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Labelling Of Food Allergens



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Food Allergies and Celiac Disease

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.



Previous Labelling Regulations

Previous 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 priority 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.



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, triticale
- Eggs
- Milk
- Soybeans
- Crustacea (common name)
- Fish (common name)
- Shellfish (common name)
- Mustard seeds



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
- Oats
- Barley
- Rye
- Triticale



Regulatory Amendments

Label Declaration

- ❑ Sources of common food allergens and gluten must be declared either:
 - in the list of ingredients, OR
 - in the statement: **“Contains”**

- ❑ Added sulphites when present at levels of 10 ppm or higher must be declared either:
 - in the list of ingredients, OR
 - in the statement: **“Contains”**

- ❑ All current requirements for ingredient continue



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



Regulatory Amendments

Sulphites

❑ All previous requirements for declaration maintained:

- sulphites will continue to be declared in the ingredient list when intentionally added as a food additive ingredient at any level in finished product
- for ingredients that are not exempted from component declaration, if sulphites are a component of one of these ingredients, they will have to be declared at any level in finished product



Regulatory Amendments

(sulphites...)

- ❑ In addition to these requirements for declaration in the list of ingredients
 - When added sulphites are present at levels of 10 parts per million or more in the finished product as a component of an exempted ingredient they must be identified either in the list of ingredients or using the statement “**Contains sulphites**”
 - When added sulphites are present at levels lower than 10 parts per million in an ingredient that is exempt from component declaration they are not required to be declared.



Regulatory Amendments

- ❑ When the statement “**Contains**” is present on a label this statement must be complete and identify all priority food allergens, gluten sources and added sulphites at 10 ppm and above in the prepackaged product



Mustard as a Food Allergen

- ❑ Mustard is a herbaceous flowering plant (Angiospermae) belonging to the family Brassicaceae
- ❑ The major types of mustard seeds used in cooking and food processing are: white (*Sinapis alba* or yellow mustard), brown (*Brassica juncea* or oriental mustard) and black (*Brassica nigra* or black mustard).
 - All three types of mustard seed are available in North America. Canada is a world leader in the international mustard seed market accounting for 50% of global exports
- ❑ The major allergen of mustard is a 2S albumin seed storage protein



Mustard as a Food Allergen

- ❑ Mustard was added to the list of allergens in the new labelling Regulations following comments from the public and a thorough assessment against specific criteria for inclusion
 - Including assessment of the available science on mustard allergy and the potential for mustard to be “hidden” in foods
- ❑ Mustard is often used as part of spice or seasonings which are exempt from component declaration
- ❑ As of August 4, 2012 mustard will have to be identified on the label whenever it is present in a food either in the list of ingredients or a “contains” statement.



Full Assessment of Mustard

The entire systematic review of mustard, including appendices and references is available on the Health Canada website at :

<http://www.hc-sc.gc.ca/fn-an/pubs/label-etiquet/mustard-moutarde/index-eng.php>

OR

google “Health Canada mustard allergy”



Example of label changes – Cake Mix

Prior to allergen labelling regulations

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

After allergen labelling regulations

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



Ovalbumin is a protein found in egg whites



Ex. of Label Change – Potato Chips

Prior to allergen labelling regulations

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

After allergen labelling regulations

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

OR

Ingredients : Potatoes, sunflower oil, salt, seasonings

Contains : mustard

Seasonings are a multi-component ingredient which are exempt from component declaration



Coming into Force

- ❑ New regulatory amendments came into force on **August 04, 2012**
- ❑ 18 months after date of registration



Other Related Labelling Files

- ❑ Gluten-Free Regulations
- ❑ Precautionary Labelling
- ❑ Adventitious Presence



Gluten Free Regulatory Amendments

Update to Section B.24.018 of FDR

- ❑ Updated terminology for gluten will now describe gluten as ‘any gluten protein, including any gluten protein fraction, referred to in Canada’s definition of gluten’, which can be found in subsection B.01.010.1(1) of the FDR
- ❑ Better reflects the current internationally adopted scientific description of ‘gluten’ (ie: CODEX)
- ❑ Will allow companies that manufacture products that do not contain gluten protein to have the option of labelling them as gluten-free in Canada, even if sourced from gluten containing grains
- ❑ A benefit to celiac patients, since it could lead to further expand the availability of healthy food choices for this group



Guidance Document on Gluten-Free Regulation

□ Health Canada has developed a guidance document related to the gluten-free regulations which outlines:

- The purpose of regulation B.24.018
- Health Canada's position on the 20 ppm level as a cut-off level for gluten-free foods
- The guidance is published on the Health Canada website and supports CFIA inspection/enforcement activities



Guidance Document on Gluten-Free Regulation

- ❑ Posted on the HC website in June 2012
- ❑ This is a non-regulatory option that supports the use of 20ppm of gluten as the threshold level for foods labelled gluten-free.
- ❑ This level is recognized internationally in the Codex Alimentarius Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Stan 118-1979).

<http://www.hc-sc.gc.ca/fn-an/securit/allerg/cel-coe/gluten-position-eng.php>



Guidance Document on Gluten-Free Regulation

Based on the available scientific evidence, Health Canada considers that gluten-free foods, prepared under good manufacturing practices, which contain levels of gluten not exceeding 20 ppm as a result of cross-contamination, meet the health and safety intent of B.24.018 when a gluten-free claim is made.



Guidance Document on Gluten-Free Regulation

Based on the enhanced labelling regulations for allergens and gluten sources, any intentionally added gluten sources, even at low levels (e.g. wheat flour as a component in a seasoning mixture which makes up a small proportion of the final food), must be declared either in the list of ingredients or in a "Contains" statement. In these cases, a gluten-free claim would be considered false and misleading." If, however, a manufacturer using a cereal-derived ingredient includes additional processing steps which are demonstrated to be effective in removing gluten, then the food may be represented as gluten-free.



Precautionary Labelling: Definition

Allergen precautionary labelling

- ❑ Labelling that warns about priority allergens that may be in products, even though they are not in the list of ingredients

Food allergen precautionary labelling statement

- ❑ A declaration on the label of a prepackaged food that identifies the priority food allergens that are not among the listed ingredients, but may have been inadvertently added to a product during the manufacturing process.

Examples: "may contain..."; "made on the same equipment as ..."; "not suitable for consumption by persons with an allergy to..."



Precautionary Labelling: Why and when?

In Canada, allergen precautionary labelling was identified as a judicious risk management measure...

- ❑ To address instances of « unavoidable » cross-contamination with priority food allergens during food processing
- ❑ To alert allergic consumers of the « unsuitability of the product » for their condition and of **a possible risk**
- ❑ Precautionary statement differs from a « contains » statement, however risk may be identical



Consumer Perception

Allergen precautionary labelling...

- ❑ Was welcomed by allergic consumers when initially introduced
- ❑ Since then has become devalued partly because of consumer perception of over-use and inconsistent application by the food industry



Consumer Perception

Reasons that some allergic consumers and/or their caregivers ignore precautionary labels include:

- ❑ Proliferation of allergen precautionary labelling statements
- ❑ No reactions to products that had not been previously labelled with allergen precautionary labelling statement
- ❑ Presumption that allergen precautionary labelling is for legal rather than health concerns



Examples



Examples

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.



Examples

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). Retir
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: 1.1kg

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

Ingredient list much shorter than allergen precautionary statement



Precautionary Labelling

- ❑ Public Consultations were held in Late 2009/early 2010
- ❑ Summary report was published recently
- ❑ Additional Policy work is required
- ❑ Health Canada has recommended the single statement “May contain :” when precautionary labelling is needed
- ❑ HC is proposing a progressive approach for its renewed policy on allergen precautionary labelling
 - voluntary implementation
- ❑ Health Canada will engage stakeholders in exploring how Canadian sector specific guidelines and education programming may be developed



Adventitious Presence

- ❑ Canadian grain standards allow some presence of other grains due to the way they are grown, harvested transported and/or processed
- ❑ In some cases these other grains could be allergens or gluten sources
 - Ex. Soy, wheat, rye, barley, mustard
- ❑ Recently some food products have been investigated for adventitious presence of allergens in other grains (soy in wheat)
- ❑ HC is investigating whether there is a need for more precautionary labelling of grain products and working with the food industry to develop guidance



Soy in Wheat

- ❑ In November 2012 a meeting was held between HC, CFIA, the food industry and Anaphylaxis Canada to discuss AP, particularly for soy in cereal grains
- ❑ Following this meeting, Health Canada has added information on the HC website specific to AP of soy
- ❑ Health Canada has also committed to a 2 year process to study this issue, gather data and develop a policy
- ❑ HC will be putting out a call for data in the near future asking for submissions from anyone with relevant information (levels of soy in cereal grains, what processes are available to minimize AP and how effective these are etc.)



Adventitious presence of Mustard

- ❑ Very little information currently exists
- ❑ Theoretically possible, but no reports of adverse reactions and no surveillance data
- ❑ If mustard is present in grains due to AP at levels that pose a health risk to mustard allergic individuals, then precautionary labelling would be warranted.
- ❑ We are looking at Soy AP as a test case and will use what we learn from the policy development on Soy AP to address other types of AP, such as mustard.



Web Links

Information page on food allergen labelling

<http://hc-sc.gc.ca/fn-an/label-etiquet/allergen/index-eng.php>

Information on Precautionary Labelling

http://hc-sc.gc.ca/fn-an/label-etiquet/allergen/precaution_label-etiquette-eng.php

Information on Gluten-Free claims

<http://www.hc-sc.gc.ca/fn-an/securit/allerg/cel-coe/gluten-position-eng.php>



Regulatory Modernization

- ❑ Health Canada has some new legislative authorities: Marketing Authorization (MA) , Temporary Marketing Authorization Letter, Incorporation by Reference (IbR)
 - **Marketing Authorisation (MA)** regulations are made by the Minister of Health. They will exempt products from specific prohibitions in the Food and Drugs Act and the Food and Drug Regulations. The MA will allow the Minister to make general rules permitting the sale of foods and the use of substances that are in - or on - foods. MAs will also be available to permit the use of substantiated health claims. Used to create exemptions that will be permanent and apply to all products.

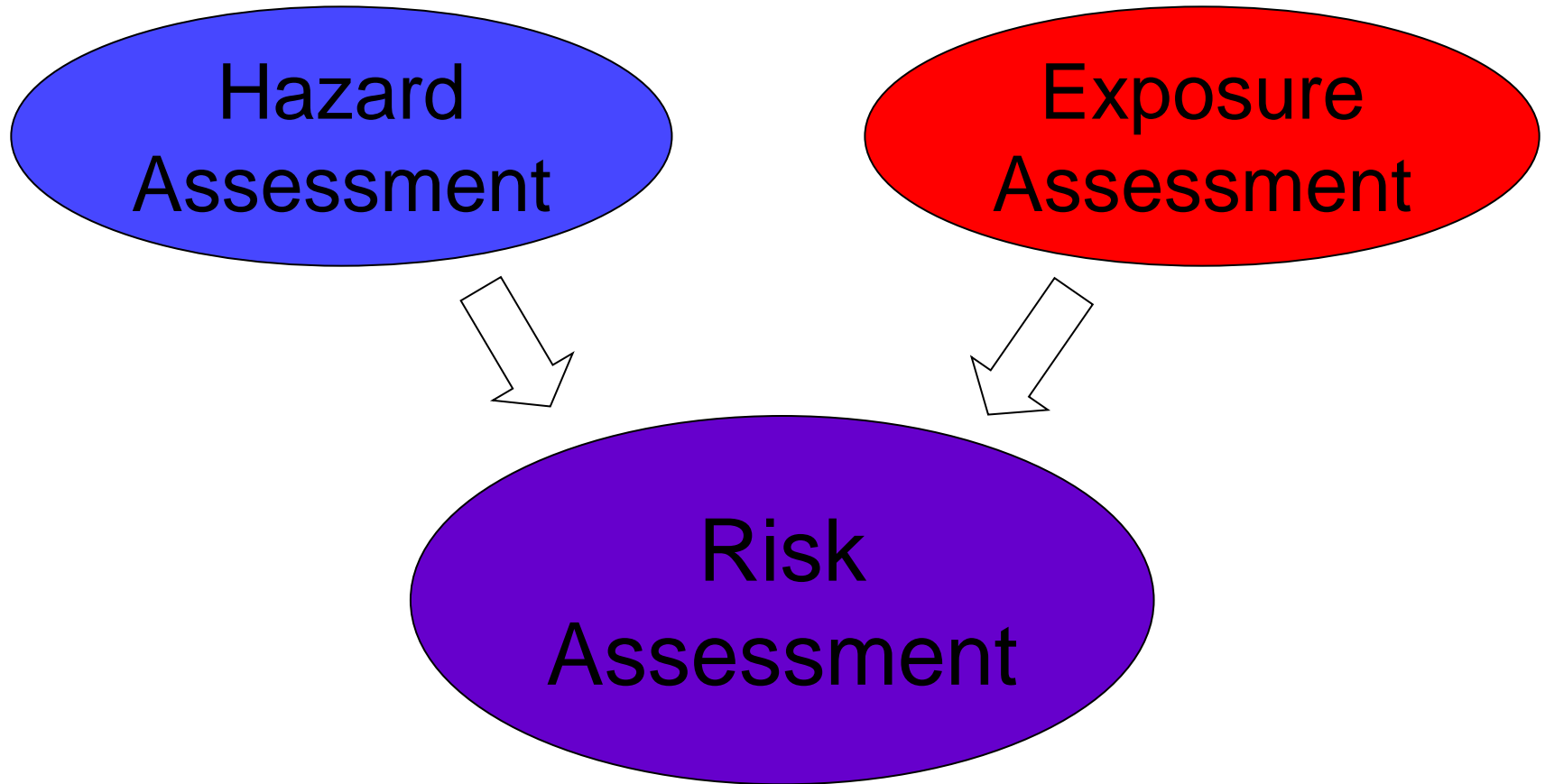


Regulatory Modernization

- ❑ 2) **Temporary Marketing Authorization Letter (TMAL)** is product specific and must include a fact finding or research gathering component that will lead to better understanding and facilitate legislative action . It is defined by a specific period of time and is product specific.
- ❑ 3) **Incorporation by reference (IbR)** authority will allow Health Canada to incorporate by reference food additive and other internally generated lists and tables into the Regulations. This will allow for changes to be adopted as soon as the scientific assessment and related consultations have been completed.



Risk assessment



Hazard Assessment

Factors to be considered

- Which food allergen(s) is/are present in the product?
- Is the amount of protein from the food allergen(s) capable of causing a severe allergic reaction if ingested by an allergic individual?



Hazard Assessment cont'd

- ❑ We do not have absolute thresholds for food allergens (for a variety of reasons)
- ❑ There is some information regarding NOAELs or LOAELs for some food allergens which can, in combination with knowledge of the amount of food allergen present in a product, aid in estimations of hazard assessment



Hazard Assessment cont'd

Food Allergen	Range of LOAEL (mg protein)
Egg	0.13 to 1.0
Peanut	0.25 to 10
Milk	0.36 to 3.6
Tree Nuts	0.02 to 7.5
Soy	88 to 522
Fish	1 to 100



From FDA - Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food

Hazard Assessment cont'd

- ❑ Though dependant on the amount of food allergen present, the hazard associated with undeclared food allergens is often very high, due to the fact that food allergens can provoke anaphylaxis even at relatively low levels.



Exposure Assessment

There are two elements to exposure :

- ❑ What amount of allergen would someone consuming the product be exposed to?
- ❑ How likely is it that someone with a particular food allergy would actually consume the product in question?



What amount of allergen would someone consuming the product be exposed to?

- Has the presence of the allergen been confirmed using analytical testing and if so, how much allergen was detected (ppm of protein)?
- If the allergen is part of the product formulation, what is the estimation of the amount of allergen present in the product?
- What is the expected serving size?
- Based on this information, what is the expected amount of allergen that would be ingested (μg or mg of protein)?



Exposure Assessment

Likelihood of consumption, factors to be considered

- ❑ How much of the product is available on the market?
 - Many units and lots or limited production?
- ❑ How widely distributed is the product?
 - Local, province wide or national distribution? Only available in specialty stores or more widely distributed?
- ❑ Is the presence or possible presence of the food allergen identified on the label of the product?
 - Either in the list of ingredients or in a precautionary statement?



Likelihood of Consumption Cont'd

□ Are there any other reasons why the product would be likely or unlikely to be consumed by a person with an allergy to the food allergen which is present in the product?

(i.e. factors which mitigate or increase the possibility of exposure)

- Does the product have an allergy-free or gluten-free statement on the label which would make it more likely for those with certain allergies or celiac disease to eat it, believing it to be safe?
- Is it a product that is listed in the Government of Canada pamphlets as a likely source of the allergen, which would be expected to decrease the chance of someone allergic to that substance consuming the product?
- In some cases contamination with a food allergen is clearly visible in the product (e.g. sesame seeds on a bun) and this is considered a mitigating factor as someone with sesame allergy is likely to see this and avoid the product



Likelihood of Consumption Cont'd

- ❑ Exposure assessment can be very challenging and we are often required to make a decision on whether or how much a particular mitigating factor or combination of factors will reduce the likelihood of an allergic individual consuming a particular product.
 - In these cases we must make assumptions about how likely it is that a consumer who is allergic to the food allergen in question would come in contact with the product and also what an average consumer (who is allergic to the food allergen in question) is likely to do if presented with this product, considering the information provided on the label.





❑ An additional factor considered is whether or not any adverse reactions have been reported after consuming the product and any details available regarding the severity of the reaction

- If a reaction has been reported, this affects both hazard assessment (suggesting the level of allergen present is capable of causing an adverse reaction), as well as the exposure assessment (it shows that at least one person with the particular allergy in question was exposed to the product, suggesting others could be). Alternatively if a product has been available on the market for a long time without any reports of adverse reactions this is generally considered a mitigating factor.
- Information about adverse reactions is often limited and generally can not be considered conclusive due to the circumstances involved (possible cross contamination in the home etc.)



Risk Assessment Cont'd

- ❑ One other additional factor which can impact on the final level of risk is whether the product in question is likely to be eaten by children (e.g. Easter candy) or alternatively if it is likely to be avoided by children (e.g. alcoholic beverage)

The fact that a product is likely to be eaten by children will increase the level of risk posed by that product.

(the prevalence of food allergies is higher in children and they are more likely to exhibit severe allergic reactions.)



Risk Assessment

- ❑ Considers both the hazard posed by the product and the likelihood of exposure elements of a given situation
- ❑ Where certain information or details are lacking we may need to consider a “worst case” scenario



Thank you!

Merci!

