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Introduction to Food Allergen and Gluten Management – A Global perspective

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Prof. Samuel Godefroy, Ph.D.

Full Professor, Food Risk Analysis and Regulatory Policies

Food Risk Analysis and Regulatory Excellence Platform (PARERA), Department of Food Sciences, Institute of Nutrition & Functional Foods (INAF)

Université Laval, Québec, QC, Canada

Outline



Current Status Of Allergen Standards At The International Level – Highlighting What Was Accomplished

Levers of Change ...

Perspectives for Enhanced International Guidance And Convergence In Food Allergen Management



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Overall: Positioning the Challenge Globally

- ❑ Food Allergies: Immune (IgE) Mediated Reactions
- ❑ Prevalence 3-5% in Adults and up to 8% in children
- ❑ Food Allergy Incidents Are Preventable
 - Avoidance Continue To Be The Most Effective Risk Management Approach For Food Allergic Consumers
- ❑ Food Allergen Related Recalls Continue To Top The List Of Recalls In North America, South-west Pacific And Europe



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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**



Possible Increased Impact

Increased Emergency Room Visits related to Anaphylaxis in Montreal



THE JOURNAL OF
**Allergy AND Clinical
Immunology**

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Article in Press

Increasing visits for anaphylaxis and the benefits of early epinephrine administration: A 4-year study at a pediatric emergency department in Montreal, Canada

[Elana Hochstadter](#), MD, [Ann Clarke](#), MD, MSc, [Sarah De Schryver](#), MD, [Sebastien LaVieille](#), MD, MSc, [Reza Alizadehfar](#), MD, [Lawrence Joseph](#), PhD, [Harley Eisman](#), MD, [Moshe Ben-Shoshan](#), MD, MSc

Altmetric 56

DOI: <http://dx.doi.org/10.1016/j.jaci.2016.02.016>

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Unknown Factors / Impacts

Medical Costs: Costs to Provincial Health Care Systems

Social Impacts : Daycare and School Policies

Psychological Costs: Stigmatization of food allergic individual



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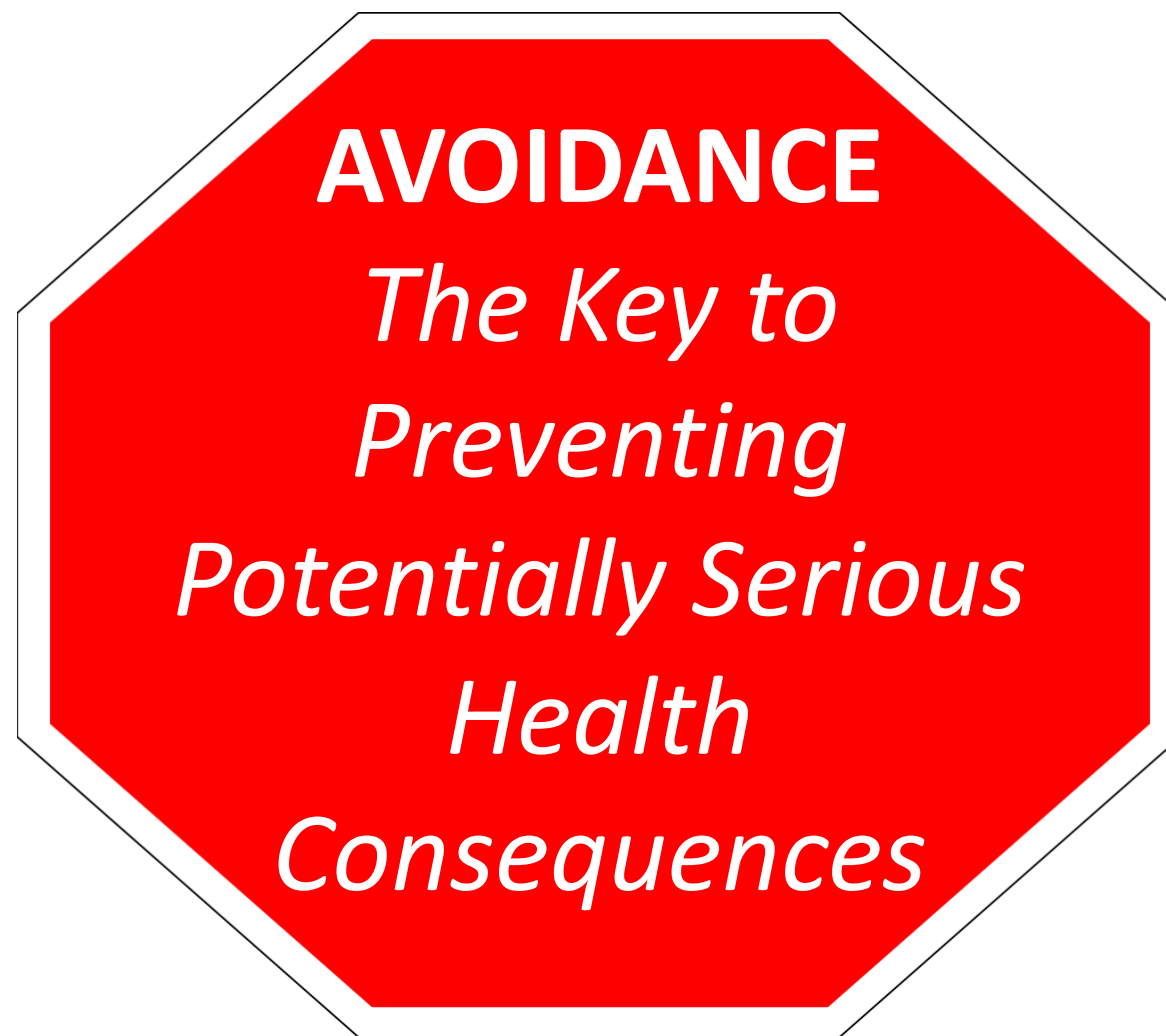
Interventions

- 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)**



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Codex Standards on Food Allergens

CCFL : Codex Committee on Food Labelling



CODEX 50 
ALIMENTARIUS 1963-2013



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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*



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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



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Example of Label Changes – Potato Chips

☐ Before

Ingredients : Potatoes, sunflower oil, salt,
seasonings

☐ After

Ingredients : Potatoes, sunflower oil, salt,
seasonings (mustard)

OR

Ingredients : Potatoes, sunflower oil, salt,
seasonings
Contains : mustard



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CCFL : Priority List for Food Allergen Labelling

- ❑ The Codex Committee on Food Labelling (CCFL) (CAC, 1999) identified priorities for such enhanced labelling

- ❑ Priority Lists worldwide were based on the Codex list and expanded to account for geographical differences
 - Different diets & prevalence in food sensitization

- ❑ A science-based / criteria-based approach is to be followed to amend the list



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Adoption in Domestic Legislation and Regulations

Countries Developed Lists For
Labelling Of Priority Allergens
Applying These Criteria

Evidence-based Process To
Mandate Labelling Of
Ingredients



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Food Allergies: Priority Allergens

European List

EU Directive 2003/89/EC
(amending Directive 2000/13/EC)
on the indication of ingredients in
food.

The Directive entered into force
in November 2004

Directive amended in 2006 and
requires food manufacturers to list
14 potentially allergic ingredients

Cereals containing gluten

fish

crustaceans

eggs

peanuts

soy

milk and dairy products

nuts

celery, mustard

Lupin

sesame seed

sulphites



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Canadian List : Priority Allergens

“Food Allergen” Defined (in regulation)

Any protein from any of the following foods or any modified protein, including any protein fraction, that is derived from the following foods:

- Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts
- Peanuts
- Sesame seeds
- Wheat, kamut, spelt, triticale
- Eggs
- Milk
- Soybeans
- Crustacea
- Fish
- Shellfish
- Mustard



Japan Priority List

Japan List

- Labelling of allergens:
 - Mandatory for 7 “specified ingredients”
 - Recommended for 18 “items corresponding to specified ingredients”
- “May contain (name of allergen)” within or outside the ingredient list is forbidden

Mandatory

- Eggs, milk, wheat, buckwheat, peanuts, shrimp, and crab

Recommended

- Abalone, Squid, Salmon Roe, Orange, Kiwifruit, Beef, Walnut, Salmon, Mackerel, Soybean, Chicken, Banana, Pork, Matsutake mushroom, Peach, Yam, Apple, and Gelatin



In 20 YearsProgress 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
- ❑ **Limited Progress in some areas:**
 - China : Does not have a 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, MD³

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.



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Labelling : Areas of Intervention so Far

- Most Progress Achieved for Labelling of Ingredients
- Limited action for Allergen Claims (other than Gluten Free)
- Limited to no action to address Precautionary Labelling



Precautionary labelling : Truthful /Helpful ?



Ingredient list much shorter than allergen precautionary statement



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Precautionary Labeling (cont...)



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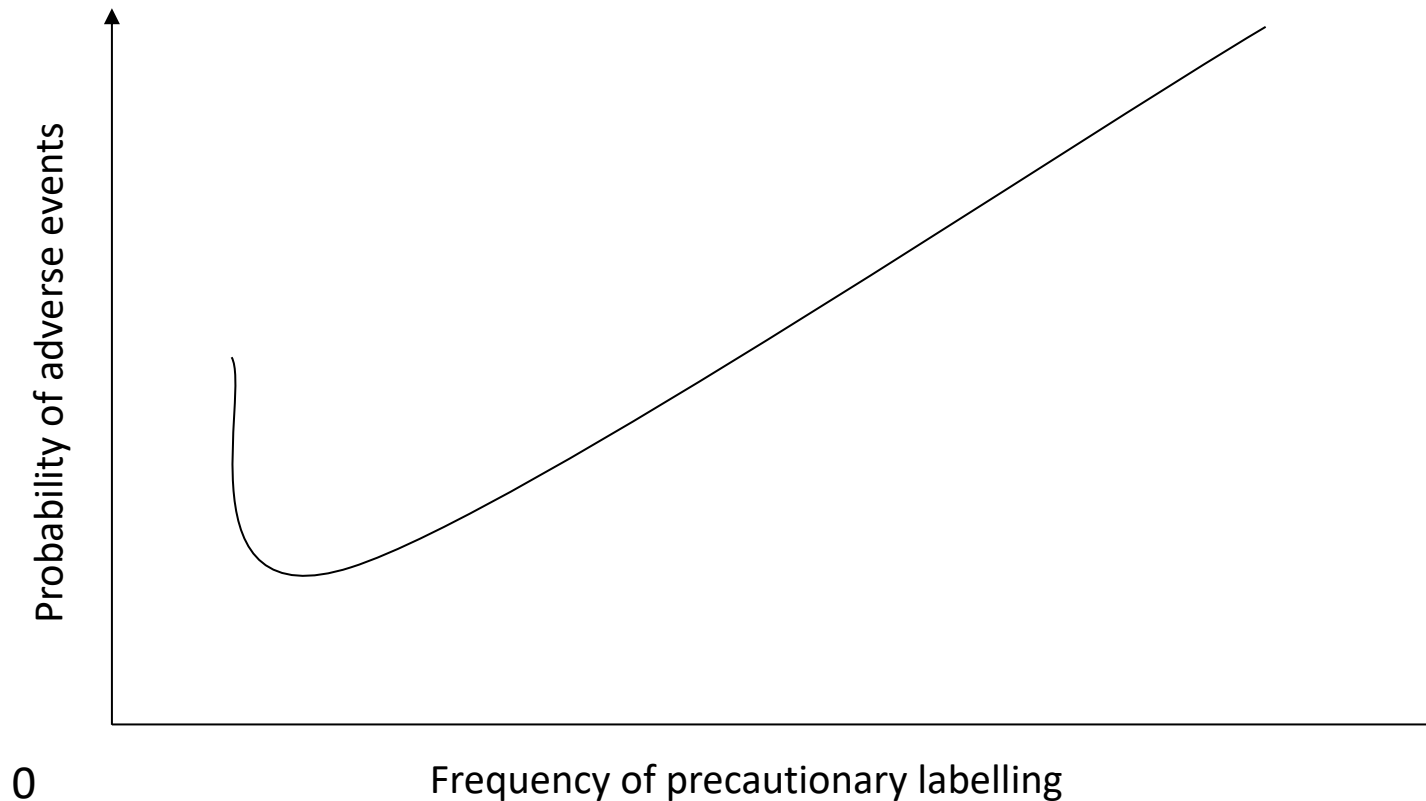
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Precautionary Labeling (cont...)

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.



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Codex Took Action



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Codex guidance adopted in 2020

❑ “CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS” (CXC 80-2020)

❑ 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

❑ Absent:

- **Precautionary Allergen Labelling**



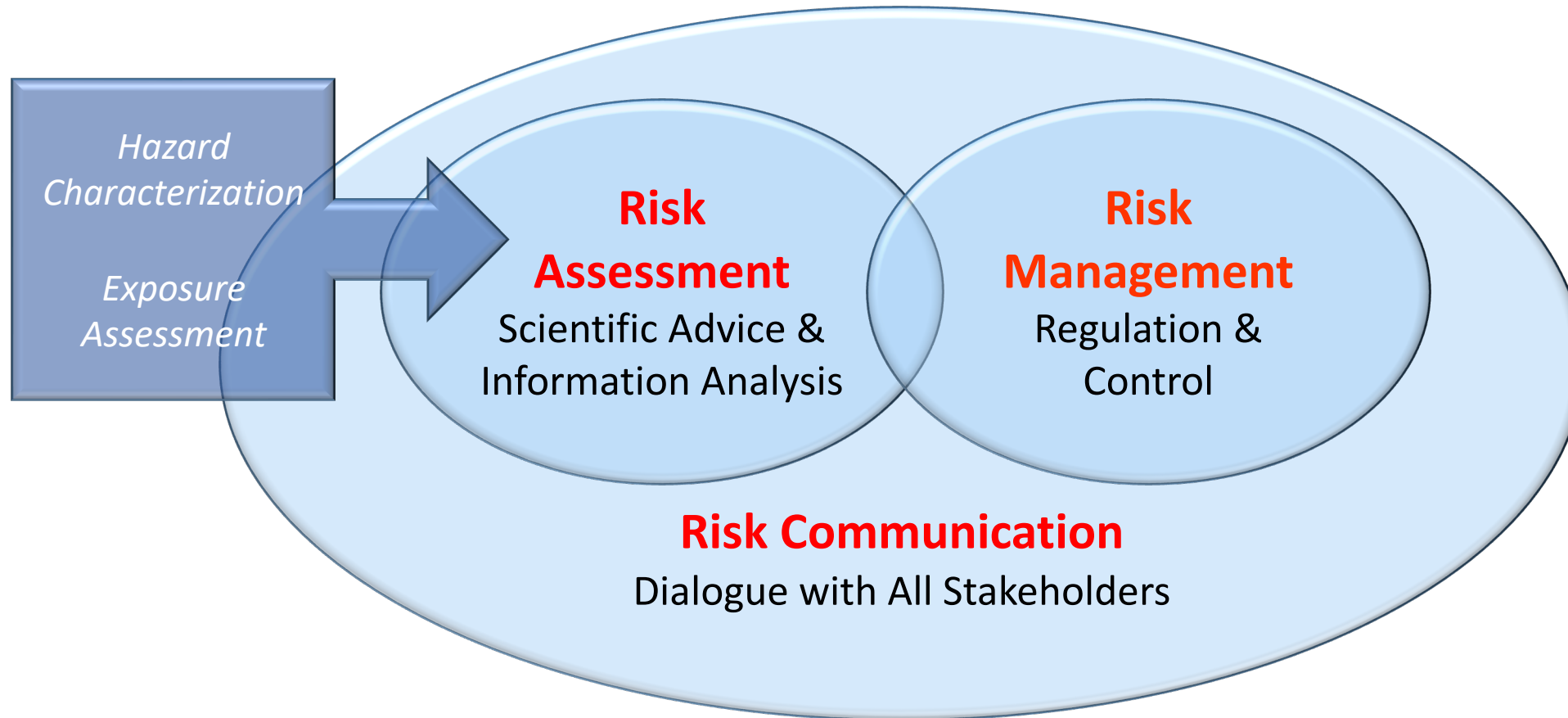
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Scientific Advice needed

FAO / WHO Risk Analysis Paradigm



FAO/WHO Expert Consultation on 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



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Several Challenges remain to be addressed

❑ Translating the Science into a Risk Management Measure :

Guidance for Food Allergen Management in the Context of Food Manufacturing (for Regulators and Industry) :

- Tools that support the implementation of new food safety law requirements (Preventive Controls)



Gluten Free Labelling Supporting Celiacs:

- ❑ 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 than 10 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.



Codex Cut-off :
20 ppm Gluten

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



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Thresholds for Gluten detection in Gluten Free Foods

100 ppm in the 1980/ 1990s

20 ppm adopted by most countries



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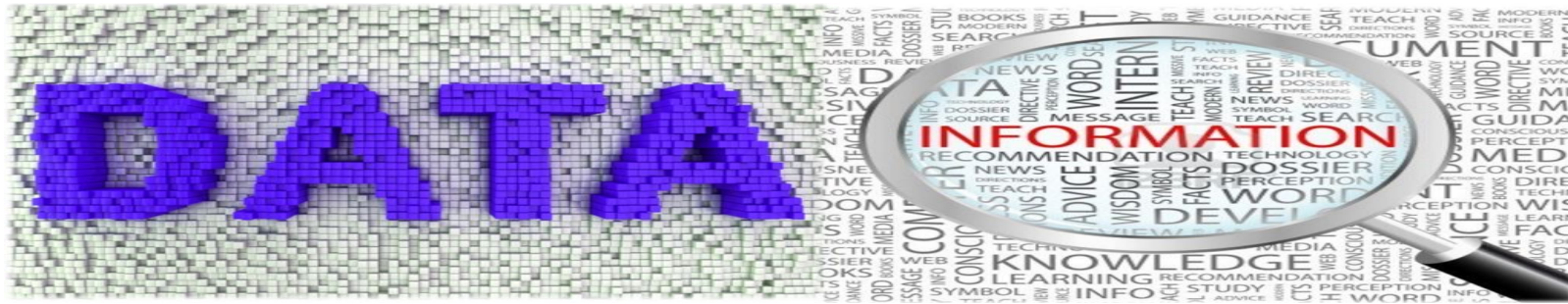


The Future.....

Information on Labels are Normalized and Trusted

□ International Consensus

- Adoption of risk-based management of allergens
- PAL labeling measures are supported by a risk assessment approach
- An e-Icon is adopted to inform consumers that the food product is allergen-controlled



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Conditions of Success

Maximum Engagement and Buy-in

