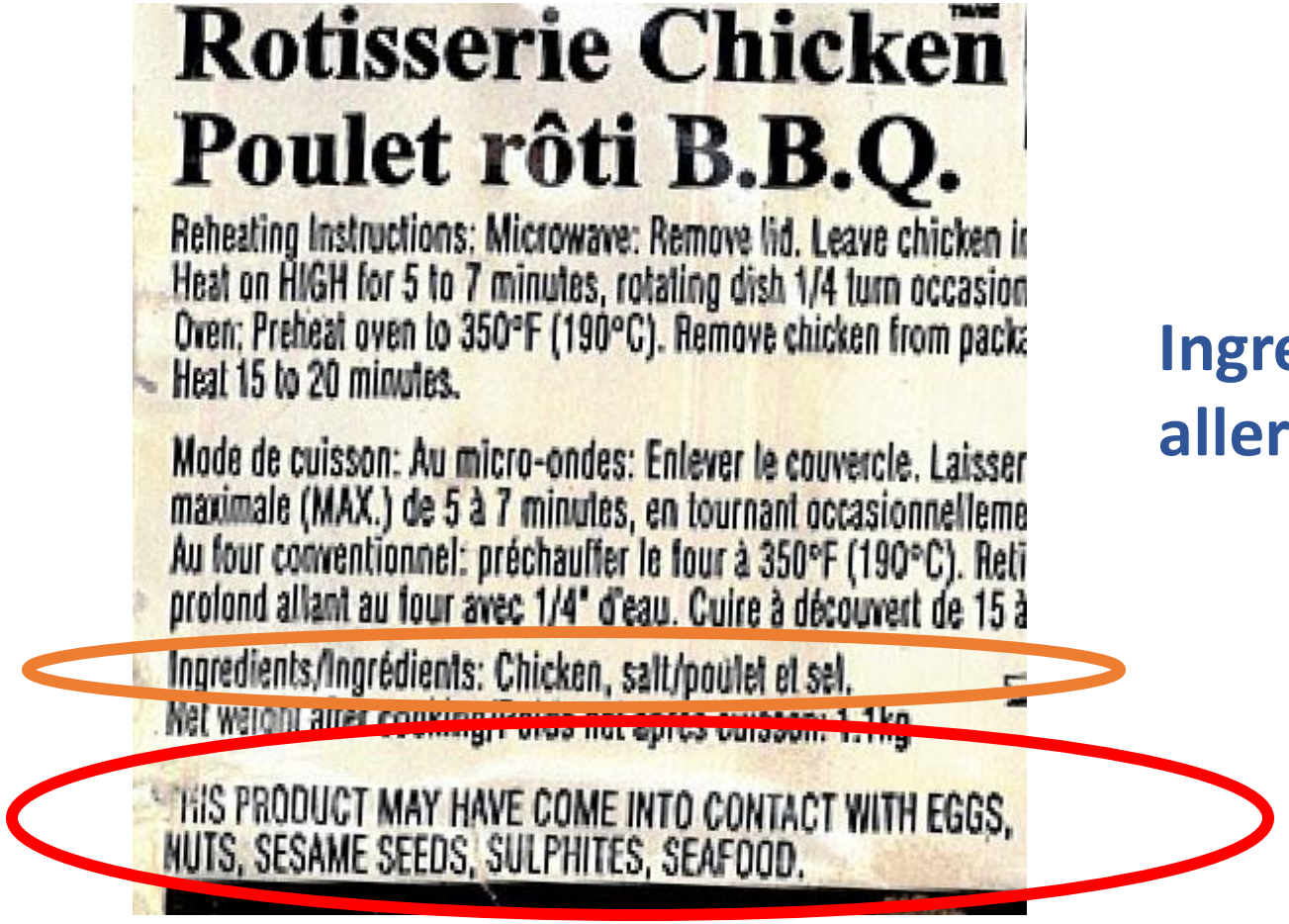
Ingredients : Sugar, **Flour (Wheat)**, **Ovalbumin (Egg)**, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

OR

Ingredients : Sugar, Flour, Ovalbumin, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

Contains: Egg, Wheat

Precautionary labelling : Truthful / Helpful ?



Rotisserie Chicken
Poulet rôti B.B.Q.

Reheating Instructions: Microwave: Remove lid. Leave chicken i
Heat on HIGH for 5 to 7 minutes, rotating dish 1/4 turn occasion
Oven: Preheat oven to 350°F (190°C). Remove chicken from packa
Heat 15 to 20 minutes.

Mode de cuisson: Au micro-ondes: Enlever le couvercle. Laisser
maximale (MAX.) de 5 à 7 minutes, en tournant occasionnelleme
Au four conventionnel: préchauffer le four à 350°F (190°C). Reti
profond allant au four avec 1/4" d'eau. Cuire à découvert de 15 à

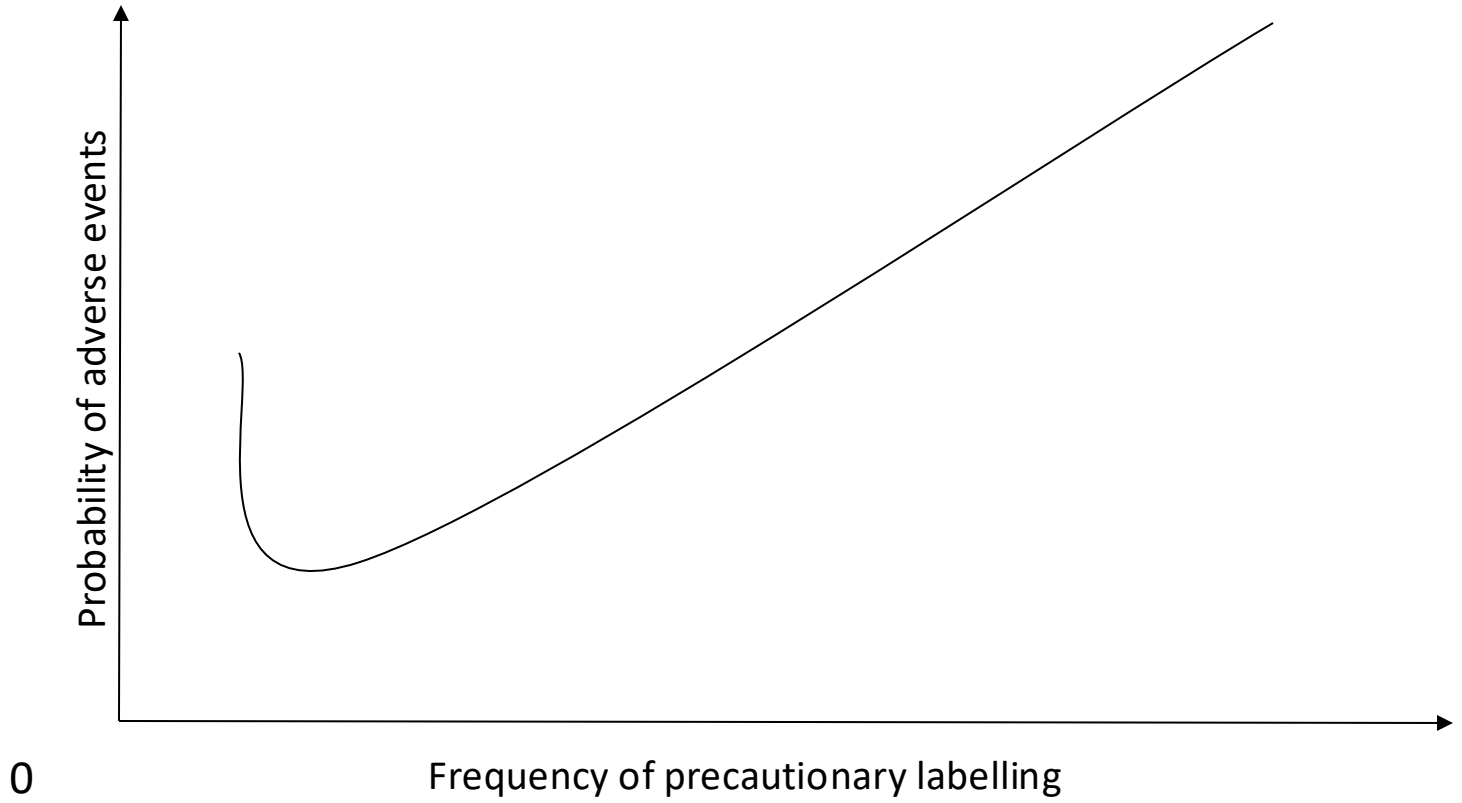
Ingredients/Ingrédients: Chicken, salt/poulet et sel.

THIS PRODUCT MAY HAVE COME INTO CONTACT WITH EGGS, NUTS, SESAME SEEDS, SULPHITES, SEAFOOD.

Ingredient list much shorter than allergen precautionary statement

Precautionary Labeling (cont...)

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.

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*

Need Guidance on Food Allergen Management

New Codex Guidance Developed (2020)

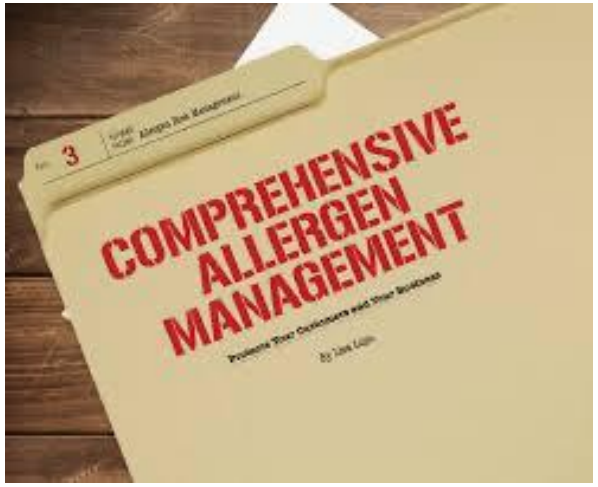
CCFH: Codex Committee on Food Hygiene

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



Source : qualityassurancemag.com

- Control measures should be part of GHP/HACCP and based on **<u>risk assessment</u>**
- Effective, proactive allergen management = reduced risk for consumers

CODEX Principles: Areas of Intervention

1. Primary Production
2. Design and Facilities
3. Control of operation
4. Maintenance and Sanitation
5. Personal hygiene
6. Transportation
7. Product Information and Consumer Awareness
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

International Risk Assessment

- JECFA (food additives, veterinary drug residues, contaminants in food)

- JMPR (pesticide residues in food)

- JEMRA (microbiological hazards in food)

- ad hoc expert consultations

Scientific advice

Requests for advice, risk assessment

International Risk Manager

CODEX ALIMENTARIUS COMMISION

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)

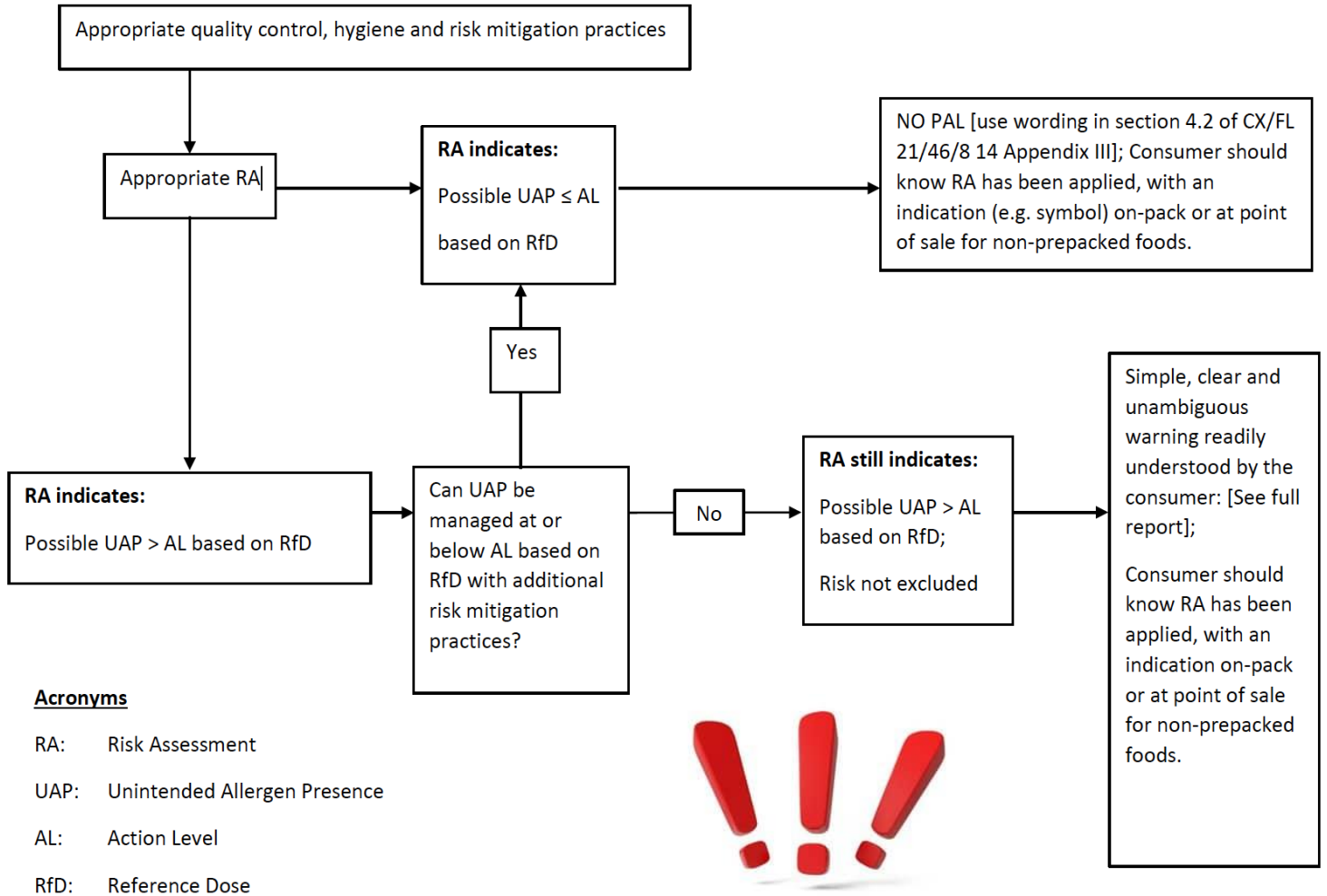
Analytical considerations:

- 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

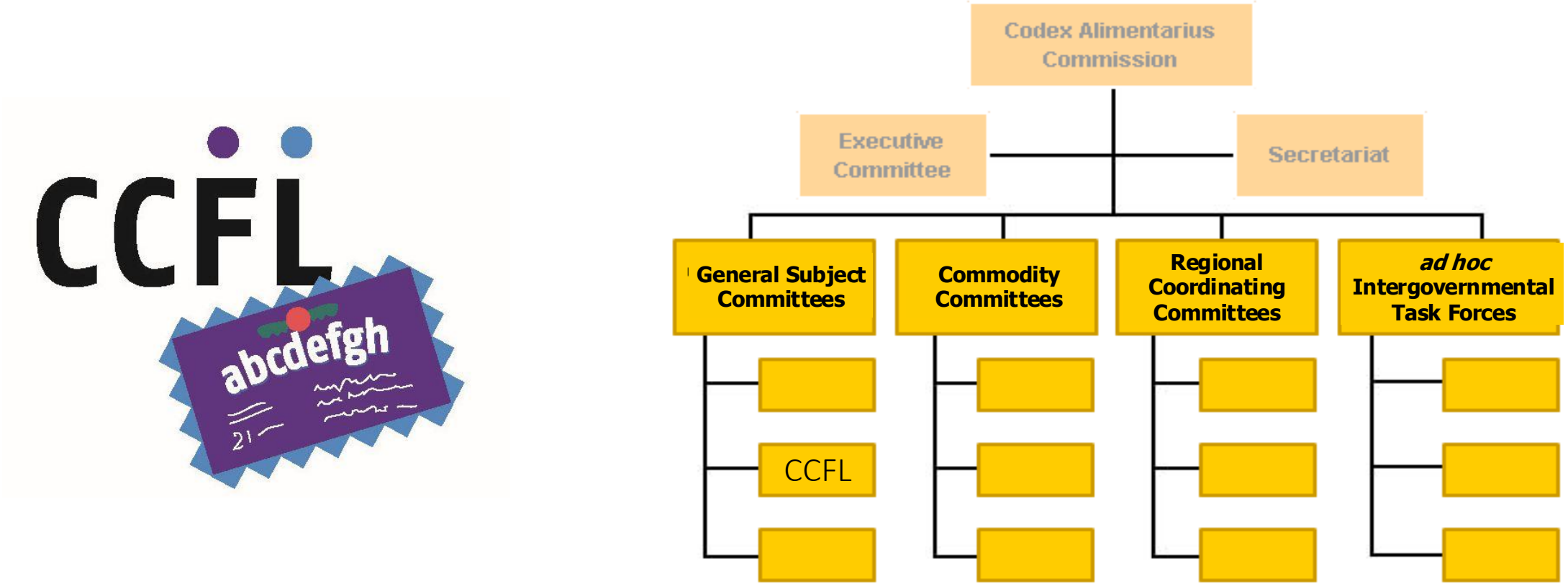
- **PAL = effective** strategy to protect consumers from UAP when based on:
  - Comprehensive allergen risk management program
  - Single clear statement
  - Effective risk communication

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



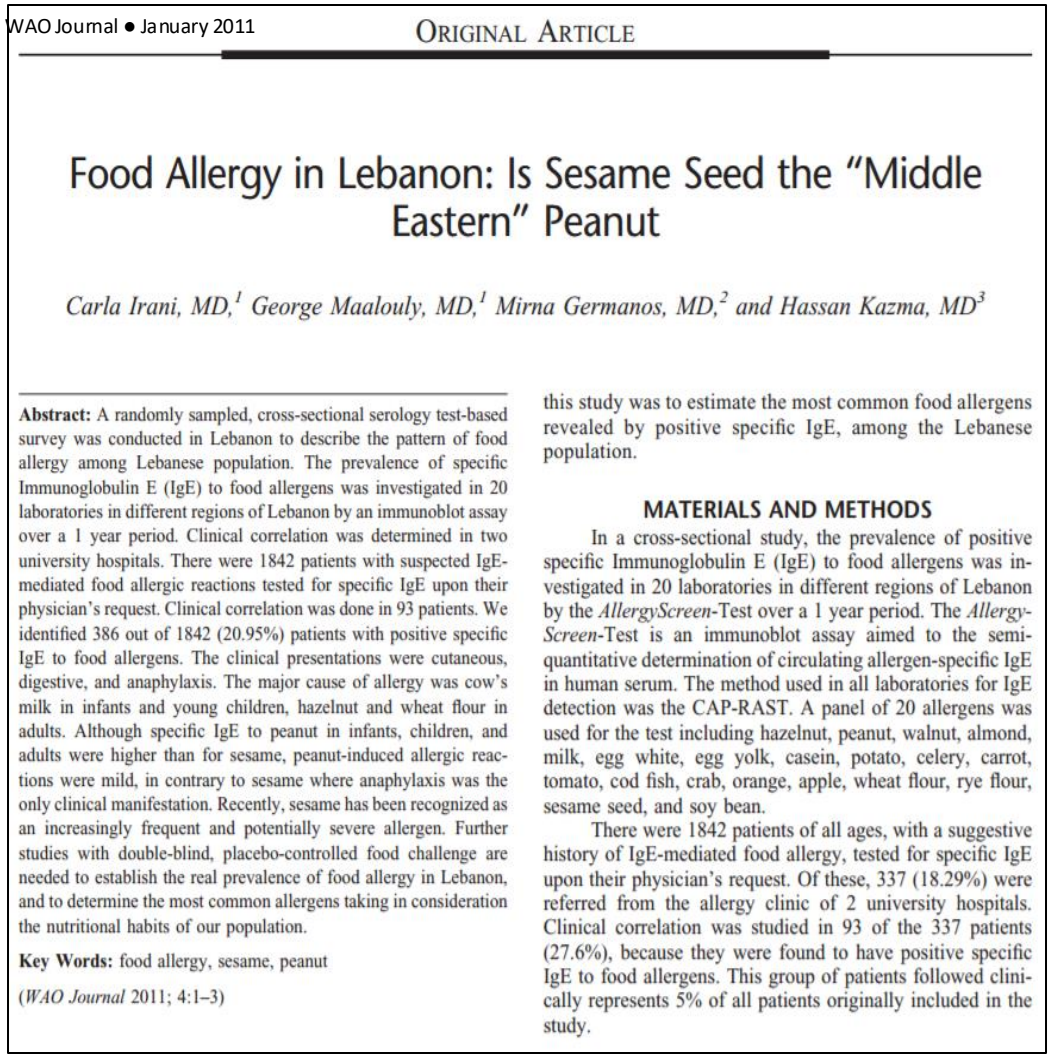
CCFL47

- Codex Committee on Food Labelling
- *One of the General Standards Committees – Hosted by Canada*



In 20 Years ….Progress has been achieved ….

- Most Countries of Asia Pacific Area including ASEAN countries have requirements for Food Allergen Labelling – based on Codex
- High Progress for the Latin American Region in Setting and Implementing Food Allergen Labelling Requirements
- **More Progress Expected**
  - China : Considering mandatory requirement for Allergen Labeling
  - Middle East and North Africa
  - Caribbean region



WAO Journal • January 2011

ORIGINAL ARTICLE

Food Allergy in Lebanon: Is Sesame Seed the "Middle Eastern" Peanut

Carla Irani, MD,[1] George Maalouly, MD,[1] Mirna Germanos, MD,[2] and Hassan Kazma, MD[3]

Abstract: A randomly sampled, cross-sectional serology test-based survey was conducted in Lebanon to describe the pattern of food allergy among Lebanese population. The prevalence of specific Immunoglobulin E (IgE) to food allergens was investigated in 20 laboratories in different regions of Lebanon by an immunoblot assay over a 1 year period. Clinical correlation was determined in two university hospitals. There were 1842 patients with suspected IgE-mediated food allergic reactions tested for specific IgE upon their physician's request. Clinical correlation was done in 93 patients. We identified 386 out of 1842 (20.95%) patients with positive specific IgE to food allergens. The clinical presentations were cutaneous, digestive, and anaphylaxis. The major cause of allergy was cow's milk in infants and young children, hazelnut and wheat flour in adults. Although specific IgE to peanut in infants, children, and adults were higher than for sesame, peanut-induced allergic reactions were mild, in contrary to sesame where anaphylaxis was the only clinical manifestation. Recently, sesame has been recognized as an increasingly frequent and potentially severe allergen. Further studies with double-blind, placebo-controlled food challenge are needed to establish the real prevalence of food allergy in Lebanon, and to determine the most common allergens taking in consideration the nutritional habits of our population.

Key Words: food allergy, sesame, peanut

(*WAO Journal* 2011; 4:1–3)

this study was to estimate the most common food allergens revealed by positive specific IgE, among the Lebanese population.

MATERIALS AND METHODS

In a cross-sectional study, the prevalence of positive specific Immunoglobulin E (IgE) to food allergens was investigated in 20 laboratories in different regions of Lebanon by the *AllergyScreen*-Test over a 1 year period. The *AllergyScreen*-Test is an immunoblot assay aimed to the semi-quantitative determination of circulating allergen-specific IgE in human serum. The method used in all laboratories for IgE detection was the CAP-RAST. A panel of 20 allergens was used for the test including hazelnut, peanut, walnut, almond, milk, egg white, egg yolk, casein, potato, celery, carrot, tomato, cod fish, crab, orange, apple, wheat flour, rye flour, sesame seed, and soy bean.

There were 1842 patients of all ages, with a suggestive history of IgE-mediated food allergy, tested for specific IgE upon their physician's request. Of these, 337 (18.29%) were referred from the allergy clinic of 2 university hospitals. Clinical correlation was studied in 93 of the 337 patients (27.6%), because they were found to have positive specific IgE to food allergens. This group of patients followed clinically represents 5% of all patients originally included in the study.

Conditions for Gluten Free Labelling

Expectation

- ❑Measures taken by Industry to remove Gluten and its sources from the foods called Gluten Free

- ❑Regulation has to consider Threshold values;
  - 10 mg/day seems acceptable based on latest scientific evidence

  - "a daily gluten intake of less than10 mg is **unlikely to cause significant histological abnormalities**." In other words, it is anticipated that the majority of people with Celiac disease will not be negatively affected if they limit their gluten intake to less than 10 mg per day.

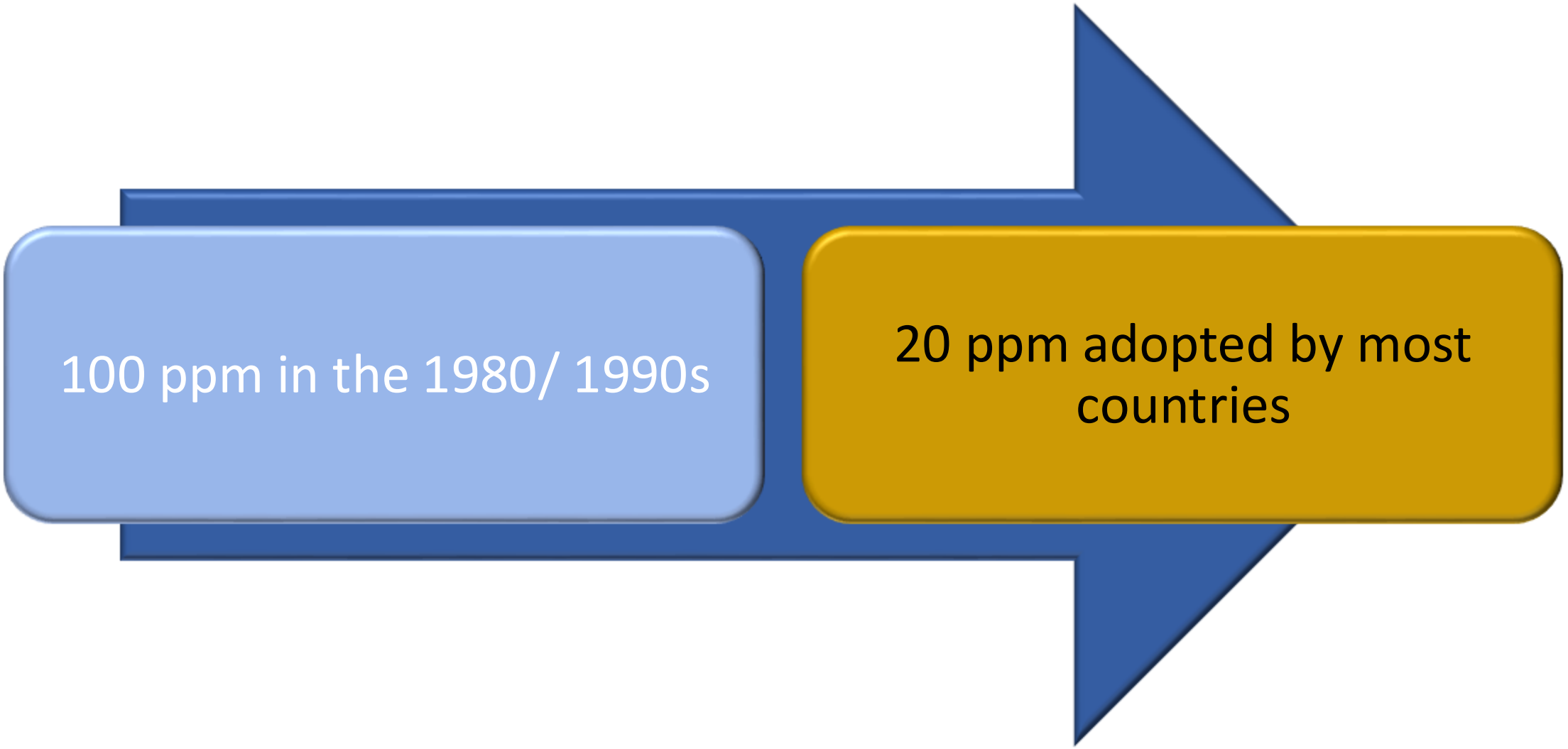
Catassi, C. Response to P.Collin et al, AmJ Clin Nutr, 2007 ; 86:260-9

Codex Standards on Gluten Free

CCNFSDU : Foods for Special Dietary Uses

CCNFSDU

Thresholds for Gluten Detection in Gluten Free Foods



International Standards

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

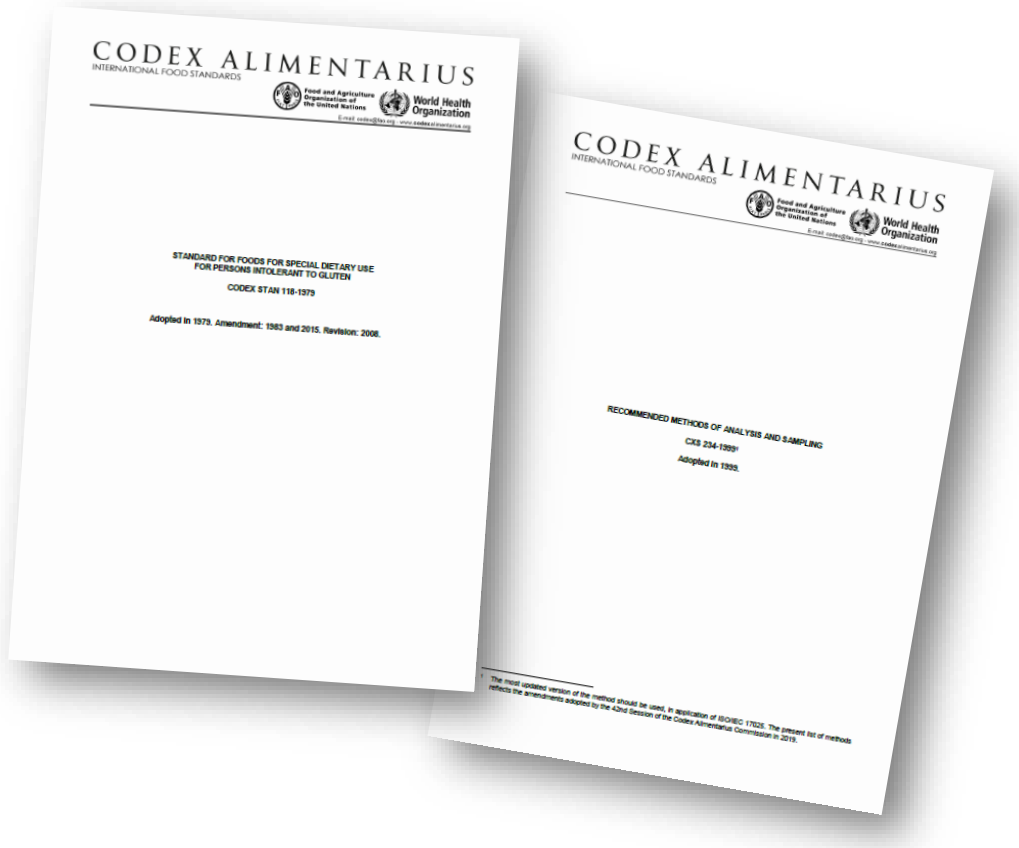
CODEX STAN 118-1979

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

RECOMMENDED METHODS OF ANALYSIS AND SAMPLING

CXS 234-1999[1]

Adopted in 1999.



[1] 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 Amendment in 2015

2.1.1 *Gluten-free foods*

Gluten-free foods are dietary foods

a) consisting of or made only from one or more ingredients which do not contain wheat (i.e. all *Triticum* species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, oats[1] or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer, and/or

b) consisting of one or more ingredients from wheat (i.e. all *Triticum* species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, oats[1] or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer.

2.2.2 *Prolamins*

Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats[1] avenin.

It is however an established custom to speak of gluten sensitivity. The prolamin content of gluten is generally taken as 50%.

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 *Eur J Gastroenterol Hepatol* 2003; 15: 465-474	Immunoassay	I

Gluten Analysis in Codex Alimentarius

Codex Alimentarius Type 1 method for gluten analysis in food

Standard CXS 234-1999 (adoption from 2019)

R5 ELISA

Gliadin

Need to have a method that works on complex food matrices: e.g., processed foods

Standardization of Food Analyses

- Reference methods defined by Codex Alimentarius
- Methods provided by non-governmental organizations like AOAC

AOAC INTERNATIONAL GUIDANCE

AOAC Official Method of Analysis (OMA):

- international, inter-laboratory comparison (several laboratories involved)
- rigorous testing and scientific suitability for the respective analytical purpose
- Comprehensive ….takes > 2 years
- method incl. full documentation can be acquired from AOAC

AOAC-RI Performance Tested Method (PTM):

- certifies that a method works according to the documented information of the manufacturer
- only **one** independent laboratory validates the method
- AOAC-RI certificate is issued

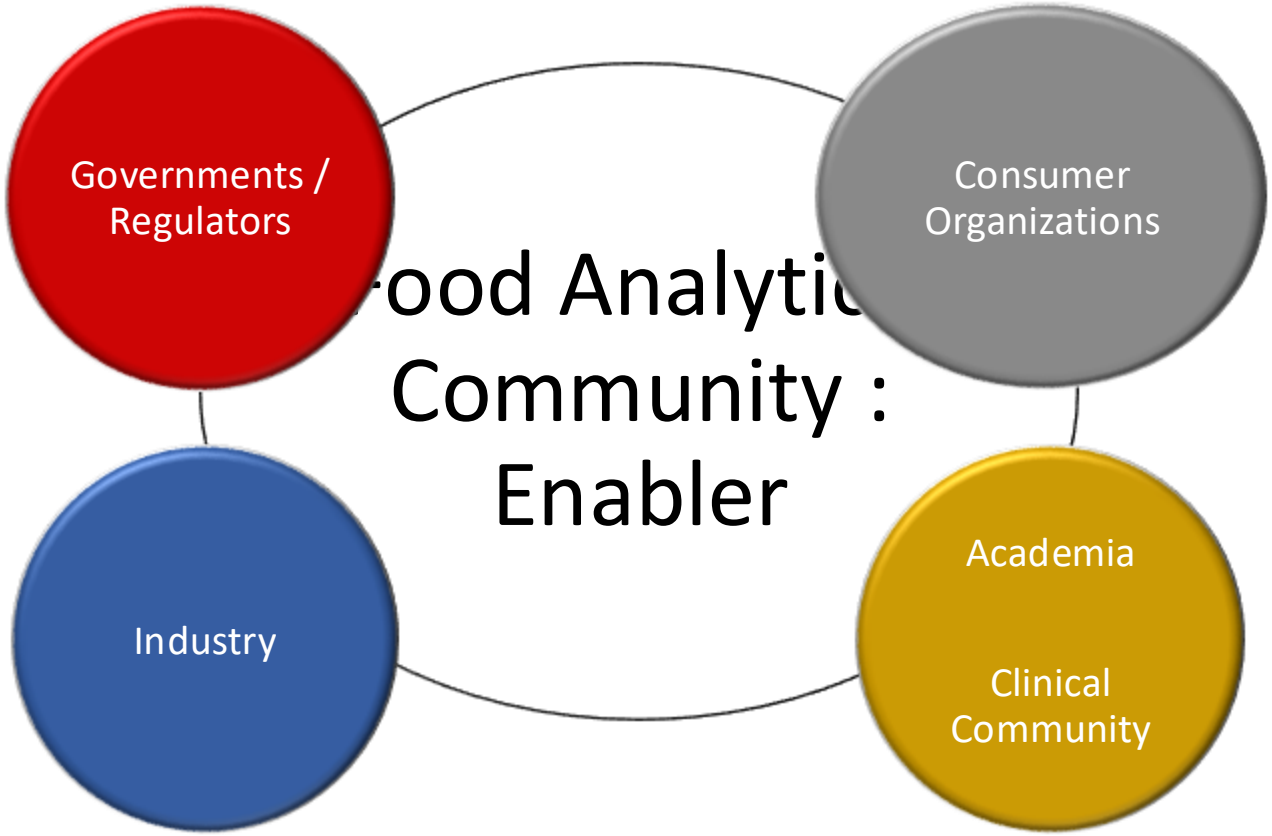
Importance of Validation Data

Methods of Analysis

Methods of Analysis are part of a complete Scheme of Quality Management System to Support Gluten Free Claims

Conditions of Success

Maximum Engagement and Buy-in




thank you
danke
謝謝
рахмат
ngiyabonga
teşekkür ederim
Баярлалаа
спасибо
faafetai lava
mersi
kia ora
barka
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