



Overview of Food Allergen Management and Control

*First Global Food Regulatory Science Symposium
20 November 2021*

Outline

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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

Overall: Positioning the Challenge Globally

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- ❑ Food Allergen-related Incidents Contribute To The Burden Of Food-related Incidents
 - Food Allergies Are A Public Health Issue
- ❑ 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



Possible Increased Impact

Increased Emergency Room Visits related to Anaphylaxis in Montreal



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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 

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



Canadian Food Recall Data: Food Allergens Top the List

April 2006 - March 2013							
	Apr 06 - Mar 07	Apr 07 - Mar 08	Apr 08 - Mar 09	Apr 09 - Mar 10	Apr 10 - Mar 11	Apr 11 - Mar 12	Apr 12 - Mar 13
Undeclared Allergen	89	54	65	65	121	142	109
Chemical	45	33	57	35	19	24	13
Extraneous Material	26	26	28	19	32	31	47
Microbiological	64	75	73	75	78	82	81
Other Food Safety	22	30	13	18	14	22	18

Source: CFIA Food Recall Data - <http://www.inspection.gc.ca/about-the-cfia/newsroom/food-safety-system/food-recalls-incidents/eng/1348756225655/1348756345745>



Unknown Factors / Impacts

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A photograph of an iceberg floating in the ocean. The tip of the iceberg is visible above the water, while the much larger, submerged part is visible below the surface. The water is dark blue, and the sky is a lighter blue with some clouds. The iceberg's submerged part is a vibrant blue, contrasting with the dark water.

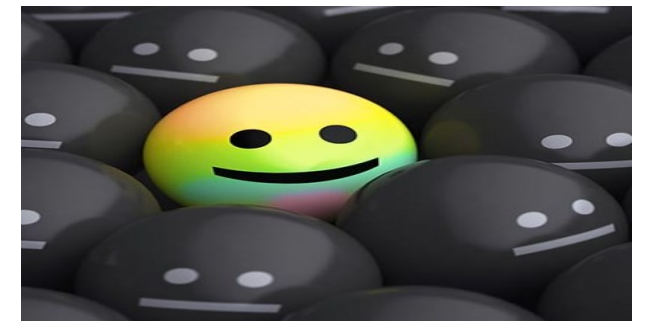
Medical Costs: Costs to Provincial Health Care Systems

Social Impacts : Daycare and School Policies

Psychological Costs: Stigmatization of food allergic individual

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

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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

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CCFL : Codex Committee on Food Labelling



CODEX5 
ALIMENTARIUS 1963-2013

Action guided by Codex

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*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

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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



Example of Label Changes – Potato Chips

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❑ Before

Ingredients : Potatoes, sunflower oil, salt,
seasonings

❑ After

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

OR

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



CCFL : Priority List for Food Allergen Labelling

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- ❑ 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



Adoption in Domestic Legislation and Regulations

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Countries Developed Lists For
Labelling Of Priority Allergens
Applying These Criteria

Evidence-based Process To
Mandate Labelling Of
Ingredients

Food Allergies: Priority Allergens

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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

Food Allergies: Priority Allergens

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US List

- ☐ The Food Allergen Labeling and Consumer Protection Act (FALCPA) has been adopted by the US Government and came into force on 1 January 2006
- ☐ The Act requires food labels to identify in plain English if the product contains any of the eight major food allergens

- ☐ milk
- ☐ eggs
- ☐ fish,
- ☐ Crustacea
- ☐ peanuts
- ☐ tree nuts
- ☐ wheat
- ☐ soybeans

“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 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

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.

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



Current Situation and Gaps

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

- ❑ Distinction between ingredient listing and advisory/precautionary labelling
- ❑ Pervasiveness of precautionary statements : Question as to their effectiveness as a risk mitigation strategy (consumer perception/understanding)



**No Guidance Was Provided
for Incident Management:
Managing Cross-Contamination or
Adventitious Presence of Allergens**

Precautionary labelling : Truthful /Helpful ?



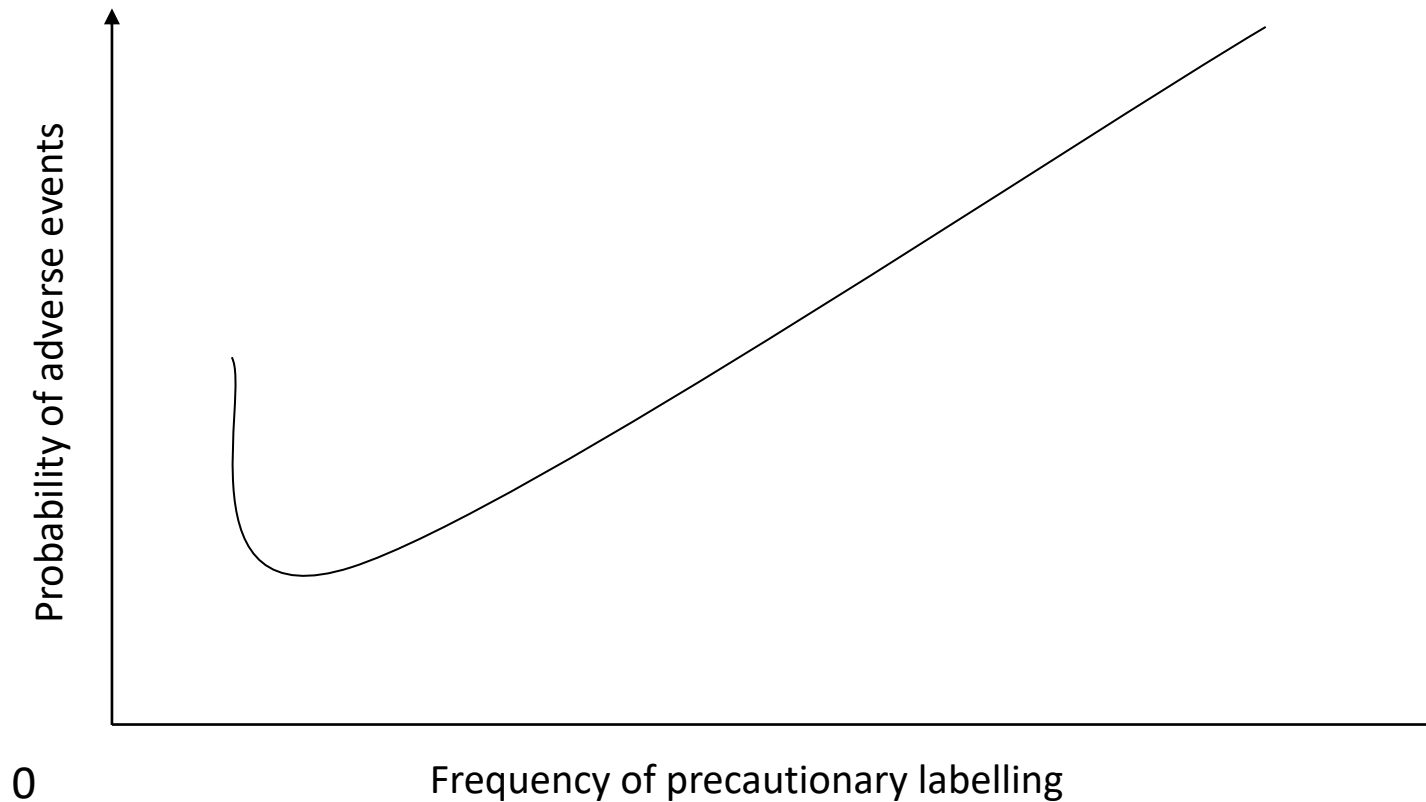
Ingredient list much shorter than allergen precautionary statement

Precautionary Labeling (cont...)



Precautionary Labeling (cont...)

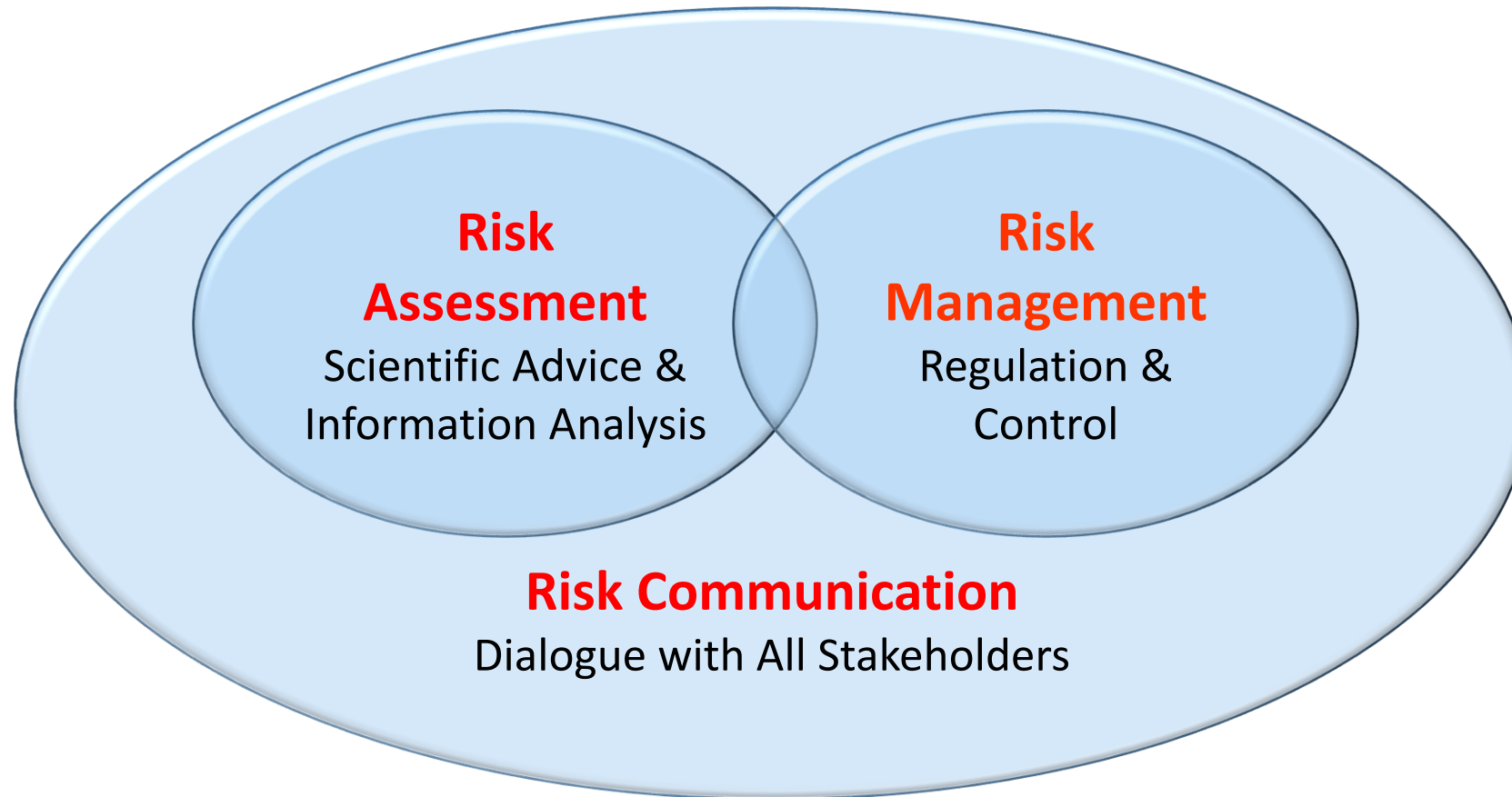
Illustration of the efficacy of precautionary labelling against frequency of use



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.

Applying Risk Analysis for Allergens: Guidance needed

FAO / WHO Risk Analysis Paradigm



What is Lacking

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- ☐ Guidance on Risk Assessment Methodologies to Regulators and Industry
- ☐ Agreed Upon Data - Accessible to All
- ☐ Recognition and adoption of Proposed Sentinel levels for Food Allergen Management (by national and international food authorities)



Identified as a Priority Issue by All Stakeholders

Confirmed Interest of International Organizations to Move Forward:



Codex Guidance Enhanced Food Allergen Control



Appendix III

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

(At Step 5)

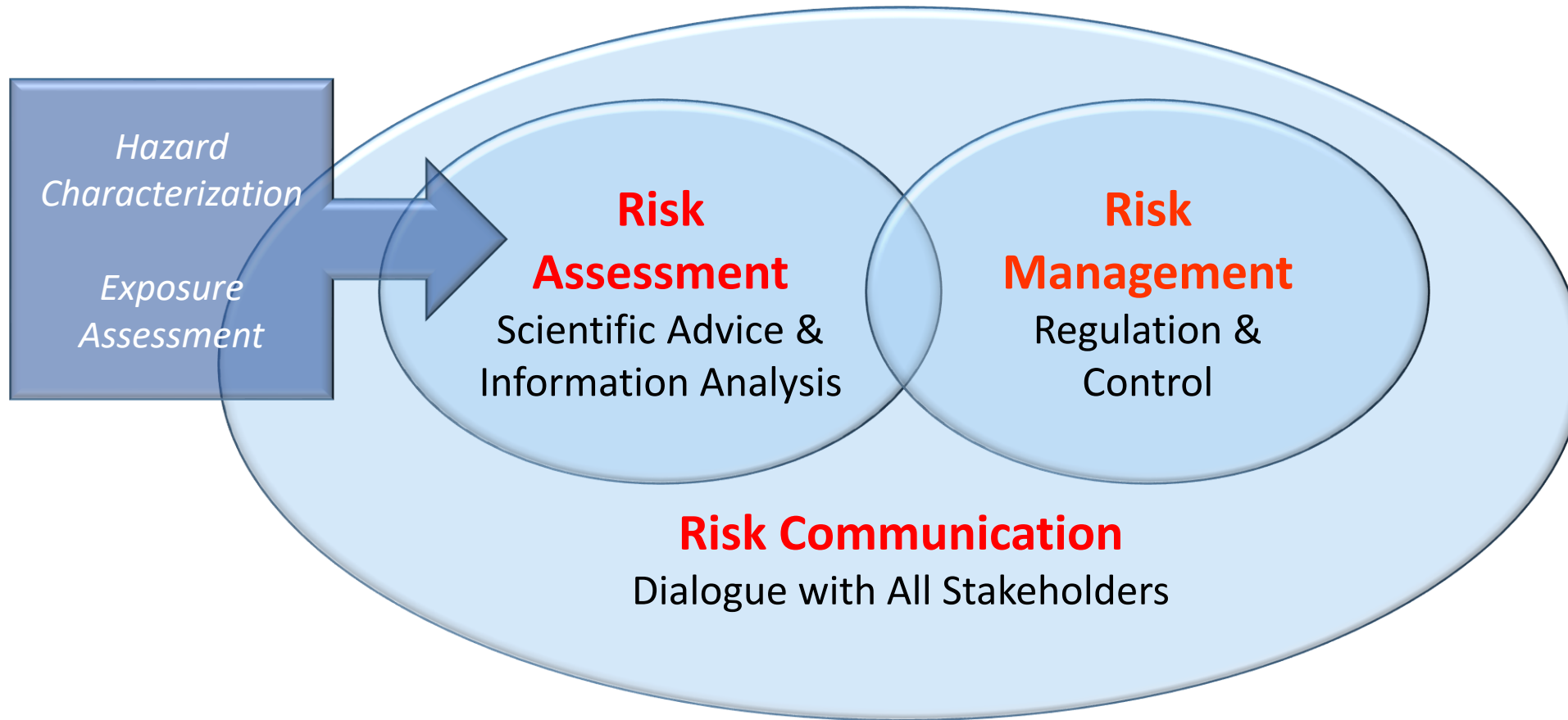
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- ❑ CCFH: Risk Management
- Approach for industries: Code of Practice on Food Allergen Management For Food Business Operators

- ❑ **New work to review and clarify the provisions relevant to allergen labelling in the GSLPF (General Standard for the Labelling of Prepackaged Food) and develop guidance on precautionary allergen or advisory labelling,**
 - Take into account the scientific advice from FAO/WHO and evidence based consumer understanding of allergen labelling and advisory statements.
- ❑ **Scientific advice relating to the list of foods and ingredients (i.e. those known to cause hypersensitivity) from FAO/WHO on:**
 - **Whether the published criteria for assessing additions and exclusions to the list is still current and appropriate.**
 - **Subject to the advice on the criteria above:**
 - whether there are foods and ingredients that should be added to or deleted from the list.
 - clarification of the groupings of foods and ingredients in the list.
 - whether certain foods and ingredients, **such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity** can be exempted from mandatory declaration.

FAO / WHO Risk Analysis Paradigm



Leveraging work conducted for 2.5 decades

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- ❑ Development of Threshold values supported by Clinical data
- ❑ Development of Sentinel levels, based on risk assessments
- ❑ Guidance for use of Precautionary levels as a result



Summary of the 2019
VITAL Scientific Expert Panel
Recommendations



Several Challenges remain to be addressed

- ❑ Enhanced International Coverage
- ❑ 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)
- ❑ Effectiveness of Regulatory measures:
Are Current Interventions having an impact on Public Health ?
 - Reduction of Emergency Room Visits ?
 - Reduction of recalls ?



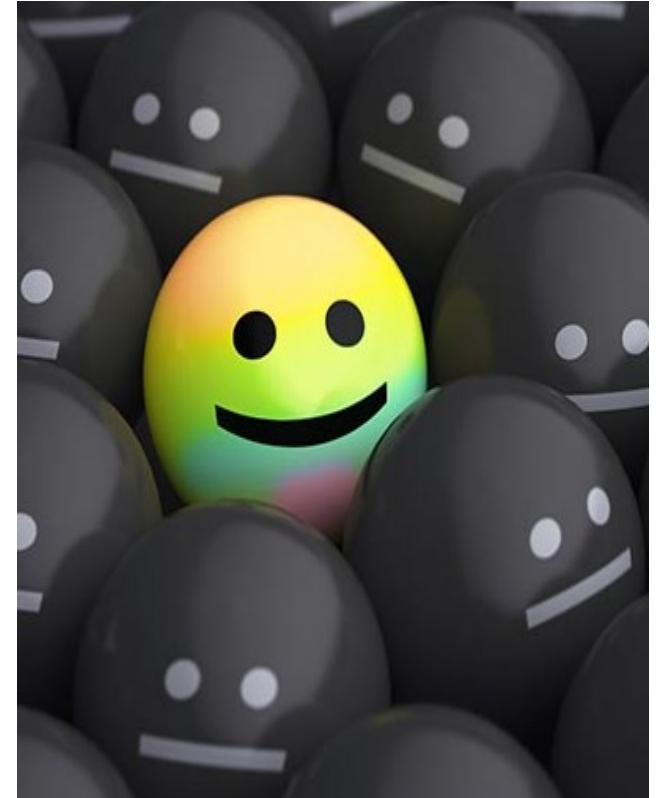
Changes Witnessed Over the Last Decade

- ❑ Consumer groups continue to be amongst the most active and reliable source of information for allergic individuals and their families
- ❑ Food Allergen Labeling requirements became a reality and are implemented
- ❑ New measures of preventive controls targeting allergens as a “food hazard” are being considered
 - New tools are being designed and implemented
- ❑ Clinical developments in immunotherapies, enhanced awareness for early detection and treatment of patients
- ❑ Enhanced industry awareness of allergen related issues
- ❑ Food Allergy policies adopted in public spaces → enhanced awareness



Optimistic View

- ❑ Effectiveness of Regulatory Measures
 - Risk-based interventions
 - Producing positive impact on public health
- ❑ Clinical Progress in Averting Fatal Reactions
- ❑ Progress in Implementing Allergen Control Practices (including effective use of analytical tools):
 - Clear(er) labeling measures
 - More educated and trusting consumers
 - More tools available for risk management
- ❑ Domestic Approaches are Supported by International Measures, with Codex taking the lead (again):
 - Addressing a globalized supply chain
 - Enabling optimal protection wherever we are



Focus

*Prevent / minimize
cross-contact*

*Limit introduction of
unintended /
undeclared allergens*

Inform consumers

1. Primary Production

5. Personal hygiene

2. Design and Facilities

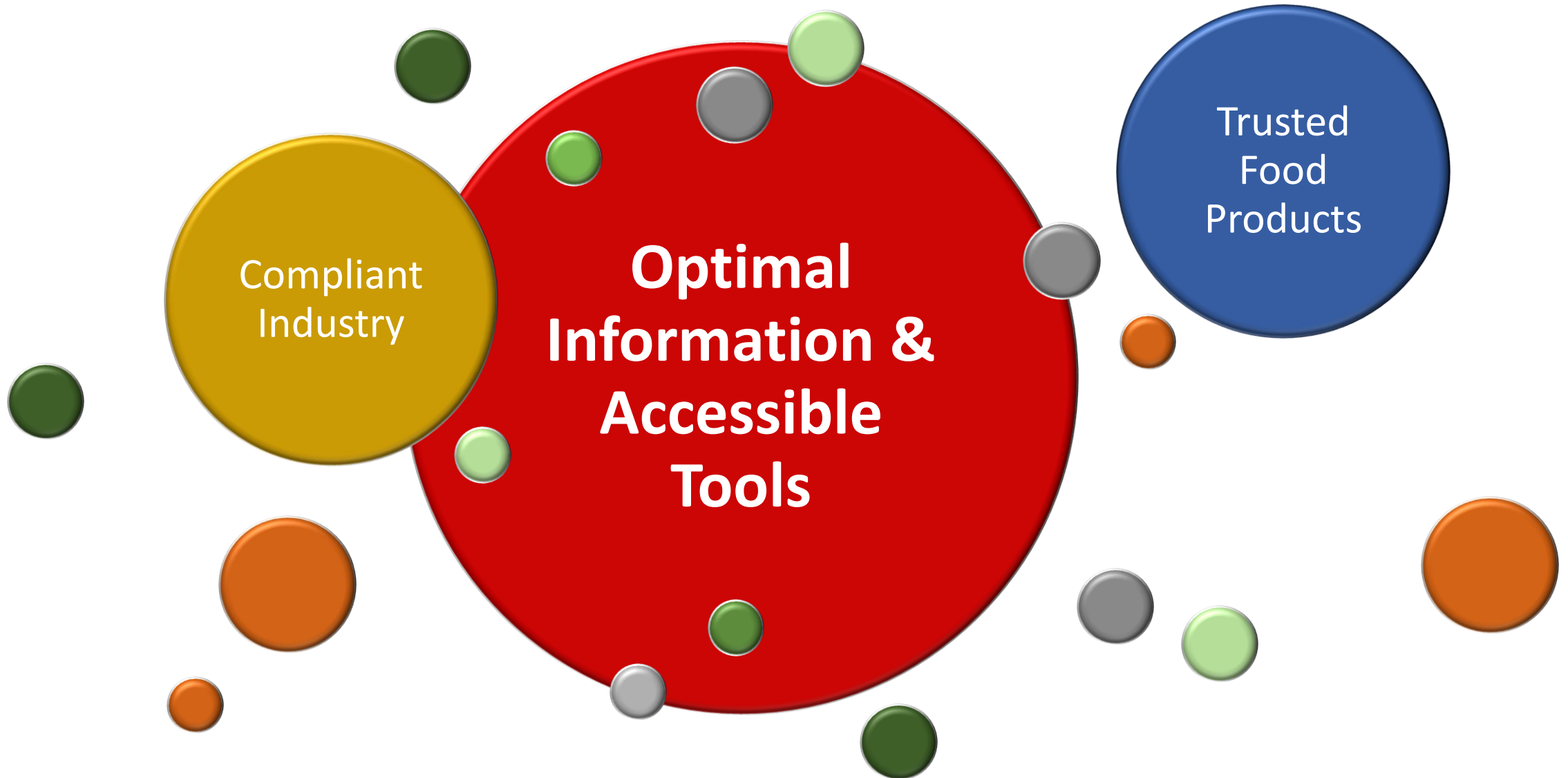
6. Transportation

3. Control of operation

7. Product information and
consumer awareness

4. Maintenance and
Sanitation

8. Training



New Purchasing Practice & Labeling Tools

❑ Reliance on e-Labels

- **Personalized** “Reading” of Labeling Information
 - Information on food products are comprehensive yet for a given consumer, only the important details are showcased
- Products to be avoided are clearly identified through “bar code reading” or other technology enabled tool

❑ e-Commerce

- Allows access to a section of food products that are adapted to a given health profile



In 2025 ...

Enhanced Traceability to Consumers

- ❑ Documentation of Food Production Processes (through Blockchain technology or other IT enabled approach will enable to document the life cycle of the product, up to the consumer)...
- Ability to trace the product forward in a most efficient and effective way
- Most effective recall of products



❑ International Consensus

-

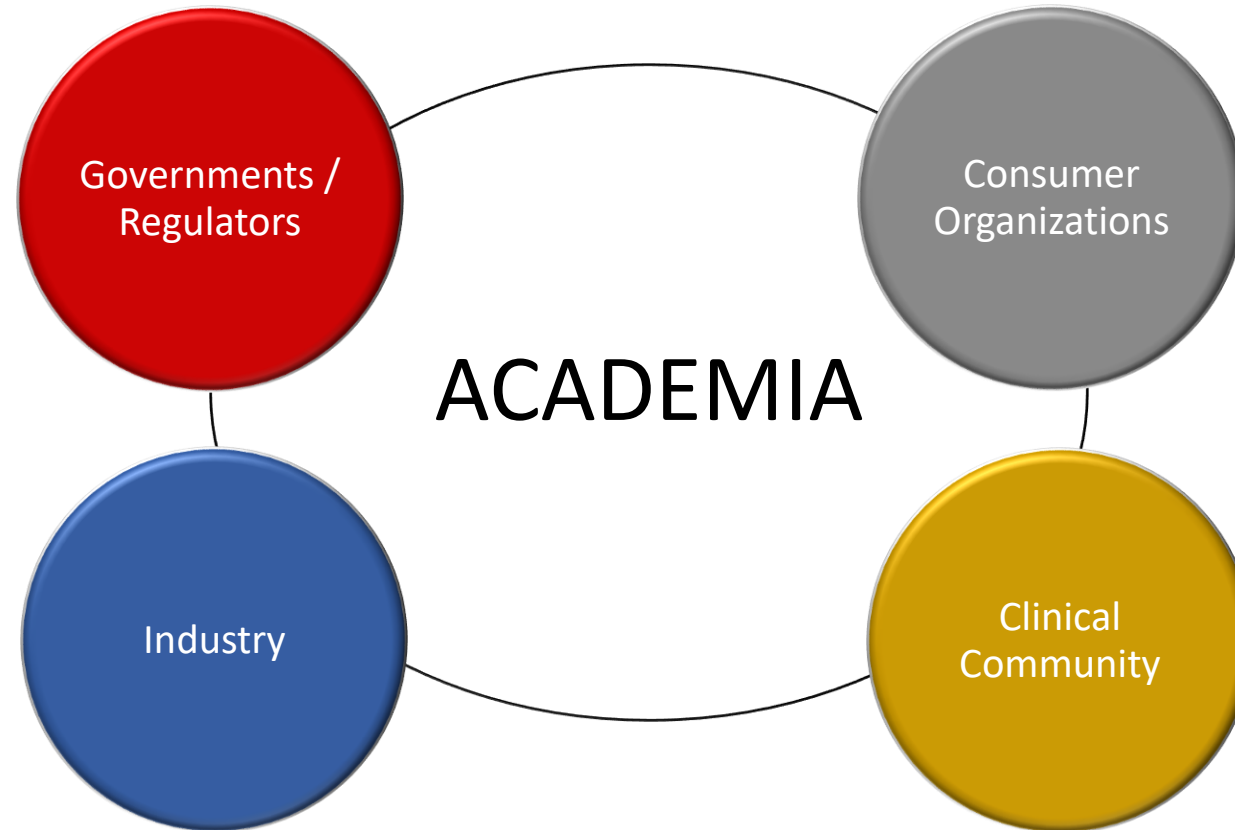
Can This be Attained?

This is Possible through Concerted Efforts and Inclusive Approaches



Conditions of Success

Maximum Engagement and Buy-in



Expected Outcomes

- ❑ Safe(r) Allergic Consumers with Limited Incidents
- ❑ No Fatal Food Allergy Incidents Ever
- ❑ Trusting Consumers – With More Accessible Food Choices
- ❑ Clear and Predictable Food Regulatory Environment for Industry:
 - With Accessible and Effective Food Allergen Management Tools



[illegible]