



HEALTH CANADA'S PROGRAMS TO ENHANCE THE PROTECTION OF FOOD ALLERGIC AND CELIAC INDIVIDUALS IN CANADA



2008 CANADIAN CELIAC ASSOCIATION CONFERENCE



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Canada

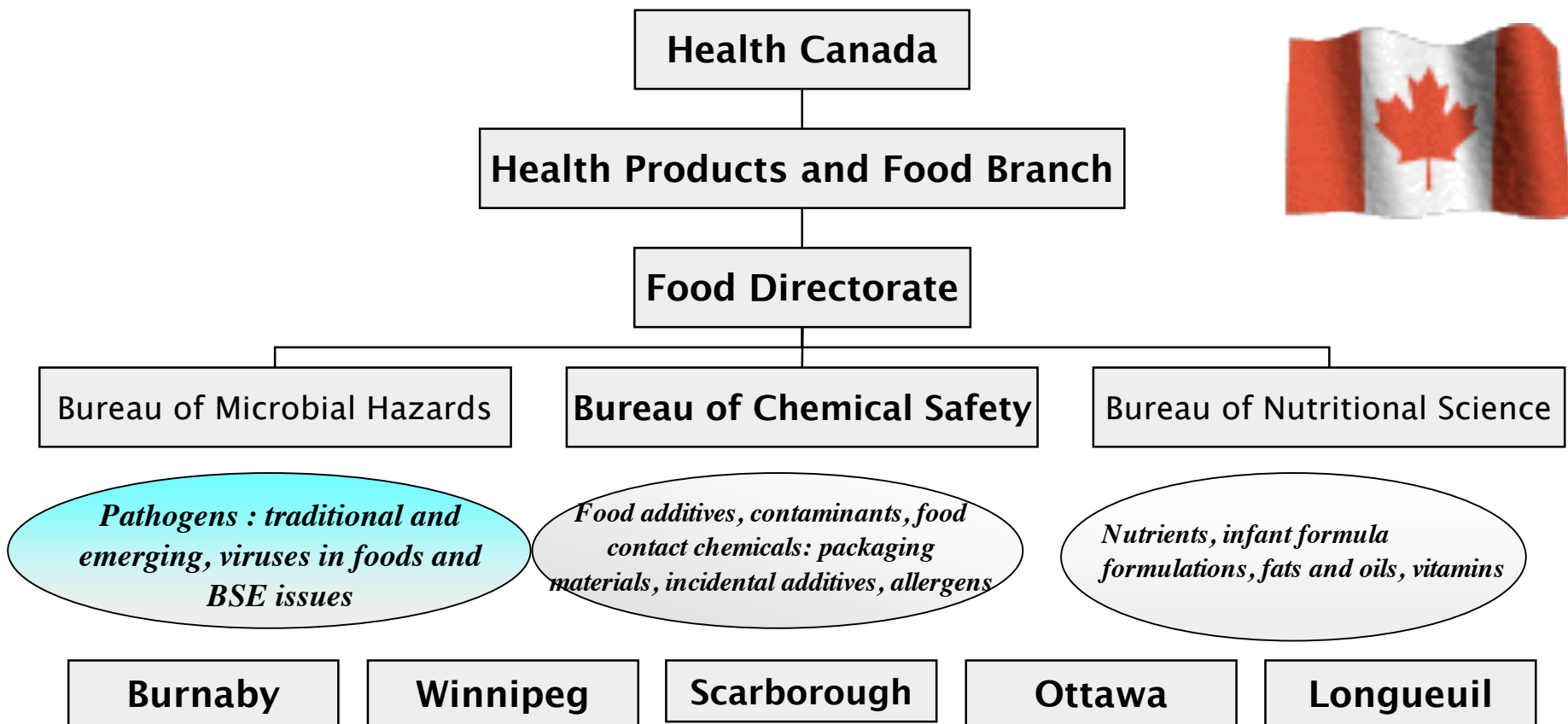


Role of Health Canada's Food Directorate

- Canada's Food Standard Setting body
- Establish policies, regulations and standards related to the safety and nutritional quality of food
- Mandate stemming from the Food and Drugs Act and Regulations, the Canadian Food Inspection Agency Act, and the Department of Health Act
- Over 400 employees across Canada with speciality in:
 - ù Chemical Safety, Microbial Safety, Nutritional Quality
 - ù Scientists, Policy Makers, Regulators



Canadian Food Standard Setting Body





Health Impact of Food Allergies/Intolerances

- o Prevalence: 2- 4 % of adults and 4-8% of children suffer from food allergies (~ 1 million Canadians)
 - o Prevalence is expected to increase
- o Food allergies/intolerances account for:
 - o 150-200 deaths/year due to food anaphylaxis
 - o High number of emergency room visits
 - o 1 in 133 diagnosed with celiac disease in Canada (many undiagnosed)
 - o Celiac disease is linked to multiple affections including osteoporosis and cancer
- q Impacts on quality of life of affected individuals and those around them: large societal impacts . . .



Food Allergy and Intolerance Prevention

POLICY OBJECTIVES

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- ∅ Minimize risks associated with inadvertent consumption of undeclared allergens in food; and
 - ∅ Maximize choice of safe and nutritious food to food allergic consumers.



Food Allergies: Tool Box of Risk Management options

- «Regulator's tools »:
 - *Food and Drugs Act and Regulations* and their enforcement
- Education, information dissemination
- Collaborative approach with stakeholders:
Allergic consumers and the food industry:
 - e.g. Improvement of manufacturing practices: codes of practice, increased awareness about food allergies



Priority List of Food Ingredients Associated with Allergies and Intolerances in Canada

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- 1 Priority Food Allergens**, which are the following foods or proteins derived from one of the following:
- a. Peanuts
 - b. The following tree nuts: almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts
 - c. Sesame seeds
 - d. Milk
 - e. Eggs
 - f. Fish, crustaceans, shellfish;
 - g. Soy
 - h. Wheat



Priority List of Food Ingredients Associated with Allergies and Intolerances in Canada

2 – Sulphites

3 - The **gluten source** when the gluten **protein** is from: barley, oats, rye, triticale or wheat, including kamut and spelt.



Declaration of Priority Allergens, Sufites and Sources of Gluten: Legislation & Regulations

Section 5 (1) of the Food and Drug Act

No person shall label, package, treat, process, sell or advertise any food in a manner that is false misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quality, **composition**, merit or **safety**



Declaration of Priority Allergens, Sufites and Sources of Gluten: REGULATIONS (Continued)

- ∅ 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.



CHOICE : GLUTEN FREE PRODUCTS

Section B.24.018 of the Canadian Food and Drug
Regulations

"No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye or triticale or any part thereof."



Labeling Regulations Shortcomings to Address:

- ∅ The Regulations exempt certain ingredients from component declaration
- ∅ The Regulations permit the use of class names for ingredients, and fully exempt certain foods from any ingredients listing.
 - Ù For example, when flavours, flour, seasoning and margarine are used as ingredients in other foods, their components do not need to be included in the list of ingredients.
 - Ù There are no requirements for clear identification of the “source” of the allergenic ingredient (Caseinate = Milk ; Ovalbulmin = Egg)



LABELLING OF INGREDIENTS:

Proposed Regulatory amendments

Proposed Changes:

- 1. Declaration of sources of priority allergens when the “protein fraction” of the allergen is deliberately added to the food**
- 2. Lifting exemptions on declaration of ingredients of ingredients**
- 3. For products exempted from ingredient declaration: if an ingredient list is “voluntarily added”, it has to be accurate for allergen content**
- 4. Declaration of sources of gluten**



LABELLING OF INGREDIENTS:

Proposed Regulatory amendments (Continued)

Some of the expected consequences:

1. Priority allergens are to be declared using their French/English COMMON NAME in the list of ingredients or in a "Contains" statement.
2. Exemptions on declaration of components of ingredients will be lifted for priority allergens, sulfites and gluten sources.
3. When hydrolyzed proteins or starches are added to foods, the source will need to be declared
4. Exemptions on ingredients declaration will be lifted for vinegars and alcoholic beverages, for priority allergenic ingredients.
5. Sources of Gluten will be declared if the protein fraction of cereals: (wheat, barley, rye, oat, triticale or wheat, including kamut and spelt) are added as ingredients.



LABELLING OF INGREDIENTS: Proposed Regulatory amendments – Path forward

Ø Regulatory process:

- Ù Publication in Canada Gazette Part I for public comments
- Ù Response to public comments
- Ù Publication in Canada Gazette Part II
- Ù New regulatory amendments enacted with a transition period.



INGREDIENTS: Proposed Regulatory amendments – Path forward

Ø Interim “Risk management options”:

- Ù Use of Section 5.1. of the FDA for risk management purposes
- Ù Section 5.1. stipulates that the “representation of the food” should not be misleading to consumers (with a potential to harm their health)
- Ù Health Canada has supported the CFIA in issuing updated guidance for allergen declaration in pre-packaged foods
- Ù Enables more “Predictability” and avoids “risk management by food recalls”



LABELLING OF INGREDIENTS: Interim **“Risk management options”:**

- o Food manufacturers and importers **must declare priority allergens, sulphites and gluten sources** on food labels without exception, either in the list of ingredients or in a statement such as “contains”
- o Should Health Canada identify a significant health risk with respect to the presence of priority food allergens, sulphites or gluten sources in pre-packaged foods, the CFIA will take appropriate enforcement action, which may include recall of the product.



LABELLING OF INGREDIENTS: Interim "Risk management options":

- This approach applies to such substances whenever they are added to pre-packaged foods having a list of ingredients as ingredients, or as components of ingredients.
- This approach focuses on multi-ingredient foods where priority food allergens, sulphites or gluten sources are deliberately added to a food, and are considered to pose a potential risk to consumers having food allergies, intolerances or sensitivities.



Update on the Use of “Allergen precautionary statements” as a risk management tool

- ∅ “Precautionary Statements” (may contain etc..), used on food labels are a valuable **risk management tool** in situations where the presence of the allergen (at low levels) is unavoidable.
- ∅ Restore the “effectiveness of precautionary statements” as a risk management tool
- ∅ Mitigate the “over-use” / mis-use of precautionary statements
- ∅ Better understanding of Consumer perceptions vis-a-vis “precautionary statements”
- ∅ Re-instate / re-enforce the use of these statements as deterrents to consume the food bearing the statement for sensitive consumers



Use of “Allergen precautionary statements” as a risk management tool

Ø Guiding principles:

- Ù Section 5.1. of the FDA
 - Ù Same policy objectives : risk mitigation, least reduction of choice
- Ø Mostly without regulations (using policies under the ACT)
- Ø Update of Health Canada’s policy on use of precautionary statements
- Ø Current direction :
- Ù A more prescriptive approach: Limit the number of options for statements possibly used on food labels
 - Ù Clarify situation of use of the retained “precautionary statements”



Use of “Allergen precautionary statements” as a risk management tool

- ∅ Work to be conducted in collaboration with Canadian Food Allergy Associations (Consumer groups), Academia, and the Food Industry

- ∅ Work to be supported by:
 - Ù findings from current Health Canada’s surveillance activities
 - Ù Consumer surveys
 - Ù Focus testing



In the Interim:

- Health Canada has issued the following guidance:
 - ∅ Precautionary labelling should only be used when, despite all measures, the inadvertent presence of allergens in food is unavoidable.
 - ∅ It must not be used when an allergen or allergen-containing ingredient is deliberately added to a food.
 - ∅ The use of a precautionary statement where there is no real risk of an allergen being present in the food is contrary to Health Canada's goal of enabling a variety of safe and nutritious food choices for the allergic consumer.



CELIAC DISEASE

Health Canada's Food Program
Initiatives to Enhance the
Protection of Celiac Individuals



Rationale

Currently, there is no cure for celiac disease

- If not treated with a **strict gluten-free diet**, celiac disease is associated with significant morbidity and increased mortality
- For many, the symptoms of the disease remain although they follow what they **think** is a gluten-free diet...



Some Difficulties of Following a Gluten-Free Diet . . .

- Pre-packaged foods do not always disclose all the information on gluten content (hidden sources).
- Finding gluten-free foods at work, when travelling or while eating in restaurants is difficult.
- The diet is complex and can be costly. Many individuals do not know:
 - all the ingredients/foods that do or may contain gluten;
 - how to shop for gluten-free ingredients and foods;
 - how to prepare gluten-free food.



HEALTH CANADA GOALS

- Enhance the protection to people who need to follow a gluten-free diet **from « hidden » gluten sources;**
- Maximize the **availability of suitable foods** from which celiac consumers can choose to include in their diet.



Regulatory Updates Targeting Gluten-Free Foods

- Review compliance policy for the “Gluten Free” Regulations
- Review definition of “Gluten-Free Food”



Additional Initiatives to Support Standard-Setting:

Health Canada will partner with the CCA to conduct two pan-canadian surveys:

Ù A dietary survey on food consumption habits of Canadians with celiac disease will support the review of the current status of **gluten-free foods** and its related compliance policy.

Ù The ***Living With a Gluten-Free Diet Survey*** will support various policy updates.



Review of gluten-Free Foods Status – the Dietary Survey

- **Evolution of detection methods:**
quantification limits of gluten in foods is now 2-3 ppm
- **Compliance policy:** Currently based on analytical threshold.
- **Current threshold for compliance** is 20 ppm.



KNOWLEDGE GAPS

- What is the impact of continued low exposure to hidden sources of gluten on health of people with celiac disease ?
- What is the estimated exposure to gluten while following the gluten-free diet?
- Is there a rationale to move towards the current, lower analytical threshold (2-3 ppm)?



Risk Assessment of Exposure to 'Hidden Gluten', as Part of a Gluten-Free Diet

- Establish an **exposure estimate** of gluten intake from all sources, as part of a gluten-free diet.
- Determine dietary consumption of people with celiac disease.
- Measure levels of hidden gluten in a market basket survey, mimicking a gluten free diet.
- Model impacts of regulatory threshold.



Survey Collaboration:

- Survey to be conducted in 2008-2009, in collaboration with key professionals from the Canadian Celiac Association



LIVING WITH A GLUTEN-FREE DIET SURVEY

Is a survey study developed by:

- The Canadian Celiac Association (CCA)
- The Faculty of Medicine, Dalhousie University
- Health Canada

With the contribution of:

- La Fondation québécoise de la maladie coeliaque (FQMC).



THIS STUDY WILL...

- Evaluate the **difficulties and coping methods** associated with a gluten-free diet.
- Determine the **'quality of life' impact** associated with the need to follow a gluten-free diet.
- Assess the **knowledge and attitudes** of individuals following a gluten-free diet and the impact of each on **compliance** with the diet.



ANTICIPATED OUTCOMES

- Increase awareness of the disease **challenges** and **coping skills** among medical providers, policy makers, and food industry.
- **Improve educational messages/tools/support** (including emotional support) destined to those following a gluten-free diet, to **improve the practical management skills of these individuals.**
- **Improve dietary compliance** of those following a gluten-free diet, contributing to better health and quality of life, thus contributing to reducing costs to Canada's health care system.
- **Review the Canadian regulations** on gluten labelling and facilitate their communication to the public.



TIMELINE OF THE SURVEY

- Questionnaires will be mailed during **Celiac Awareness Month** (October) 2008 to **all members** of The Canadian Celiac Association and La Fondation québécoise de la maladie céliaque.
- Member response is **critical** to the success of the study!



In Summary: To Enhance the Protection of Food Allergic Consumers and Celiac Individuals:

1. **Rapid Response:** system of response – (available 24hr/day, 7day/week) for risk assessment & recommended course of action in support of recalls.
2. **Renewal:** identify short-comings & risk; updating of regulations and policies; education
3. **Prevention of adverse reactions:** active education (industry/consumer) & regulatory guidance (industry).



Recent Accomplishments

- Review of safety of “pure – uncontaminated oats” for Celiac individuals
- More information about Celiac Disease on HC website
- Support to Codex standard on Gluten free foods



For more information

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- o www.healthcanada.gc.ca/ceciac
 - o www.healthcanada.gc.ca/foodallergies
 - o www.santecanada.gc.ca/coeliaque
 - o www.santecanada.gc.ca/allergiesalimentaires

