Santé Canada

> The Canadian Criteria for the Establishment of New Priority Food Allergens





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The Canadian Criteria for the Establishment of New Priority Food Allergens



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Executive Summary

In order to ensure that Canadian allergic consumers are duly protected amendments to the Food Allergen Labelling Regulations require enhanced labelling for priority allergens in pre-packaged foods. Subsequently, Health Canada has adopted criteria in order to determine the scientific validity of including new foods or food ingredients on the list of priority food allergens in Canada. The main Canadian criteria include the scientific recommendations required to amend the Codex Alimentarius Commission¹ list of priority allergenic foods by individual countries (CAC, 1999). These recommendations are as follows:

- The existence of a credible cause-effect relationship, based upon positive double blind, placebo-controlled food challenges (DBPCFC) or unequivocal reports of reactions with typical features of severe allergic or intolerance reactions.
- Reports of severe systemic reactions following exposure to the foodstuff.
- Assessment of available prevalence data in children and adults, supported by appropriate clinical studies with subjects from the general population of several countries or alternatively available prevalence data from clinical studies with groups of allergy patients from several countries supported as per the first recommendation.

In addition to these recommendations, the main Canadian criteria also consider the allergenic potency of the food or food ingredient (Björkstén *et al.*, 2008), the potential Canadian exposure to the food or food ingredient with specific consideration as to whether the food or food ingredient may become a hidden source² of food allergens in pre-packaged food products for sale in Canada, as a result of the Canadian Regulatory context, and whether the food or food ingredient is subject to the Canadian proposed definition of a food allergen, which emphasizes that the protein portion of the food is responsible for eliciting an allergic reaction. Additional consideration is also given to other factors that are considered applicable to the Canadian scenario and relevant to risk management.

The Canadian criteria will be applied to the assessment of scientific information obtained from a systematic review of available literature. In order to ensure a consistent and transparent approach when assessing the potential allergenicity of a food or food ingredient, methods for the management and evaluation of available scientific information were developed. Specifically, these methods provide guidance for:

- Systematic Data Collection
- Criteria for Assessing the Strength-of-Evidence
- Organization & Tabulation of Data
- Criteria for Evaluating the Severity of Clinical Reactions

The information obtained and evaluated using these methods will be assessed using the Canadian criteria for establishing new priority food allergens. A weight-of-evidence approach will determine whether the available evidence fulfills the criteria and substantiates the addition of a new food or food ingredient to the list of priority food allergens in Canada. These practices will facilitate a consistent scientific approach for declaring new priority food allergens and for the application of the Food Allergen Labelling Regulations in Canada.

¹ The Codex Alimentarius Commission was created in 1963 by Food and Agricultural Organization of the United Nations (FAO) and World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

² Subsections B.01.009(1) and (2) of the Canadian Food and Drug Regulations specifically exempt components of certain ingredients, preparations and mixtures from declaration in the list of ingredients, such as spices and seasonings. As a result, pre-packaged food products may contain undeclared (hidden) sources of food allergens.

Issue

On July 26, 2008, Health Canada published its proposed amendments to the *Food and Drug Regulations* (1220 – Enhanced Labelling for Food Allergens and Gluten Sources and Added Sulphites) in *Canada Gazette*, Part I (CGI). These proposed regulatory amendments are available on the Health Canada website, http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/index-eng.php. A public consultation regarding the proposed amendments was held until November 28, 2008. Comments received during this period are being taken under consideration before the regulations are finalized and published in *Canada Gazette*, Part II (CGII).

Just over 140 comments were received from the general public, patient groups, health professionals, a consumer organization, and governmental agencies. Of the responses, there were several requests for new foods or food ingredients to be added to the list of priority allergens in the regulatory amendments.

In response to the feedback received during the public consultation, Health Canada has adopted criteria to evaluate the scientific validity of including new foods or food ingredients on the list of defined priority food allergens in Canada. These criteria will facilitate a consistent scientific approach for declaring new priority food allergens and for the application of the Food Allergen Labelling Regulations.

Background

Certain foods or food ingredients can cause severe allergic reactions that can result in death. Allergic reactions differ from other adverse reactions that are a result of exposure to either chemical or microbiological contaminants or to pharmacologically active ingredients in the food, in that; allergic reactions cannot be mitigated through food contaminant risk management strategies (Godefroy and Popping, 2009).

The term food allergy is appropriate where an immune mechanism is involved in a previously sensitized individual. Based on the nomenclature suggested by the European Academy of Allergology and Clinical Immunology (EAACI), food allergies are a form of hypersensitivity (reproducible, abnormal, non-psychologically mediated reaction to food) for which the immune mechanism involved is either Immunoglobulin E (IgE) or non-IgE mediated (Johansson *et al.*, 2001).

There are currently no known therapeutic options to cure food allergies. The only viable option for an individual with a food allergy is to prevent allergic reactions by avoiding the food to which they are sensitive. Food allergic consumers must rely on information provided by food processors and importers in order to avoid foods that contain the ingredients to which individuals are likely to react. For pre-packaged foods, it is critical that such information be included on the food label. Labelling has been identified as a *public health tool* enabling the consumer to manage avoidance, but also allowing informed choice of safe food sources (Godefroy and Popping, 2009; Björkstén *et al.*, 2008).

Labelling of pre-packaged foods is subject to food legislative and regulatory obligations set by each national jurisdiction (Godefroy and Popping, 2009; Taylor and Hefle, 2006). The Codex Committee on Food Labelling (CCFL) has considered allergen labelling an area of priority and has made recommendations that were adopted by the Codex Alimentarius Commission (CAC) in 1999 (CAC, 1999). The CCFL recommended that science-based

criteria be used to determine which foods or food products should be placed on a priority list based on their potential to induce an allergic reaction and that these foods should always be declared in the list of ingredients on food labels. The retained Codex list includes the following foods:

- Cereals containing gluten; i.e. wheat, rye, barley, oats³, spelt or their hybridised strains and products of these;
- Crustaceans and products of these;
- Egg and egg product;
- Fish and fish products;
- Peanuts;
- Soybeans;
- Milk and milk products;
- Tree nuts and nut products;
- Sulphites at concentrations of 10 mg/kg or higher.

Subsequent to the adoption of this list, the World Health Organisation (WHO) convened a food allergens expert panel to provide guidance to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which is the committee that advises the Codex Alimentarius Commission on food additives and other chemicals and ingredients in food. The food allergens expert panel was tasked with the establishment of criteria for amending the Codex list of priority allergenic foods. The panel advised that the identification of priority food allergens should be based on the following criteria: the existence of a cause-and-effect relationship, based upon positive double-blind, placebo-controlled food challenge (DBPCFC) or unequivocal reports of reactions, including severe symptoms associated with exposure to the food commodity and prevalence data in children and adults, supported by clinical studies relying on DBPCFC studies from the general population of several countries. The expert panel acknowledged that availability of such data for infants, some foods and in certain regions of the world would represent a challenge. As an alternative, the use of comparative prevalence data in groups of allergy patients from several countries supported by DBPCFC data would be appropriate (Godefroy and Popping, 2009; CAC, 1999).

National food regulatory agencies have used this guidance to build on the Codex list and develop their own lists of priority foods that should be targeted for mandatory labelling on foods available for sale in the country or region under their oversight. In Canada, Health Canada has the mandate to establish food standards, policies, regulations and guidelines with an oversight on labelling requirements associated with health, safety and nutritional quality concerns. Amendments to the *Food and Drug Regulations* in Canada are meant to enhance the labelling of prepackaged food products by requiring the mandatory declaration of the sources of the priority food allergens, gluten, and sulphites present in quantities equal to or in excess of 10ppm, when present in a pre-packaged food product.

In Canada, foods that are most frequently associated with allergic reactions and are defined in the proposed list of food allergens are: almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts, peanuts, sesame seeds, wheat, kamut, spelt, triticale, eggs, milk, soybeans, crustaceans, fish and shellfish, and sulphites present in quantities equal to or in excess of 10ppm (Godefroy and Popping, 2009). Current estimates are that food allergies affect as many as 6% of young children and 3% to 4% of adults (Rona *et al.*, 2007).

³ Oats is included in the list of cereal grains capable of inducing adverse effects on persons with celiac disease. However, a recent review conducted by Health Canada indicates that most individuals with celiac disease can tolerate moderate amounts of oats free from contamination with other sources of gluten.

The current *Food and Drug Regulations* require that the ingredients of pre-packaged food products be declared in descending order of their proportion in a list of ingredients on the label of most pre-packaged products. However, subsections B.01.009(1) and (2) of the *Canadian Food and Drug Regulations* specifically exempt components of certain ingredients, preparations and mixtures from declaration in the list of ingredients, such as spices and seasonings. As a result, pre-packaged food products may contain undeclared sources of food allergens, or substances that some consumers are sensitive to, for example, gluten. On account of this possibility, consumers with a food allergy or sensitivity may not be able to avoid with certainty allergens or substances that can cause adverse effects to their health (Godefroy and Popping, 2009).

The proposed regulatory amendments would require the declaration of a priority food allergen, or gluten, or sulphites present in quantities equal to or in excess of 10ppm, when it is present in the pre-packaged food product. The amendments defined "food allergen" as any protein from any of the foods specifically listed in the proposed definition, or any modified protein, (including any protein fraction) that is derived from any of these foods. This definition is based on the fact that protein is the portion of the food to which an individual with a food allergy or celiac disease will react.

Canadian Criteria

In order to determine the scientific validity of including new foods or food ingredients on the Canadian list of priority food allergens, Health Canada has adopted the criteria for amending the Codex list of priority allergenic foods. In accordance with the JECFA guidelines these criteria include (CAC, 1999):

- 1. The existence of a credible cause-effect relationship, based upon positive DBPC food challenges or unequivocal reports of reactions with typical features of severe allergic or intolerance reactions.
- 2. Reports of severe systemic reactions following exposure to the foodstuff.
- 3. Assessment of available prevalence data in children and adults, supported by appropriate clinical studies with subjects from the general population of several countries or alternatively available prevalence data from clinical studies with groups of allergy patients from several countries supported as per criterion 1.

In addition to the above listed criteria, the assessment of the allergenicity of a food or food ingredient will consider the allergenic potency. In this context, the term allergenic potency is defined as the amount of food or food ingredient required to elicit a reaction in an already sensitized individual (Björkstén *et al.*, 2008).

Consideration will also be given to the potential Canadian exposure to the food or food ingredient with specific consideration as to whether the current applications of the food or food ingredient are hidden because the use of the food or food ingredient is exempt from declaration in the list of ingredients on food packages, as per subsections B.01.009(1) and (2) of the *Canadian Food and Drug Regulations*. The intent of the proposed amendments to the *Food and Drug Regulations* is to enhance food labelling as a *public health tool* for food allergic consumers, enabling consumers to avoid allergens to which they are susceptible and allowing informed choices of safe food sources. The proposed regulatory amendments would require the declaration of potential hidden sources of food allergens in pre-packaged food products.

Furthermore, consideration will be given to whether it is subject to the proposed definition of a food allergen. In Canada, the proposed definition of a food allergen emphasizes that the protein portion of the food is responsible for eliciting an allergic reaction. Therefore, protein from any of the defined food allergens, or any modified protein, (including any protein fraction) that is derived from any of these foods, is considered a health risk to individuals with food allergies.

Additional consideration will also be given to other factors that are considered applicable to the Canadian scenario and relevant to risk management. For example, these factors may include, but are not limited to, consideration of allergen cross-reactivity.

Methods

The Canadian criteria will be applied to the assessment of scientific information obtained from a systematic review of available literature. Methods for the management and evaluation of available scientific information have been developed in order to ensure a consistent and transparent approach when assessing the potential allergenicity of a food or food ingredient.

Systematic Data Collection

An electronic database search will be conducted utilizing, but not limited to, current versions of the following databases: Ovid Medline, Ovid Embase, and FSTA Direct. The abstracts for all publications directly relevant to the allergenicity of the food or food ingredient will be reviewed and sorted for inclusion or exclusion based on the following criteria:

Include publication if –

- 1. Relevant to humans (adults or children)
- 2. Relevant to an allergy via oral exposure through foodstuff
- 3. Relevant to the identification and characterization of the specific allergenic proteins

Exclude publication if –

- 1. Experimental study assessing the allergenicity using animal models or in vitro methods
- 2. Relevant to humans but the route of exposure is not via the oral route through foodstuff e.g. occupational exposures (dermal/respiratory)

References fulfilling the selection criteria will be assessed as needed by one or more investigators. In the case of a discrepancy, data interpretation will be reached by consensus. All of the references for the publications fulfilling the criteria for inclusion will be transferred to a current reference software manager and reprints requested. Excluded references will be placed in a separate database file (e.g. occupational allergies) for future use/access if required.

Criteria for Assessing the Strength-of-Evidence

In order to determine the strength of the evidence provided by the publications in the database, the study designs will be categorized and rated in accordance with guidelines established by the Joint Task Force on Practice Parameters. This Joint Task Force is comprised of specialists in the field of allergy and immunology. The guidelines to establish the strength of clinical recommendations by rating categories of evidence from clinical studies are supported by three U.S. national allergy and immunology societies: the American College of Allergy, Asthma and Immunology (ACAAI), the American Academy of Allergy, Asthma and Immunology (AAAAI), and the Joint Council of Allergy, Asthma and Immunology (JCAAI). In effect, the criteria used to assess the strength of evidence in the database (in descending order from the strongest to weakest evidence), is as follows: meta-analysis of randomized controlled trials, randomized controlled trials, quasi-experimental

studies, non-experimental descriptive studies (comparative, correlation, or case-controlled studies), expert committee reports or opinions or clinical experience of respected authorities, laboratory-based studies (ACAAI, 2006; Bernstein, 2008).

Organization and Tabulation of Data

All publications fulfilling the selection criteria will be reviewed and categorized based on the criteria for assessing the strength of evidence. Publications that cannot be categorized by these criteria will be referenced in the results under an appropriate heading. Evidence from publications that fulfilled the strength-of-evidence parameters will be tabulated under the following categories:

- 1. Pivotal Clinical Studies (evidence from meta-analysis and randomized and non-randomized controlled trials)
- 2. Non-Pivotal Clinical Studies (evidence from quasi-experimental studies)
- 3. Other Relevant Studies (evidence from non-experimental descriptive studies (comparative/correlation))
- 4. Case reports (evidence from non-experimental descriptive studies)

Within these categories, studies will be organized chronologically by publication date.

The following parameters will be tabulated from each publication in category 1–3:

Reference (author, year, country of origin); Study design details (i.e. method of assessment); Subjects (adults vs. children, age, sex); Clinical history (including pre-morbid conditions and family history); Symptoms and signs (before challenge); Symptoms and signs (after challenge with emphasis on the severity of reaction); Diagnostic tests (confirm allergenic response); Eliciting dose; Eliciting allergen (source and type of the allergens, including type of food eaten when reaction was elicited); Prevalence; Comments (relevant notes made by investigator(s)).

The following parameters will be tabulated from each publication in category 4:

Reference (author, year, country of origin); Cases (number of cases, sex, age); Clinical history (including pre-morbid conditions and family history); Symptoms and signs (with emphasis on the severity of reaction); Diagnostic tests (confirm allergenic response); Eliciting dose; Eliciting allergen (source and type of the allergens, including type of food eaten when reaction was elicited); Comments (relevant notes made by investigator(s)).

Criteria for Evaluating the Severity of Clinical Reactions

A wide range of symptoms that are associated with food allergies include:

- Gastrointestinal symptoms: e.g., vomiting, diarrhoea, abdominal pain (colic)
- Respiratory manifestations: e.g., rhinitis, asthma
- Cutaneous manifestation: e.g., urticaria, edema, angio-edema
- Anaphylaxis

Anaphylaxis is a generalized reaction that may include skin, respiratory, cardiovascular and gastrointestinal symptoms and may result in death. Symptoms of anaphylaxis can occur within minutes to hours of ingestion of the food allergen. Existing grading systems for acute systemic hypersensitivity reactions, like anaphylaxis, vary

considerably, have a number of deficiencies, and lack a consistent definition of anaphylaxis. For consistency in the evaluation of the severity of the symptoms described in the literature, the clinical criteria and grading system of anaphylaxis as outlined in the publication by Brown (2004) will be applied as follows:

- a. Severe reactions include symptoms that are strongly associated with hypotension and hypoxia (life-threatening upper airway obstruction) or neurologic compromise: confusion, collapse, loss of consciousness, and incontinence. Pre-existing asthma and lung disease are viewed as an increased risk of hypoxia. In children, anaphylaxis is most often caused by a bronchospasm associated with food intake, there is also usually a background of atopy and asthma (Brown *et al.*, 2006).
- b. Moderate reactions include diaphoresis, dizziness, pre-syncope, dyspnea, stridor, wheezing, chest/throat tightness, nausea, vomiting, and abdominal pain
- c. Mild reactions are limited to the skin (urticaria, erythema, and angioedema). However, when angioedema affects the face and involves the glottis, it is associated with hypoxia and graded as severe.

Other information that will be considered when assessing the literature on the severity of the reaction includes the perception of the author(s) and any description of the use of epinephrine, emergency medical attention or hospitalization. Definitions of medical terms are available in **Appendix 1**.

Conclusions

In order to establish a new priority allergen in Canada, scientific information obtained from a systematic review of available literature must provide a sufficient weight-of-evidence to fulfill the Canadian criteria. The main Canadian criteria includes the scientific recommendations required to amend the Codex Alimentarius Commission list of priority allergenic foods by individual countries (CAC, 1999), consideration of the allergenic potency of the food or food ingredient (Björkstén *et al.*, 2008), consideration of the potential Canadian exposure to the food or food ingredient with additional consideration as to whether the food or food ingredient may become a hidden source of food allergens in pre-packaged food products for sale in Canada, as a result of the Canadian Regulatory context, and consideration as to whether the food or food ingredient is subject to the Canadian proposed definition of a food allergen. Additional consideration is also given to other factors that are considered applicable to the Canadian scenario and relevant to risk management.

In order to ensure a consistent and transparent approach when assessing the potential allergenicity of a food or food ingredient, methods for the management and evaluation of available information were developed for the following areas: systematic data collection, criteria for assessing the strength-of-evidence, organization and tabulation of data, and criteria for evaluating the severity of clinical reactions. These practices will facilitate a consistent scientific approach for amending the Canadian list of priority food allergens and for the application of the Food Allergen Labelling Regulations in Canada.

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Appendix 1: Glossary of Medical Terms

The medical terms used throughout the document and tables are listed below alphabetically. The source of the definition is captured in the endnotes.

Anaphylaxis – A systemic allergic reaction that can be fatal within minutes, either through swelling that shuts off airways or through a dramatic drop in blood pressure. Contact with or ingestion of an

allergen may set off a chain reaction in a person's immune system that may lead to swelling of the airways, loss of blood pressure, and loss of consciousness, resulting in anaphylactic shock. Some anaphylactic reactions involve only one organ system, such as the respiratory tract or skin. However, in anaphylaxis, several systems are usually affected simultaneously, including

the upper and lower respiratory tracts, cardiovascular system, and gastrointestinal tract.¹

Asthma – A common disorder in which chronic inflammation of the bronchial tubes (bronchi) makes them swell, narrowing the airways. Asthma involves only the bronchial tubes and does not

affect the air sacs (alveoli) or the lung tissue (the parenchyma of the lung) itself.i

Atopic dermatitis – Dermatitis is an umbrella term for local inflammation of the skin; Atopic Dermatitis refers

to the underlying inflammation being dominated by an IgE-antibody associated reaction. ii

Atopy – A personal or familial tendency to produce IgE antibodies in response to low doses of

allergens, usually proteins, and develop typical symptoms such as asthma, rhinoconjunctivitis

or eczema/dermatitis.²

Angioedema – Characterized by locally diffuse and painful soft-tissue swelling that may be asymmetric,

especially on the eyelids, lips, face, and tongue but also on the back of hands or feet and on the genitals. Edema of the upper airways may cause respiratory distress. Complete airway

obstruction may occur.³

Bronchial Asthma – Refer to the definition of asthma.

Bronchospasm – Spasmodic contraction of the muscular walls of the bronchial air passages to the lungs,

as in asthma, which makes breathing difficult.⁴

Conjunctivitis – Inflammation of the mucous membrane lining the inner surface of the eyelids and covering

the front part of the eyeball.iv

Cardiovascular – The heart and the blood vessels as a unified body system. iv

Diaphoresis – Perspiration, especially when profuse. iv

Dyspnea – Shortness of breath.iv

Eczema – A non-contiguous skin disorder, characterized by inflammation, itching, and the formation

of scales.iv

Erythema – An abnormal redness of the skin caused by various agents, as sunlight, drugs, etc., that irritate

and congest the capillaries.iv

Exercise induced Anaphylaxis –

Exercise can induce an allergic reaction to food. The usual scenario is that of a person eating a specific food and then exercising. As the individual exercises and their body temperature increases, they begins to itch, gets lightheaded, and soon develops the characteristic allergic reactions of hives, asthma, abdominal symptoms, and even anaphylaxis. Refer to the definition of anaphylaxis or systemic reaction.ⁱ

Glottis – The opening between the vocal cords in the larynx.iv

Gastrointestinal – The stomach and the intestines.iv Hypotension -Abnormally low blood pressure. iv

An abnormal condition resulting from a decrease in the oxygen supplied to or utilized Hypoxia –

by body tissue.iv

Inability to restrain a natural discharge of urine from the body.iv Incontinence -

Oral Allergy Syndrome –

Oral allergy syndrome is a type of cross-reactivity. This syndrome occurs in people who are highly sensitive, for example, to ragweed or birch pollen. During the seasons that these allergens pollinate, the affected individual may find that when he or she tries to eat fruits, chiefly melons and apples, a rapid onset of itching is experienced in the mouth and throat, and the fruit cannot be eaten. The symptoms of this allergy, which is caused simply by the direct contact of the food with the lining of the mouth and throat, resolve rapidly.

Rhinitis -Hypersensitivity symptoms from the nose, eg, itching, sneezing, increased secretion, and blockage.i

Rhinoconjunctivitis – Allergic conjunctivitis, is also called "rhinoconjunctivitis," it is the most common allergic eye disorder. The condition is usually seasonal and is associated with hay fever. The main cause is pollens, although indoor allergens such as dust mites, molds, and dander from household pets such as cats and dogs may affect the eyes year-round. Typical complaints include itching, redness, tearing, burning, watery discharge, and eyelid swelling. To a large degree, the acute (initial) symptoms appear related to histamine release.

Stridor – A harsh, high-pitched whistling sound, produced in breathing by an obstruction in the bronchi, trachea, or larynx.iv

Syncope – The temporary loss of consciousness followed by the return to full wakefulness; fainting.

Several systems within the body are affected simultaneously, including the upper and lower Systemic reactions – respiratory tracts, cardiovascular system, and gastrointestinal tract. iv Refer to Anaphylaxis.

Urticaria – An allergic skin condition characterized by itching, burning, stinging, and the formation of smooth patches, or wheals, usually red; hives.iv

(Endnotes)

- $1 \quad \text{MedicineNet.com} \\ @ 1996-2009 \\ \text{ website: http://www.medicinenet.com/script/main/hp.asp}$
- 2 Johansson, S.G.O., Hourihane, J.O'B., Bourset, J., Bruijnzeel-Koomen, C., Dreborg, S., Haahtela, T., Kowalski, M.L., Mygind, N., Ring, J., van Cauwenberge, P., van Hage-Hamsten, M., and Wuthrich, B. (2001) A revised Nomenclature for Allergy: An EAACI position statement from the EAACI nomenclature task force. Allergy 56: 813-824.
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