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Regulatory Environment for Food Allergen Labelling in Canada:

Current situation and future perspectives

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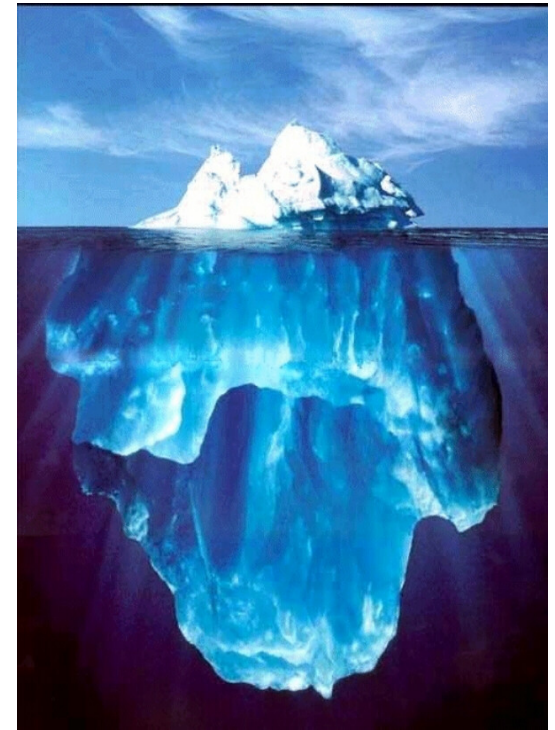
*Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch*

Canada

Food Allergies and Celiac Disease

A High Priority Public Health Issue ? - Prevalence

- ❑ Food allergies affect an estimated 6% of Canadian children and 3-4% of adults.
- ❑ Celiac disease affects approximately 1% of the Canadian population.
- ❑ Celiac Disease is widely under-diagnosed.



Food Allergies and Celiac Disease

A High Priority Public Health Issue ? - Impacts

- ❑ 150-200 deaths/year due to food anaphylaxis in North America
- ❑ Estimated 2.6 deaths/year in Ontario (Largest Canadian province), attributed to Food Anaphylaxis
- ❑ Celiac disease is linked to multiple affections including osteoporosis and cancer
- ❑ Impacts go beyond family circle: Societal impacts

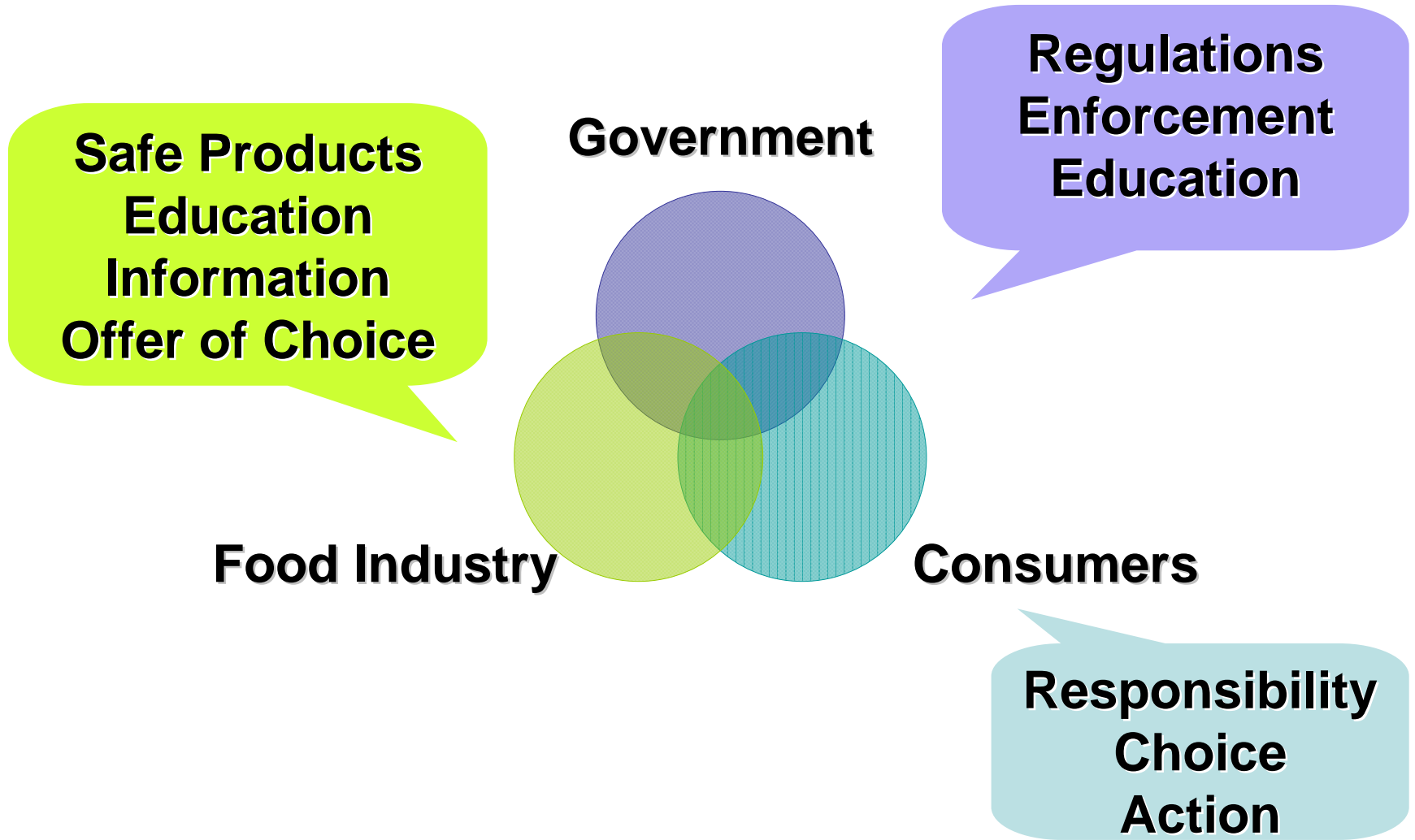


Food Allergy Incidents: rationale for action

- ❑ Food Allergy Incidents are preventable
- ❑ Avoidance is the most effective risk management approach for food allergic consumers



Stakeholders: Actors



Policy Objectives

- ❑ **Enhanced protection to avoid inadvertent consumption of foods containing the « culprit ingredient »:**
 - Minimize risks associated with inadvertent consumption of undeclared allergens in food;
- ❑ **Avoid undue restrictions on choice for a safe and nutritious food supply:**
 - Maximize Choices for food allergic consumers



Prevention of food allergy incidents

- ❑ **Legislative and Regulatory instruments:**
 - *Food and Drugs Act and Regulations* and their enforcement
- ❑ **Education, information dissemination**
- ❑ **Collaboration between stakeholders: Allergic consumers and the food industry (**Government plays a facilitation role**)**
 - e.g. Improvement of manufacturing practices: codes of practice
 - Certification programs



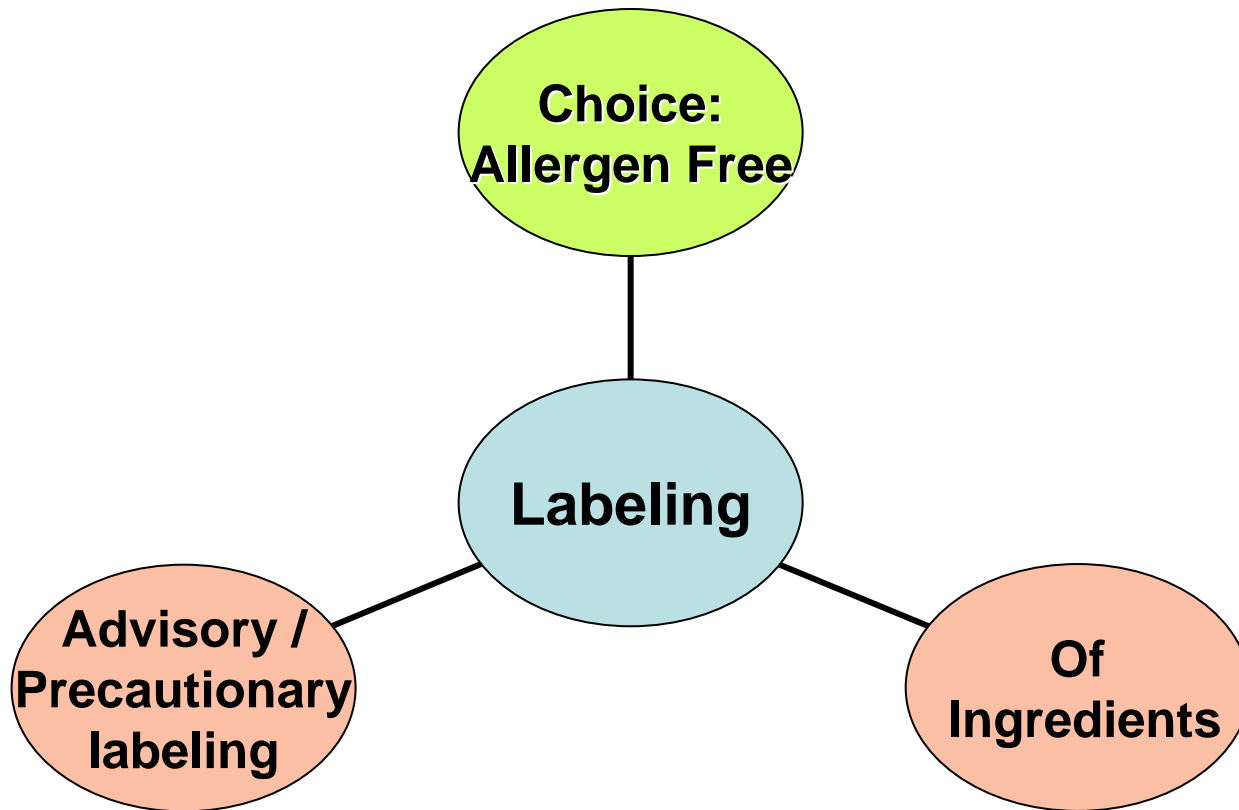
AVOIDANCE

The Key to Preventing Potentially Serious Health Consequences

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



Labeling : Key to identify common allergens





Prepackaged foods : Importance of food labels

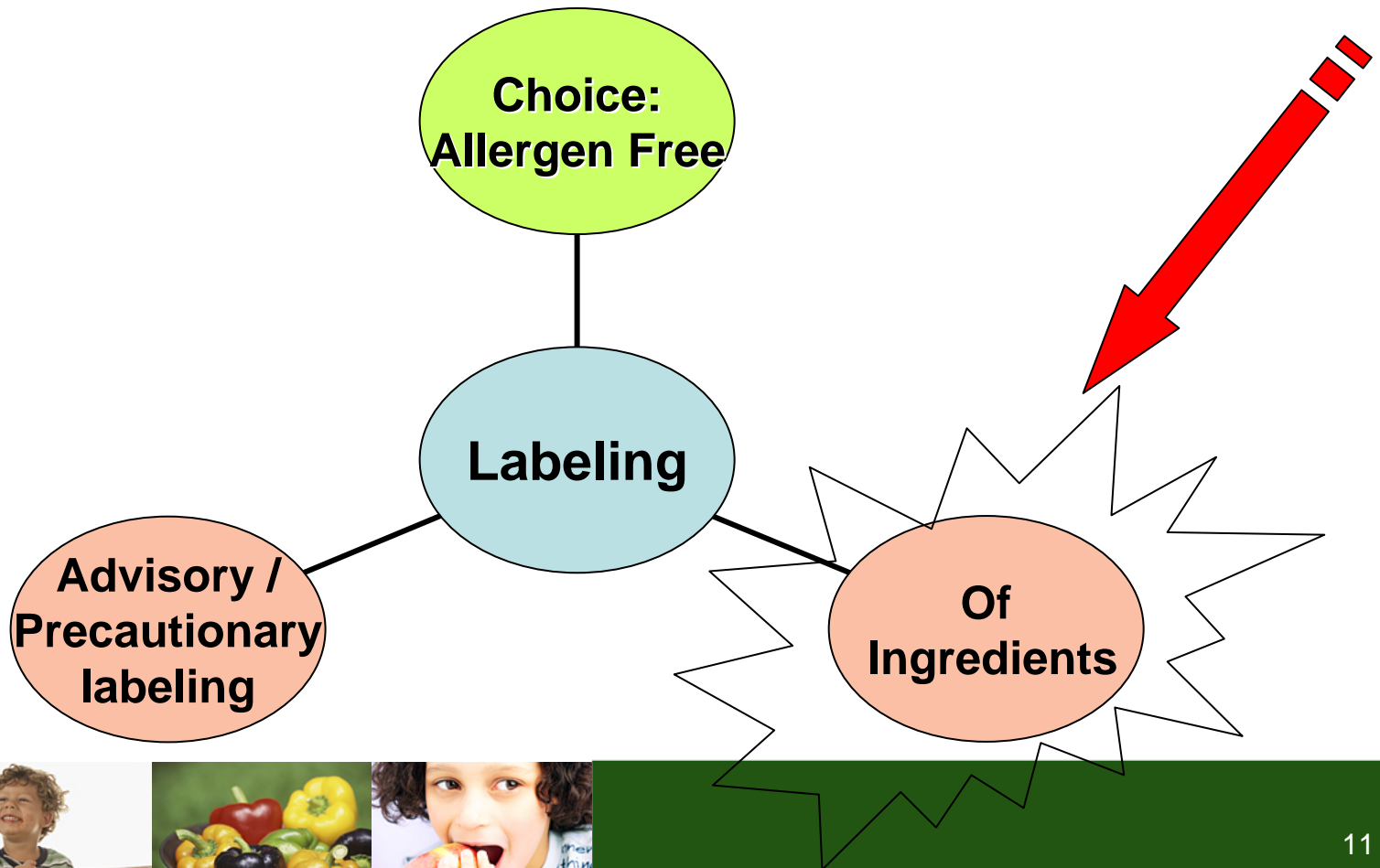
Labeling : Key to identify common allergens

□ Consumer Surveys indicating importance of labeling:

- Canadian Survey 2008: **41.5%** respondents experienced accidental exposure to allergens in their lifetime
 - From those, 33.6% attributed this accident to complex, incomplete labelling or mislabelling
 - **31.9%** attributed this accident to failure to read the label
 - **6.3%** to ignoring a precautionary statement



Labeling : Key to identify common allergens



Current Labelling Regulations

Current Requirements

- ❑ The *Food and Drug Regulations* require that a complete and accurate list of ingredients appear on the label of most prepackaged foods
- ❑ In most cases, the list of ingredients must include the components of ingredients (i.e. ingredients of ingredients).

Gaps

- ❑ Certain ingredients are exempt from component declaration.
- ❑ Some prepackaged foods do not require a list of ingredients
- ❑ Ingredient names do not always reflect the “source” of the ingredient



Regulatory Amendments

Primary Objectives

- ❑ To require the mandatory “source” declaration of the common food allergens and gluten using simple, plain language in English and French
 - Including allergens and gluten present in components of ingredients that are currently exempt from component declaration.
- ❑ To enhance the declaration of sulphites when present in the prepackaged food in a total amount of 10 ppm or more.
- ❑ Scope: Applicable for all ingredients intentionally added to prepackaged foods.





Proposed Regulatory Amendments

“Food Allergen” Defined

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





Proposed Regulatory Amendments

“Gluten” Defined

Any gluten protein from the grain of any of the following cereals or the grain of a hybridized strain created from at least one of the following cereals :

- Wheat, spelt, kamut
- Oats
- Barley
- Rye
- Triticale



Proposed Regulatory Amendments

Label Declaration

- ❑ Sources of common food allergens and gluten must be declared either
 - in the list of ingredients,
- OR
- in the statement: **“Allergy and Intolerance Information – Contains:”**
- ❑ Sulphites must be declared
 - in a statement **“Allergy and Intolerance Information – Contains:”** when present at levels of 10 ppm or higher
- ❑ All current requirements for ingredient declaration remain valid



Regulatory Amendments

- ❑ For products which do not require a list of ingredients but which choose to add an ingredient list, the list will have to be complete and accurate for food allergens, gluten sources and sulphites



Proposed Regulatory Amendments

Common names of starches, modified starches, hydrolyzed protein and lecithin would now be modified as follows :

- ❑ The name of the source of protein be identified in the common name of all **hydrolyzed proteins**
- ❑ The name of the plant source be identified in the common name of all forms of **starch or modified starch**
- ❑ The name of the source of lecithin be identified in the common name of **lecithin**.

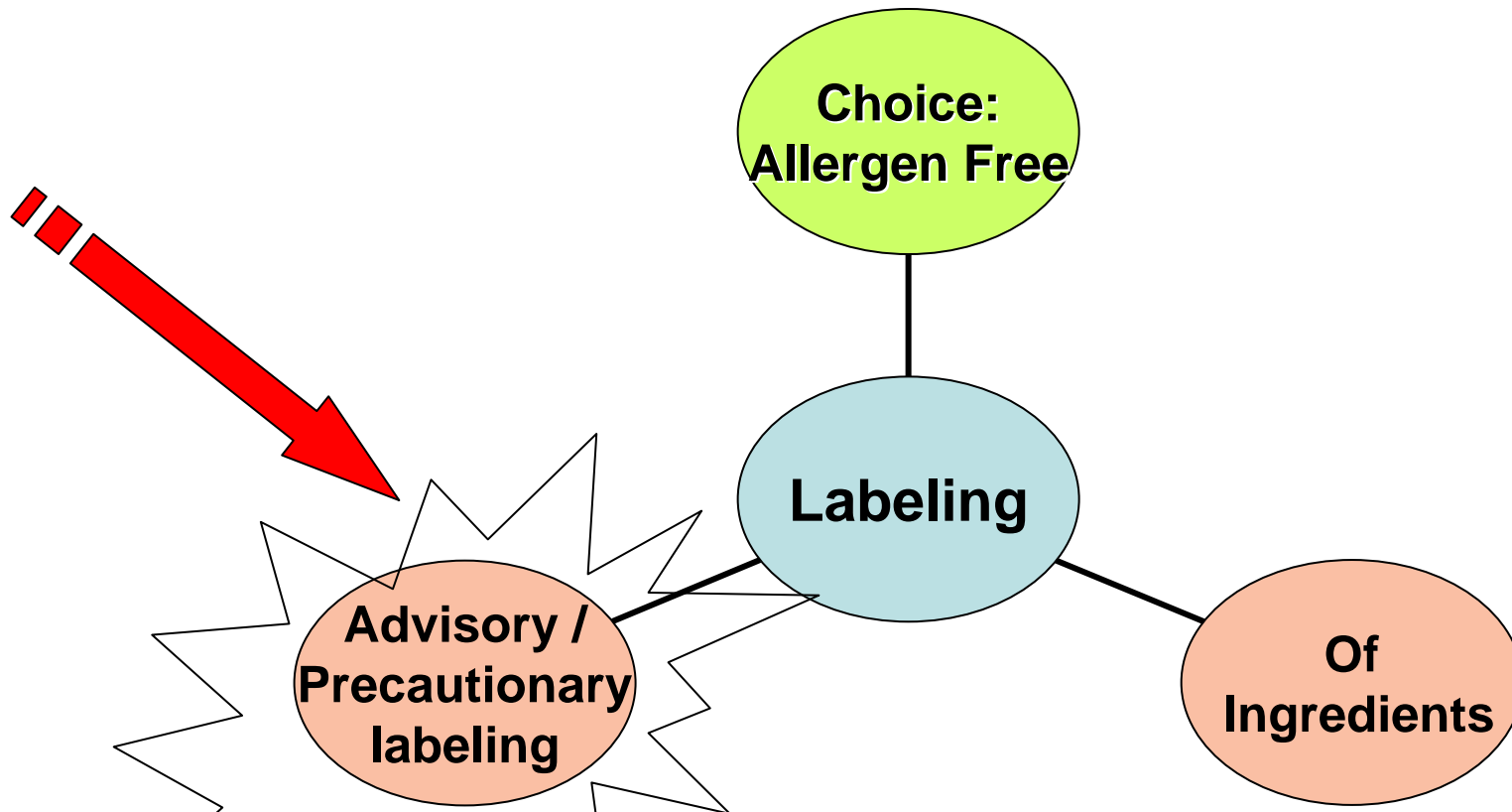


Next Steps

- ❑ Publication in CGI – in July 2008
- ❑ Health Canada response to public comments
 - *Early 2009*
- ❑ Preparation of final version of amendments
- ❑ Publication in Canada Gazette Part II
 - *By January, 2010*
- ❑ New regulatory amendments enacted with a one year transition period.



Labeling : Key to identify common allergens



Precautionary Labeling

“may contain”: Why and when?

- ❑ In Canada, « may contain » labeling was identified as a judicious risk management measure
 - To address instances of « unavoidable » cross-contamination or cross-contact during food processing
 - To alert allergic consumers of the « unsuitability of the product » for their condition and of **a possible risk**
 - Statement differs from a « contains » statement, however risk may be identical



Precautionary Labeling

Precautionary labelling : Now !

- ❑ Current studies show instances of over-use / mis-use of precautionary statements, which impact on food allergic consumers:
 - **Precautionary statements...**
 - No longer provide meaningful information to allergic consumers or their family/social circles
 - Can lead to allergic incidents (warning statements do not clearly reflect the risk level and/or are misinterpreted or ignored)
 - Can unnecessarily limit their food choices



Precautionary labelling : Truthful /Helpful ?

Rotisserie Chicken™ Poulet rôti B.B.Q.

Reheating Instructions: Microwave: Remove lid. Leave chicken in
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 pack
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.

Net weight after cooking/Poids net après cuisson: 1.1 kg

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

Ingredient list much shorter than allergen precautionary statement



What does it mean ?

Risk? /No risk ?

INGREDIENTS: Seasoned Beef (beef, water, salt, sodium phosphate, dextrose, spice), BBQ Sauce (water, tomato paste, sugar, dextrose, vinegar, maltodextrin, salt, autolyzed yeast extract, spices, citric acid, colour, sodium benzoate, potassium sorbate, flavour, corn syrup solids, silicon dioxide, sulphites (less than 3 ppm)).

INGRÉDIENTS : Boeuf assaisonné (boeuf, eau, sel, phosphate de sodium, dextrose, épice), sauce au BBQ (eau, pâte de tomates, sucre, dextrose, vinaigre, maltodextrine, sel, extrait de levure autolysée, épices, acide citrique, couleur, benzoate de sodium, sorbate de potassium, saveur, matières sèches du sirop de maïs, dioxyde de silicium, sulfites (moins de 3 ppm)).

ALLERGENS: Manufactured in a facility with the following allergens present: wheat, soya milk, sulfites.

ALLERGÈNES : Fabriqué dans une usine où les allergènes suivants sont présents : blé, soya lait, sulfites.







Precautionary Labeling

Precautionary labelling: what's in the products?

- Health Canada recently surveyed (2007) chocolate and granola bars...
 - The most common PS found was « *May contain traces of...* »
 - Levels of food allergens found varied widely, from non-detected to 6 500ppm (or 0.65%) in a chocolate product which consistently used « may contain **traces** »:
 - The word « traces » can be misleading
 - Corroborate the fact that allergic consumers **must avoid** products with PS





Consumer behaviour surveys

- A Canadian survey (2008) conducted among allergic consumers showed that:
 - The most deterring statement was « Not suitable for people with an allergy to X » (**93% would never purchase**)
 - « May contain X » and « Manufactured on same equipment... » had also good deterring power (**87% would never purchase**)
 - « May contain traces of X » and « Packaged/Manufactured in a facility that also... » were least likely to result in avoidance (72%)



Precautionary labeling: “may contain”

- ❑ Reinstating the use of precautionary statements as a meaningful and effective risk management tool in order to:
 - minimize risks associated with inadvertent consumption of undeclared priority allergens in food; and
 - maximize available choice of safe and nutritious foods for consumers with food allergies and celiac disease.

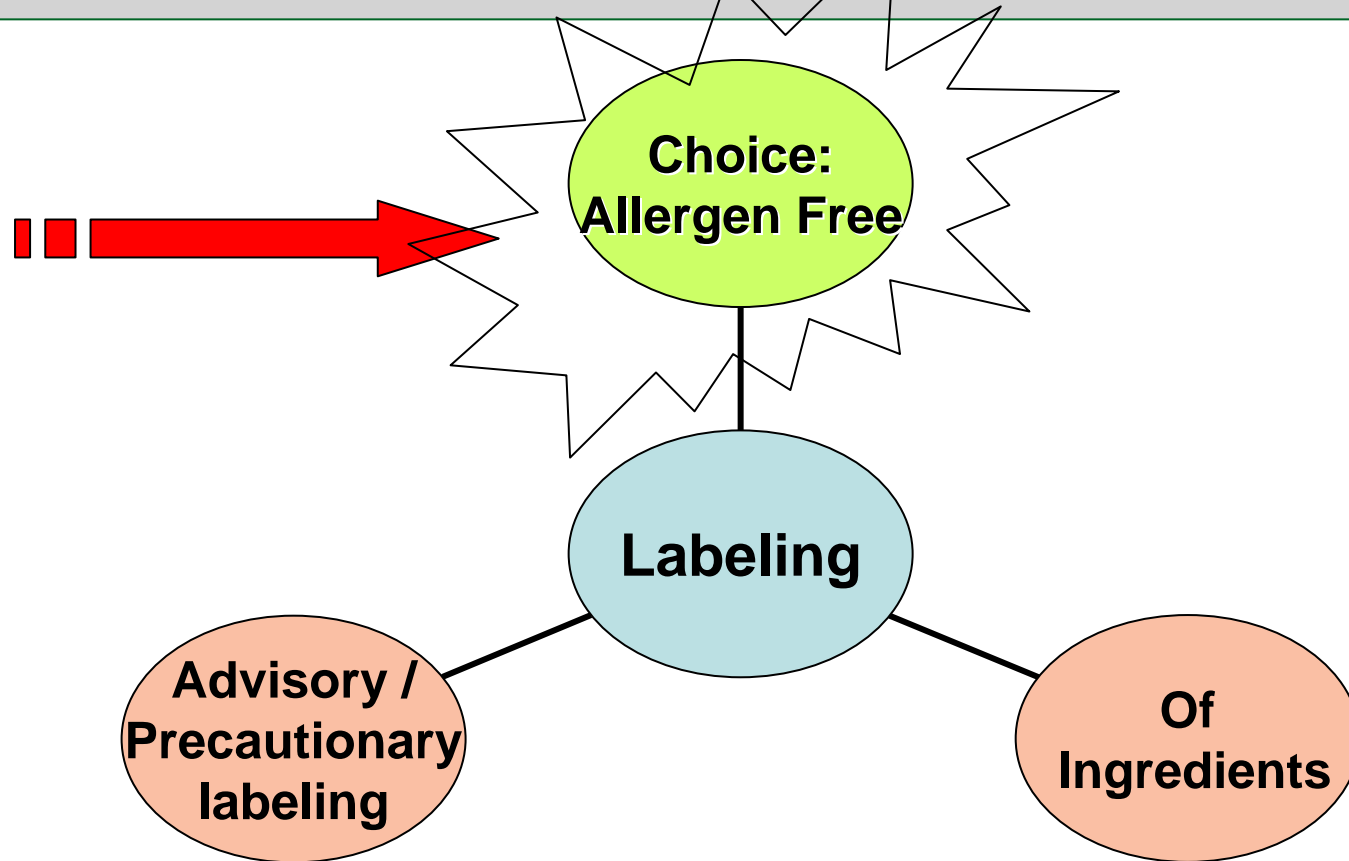


Proposed option for policy change

- ❑ The renewed policy on precautionary labeling would:
 - **Restrict statements from a short list of precautionary statements (PS) :**
 - Any other PS than those on the short list would be considered misleading and enforcement would take place if they are used
 - **Mandate the justification of the use of precautionary labeling**
 - i.e. documentation of the reasons invoked by the manufacturer/processor to use PS as a risk mitigating tool
 - **Be complemented by the development and implementation of:**
 - *Education initiatives (consumers/industry)*
 - *A code of practice on allergens handling*



Labeling : Key to identify common allergens





Providing Choice: « Allergen Free Foods »

- ❑ Food Allergic Consumers are asking for foods clearly identified as being suitable and safe for their conditions
- ❑ Area of « Special Purpose foods »
- ❑ Considered as a rising segment in agri-food innovation

- ❑ Consideration for change:
 - Regulatory frameworks:
 - « Gluten Free » foods covered by national and international standards
 - Other regulations ?
 - Consideration for change using a pre-market oversight.



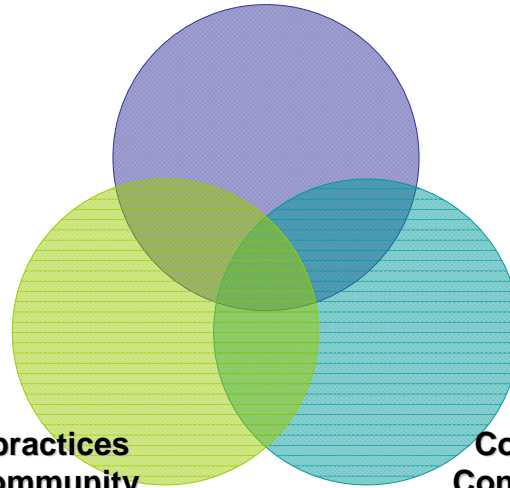


Food Allergic Consumers

Enhanced Protection



Enhanced Legislative / Regulatory frameworks
Regulations adaptable to science and consumer changes



Improved food processing practices
Food Destined to allergic community

Consumers aware of Risks
Consumers aware of choices



Thank-you!



**For more information, please visit us
@**

www.healthcanada.gc.ca/foodallergies



www.inspection.gc.ca/english/fssa/fssae.shtml



THANK YOU FOR YOUR ATTENTION



고맙습니다 谢谢 תודה!
mahalo *děkuji*

Thank You

شكرا *köszönöm* *gracias*

Ευχαριστώ *merci*

どうもありがとう *danke*

