

# **Food Allergen Labelling Position Paper**

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## **ABOUT ANAPHYLAXIS CANADA**

Anaphylaxis Canada is a hybrid of the recently merged Anaphylaxis Network of Canada and Anaphylaxis Foundation of Canada (July 2001). As a national charitable organization, our mission is to inform, support, educate, and advocate for the needs of individuals and families living with anaphylaxis and to support research related to anaphylaxis.

Anaphylaxis, a potentially life-threatening allergic reaction, affects an estimated 1-2% of Canadian adults and 2%-4% of Canadian children... and this number is growing. Through research, improved diagnosis, and increased awareness, allergic individuals are in a much better position today to manage this condition. While guidelines in food labelling practices have improved over the past decade, the selection of safe foods presents an ongoing challenge for allergic consumers due to inconsistent labelling practices. Our intent, in presenting this position paper, is to provide recommendations to improve this situation, our ultimate goal being the safety of the food allergic consumer.

## **INTRODUCTION**

It has been almost ten years since the first labelling changes were made with respect to priority allergens, e.g. voluntary, temporary precautionary labelling and labelling of peanut oil. Since that time, we have seen a rise in all allergies in the last decade, primarily amongst western industrialized nations. Overall, more than 170 foods have been documented as causing food allergies.<sup>1</sup> Given the impact on public health, food allergies must be given due consideration by regulatory bodies in both Canada and abroad.

While improvements in food labelling have been made, there are several areas that need to be addressed. In highlighting these areas, we have referred to initiatives taking place domestically and on the international scene, incorporating best practices, where applicable. The following represent key areas to be addressed:

1. Priority\* allergens must be labeled.
2. "Hidden" allergens should be disclosed.
3. Precautionary labels should be used in a responsible way.
4. Allergens should be placed in prominent place on the label.
5. Allergens should be noted in 'plain' English.
6. Consumers should be easily able to contact the company for product information.
7. Labels must be legible.
8. Criteria should be developed for an allergen management plan.
9. Guidelines should be developed to regulate 'allergen free' claims.

\*For the purpose of this discussion, the term 'priority allergen' will be used synonymously with other terms - 'common' or major allergen'.

Other issues have been highlighted at the end of this document, as points for discussion. They are not included in our recommendations.

## KEY AREAS TO BE ADDRESSED

### 1. Priority allergens must be labeled.

As threshold doses of priority allergens have yet to be determined, and there is no cure for anaphylaxis, it is imperative that allergic individuals are able to avoid their allergen(s). This can only be achieved if allergens are properly disclosed on the label. Anaphylaxis Canada supports mandatory labelling of priority allergens, as outlined in the report by the joint Canadian Food Inspection Agency and Health Canada Committee, in foodstuffs, prescription and non-prescription drugs, cosmetics, toys, pet supplies, and any general household products.

While the priority allergens, recognized by Canada and the Codex Alimentarius Commission ("Codex") are similar, we would like to note the following:

- Sesame has been recently identified as a major food allergen among infants and young children in Israel<sup>2</sup> and therefore may be emerging as a more common food allergen. While sesame does not appear on the Codex list, it should be considered a priority allergen, as currently noted on the Canadian list.
- Anaphylaxis Canada supports the labelling of sulphites greater than ten parts per million, as adopted by regulatory authorities in the US and several other countries.<sup>3</sup>
- We would prefer to see gluten products listed separately, with an explanation of Celiac Disease and why it is important to label foods containing gluten. This would help to eliminate current confusion about the priority allergens. It is included in the Codex, but not the Canadian list.

Lists for Canada and Codex are provided below for reference:

#### Canada<sup>4</sup>

##### REVISED RECOMMENDATION 1

The following foods and their derivatives should be declared in the list of ingredients, by their specific common names, when they are present as ingredients or components of ingredients in foods:

- |                     |                                     |
|---------------------|-------------------------------------|
| - peanuts           | - fish                              |
| - tree nuts (named) | - crustaceans and shellfish (named) |
| - sesame seeds      | - soy                               |
| - milk              | - wheat                             |
| - eggs              | - sulphite                          |

#### Codex Alimentarius Commission<sup>5</sup>

##### Common allergenic foods

Foods and ingredients that are known to cause hypersensitivity should always be declared. These include: cereals containing gluten, i.e. wheat, rye, barley, oats and spelt, their hybridized strains and products of these; crustacea and products of these; eggs and egg products; fish and fish products; peanuts, soybeans and products of these; milk and milk products (lactose included); tree nuts and nut products; sulphites in concentrations of 10 mg per kilogram or more.

This list was adopted as a final text by the Codex Alimentarius Commission (CAC) in June 1999 with the understanding that future additions and/or deletions will be considered by CCFL, taking into account advice received from the Joint FAO/World Health Organization (WHO) Expert Committee on Food Additives (JECFA).

## **2. "Hidden" allergens should be disclosed.**

Currently, priority allergens are labelled on a voluntary basis. Some food terms and allowable exemptions for the identification of component ingredients do not clearly denote allergens within a product. Ingredients are often listed under collective terms and the source of the ingredient is not revealed. Thus they become 'hidden'. The result is that consumers cannot adequately judge whether or not a product is safe simply by reading a label.

Good labelling is the key to the implementation of safe and effective avoidance diets by individuals with food allergies and intolerances. Guidelines must be set to ensure that labels properly disclose allergens.

The following are points for consideration:

### **Highly Refined Oils**

All oil sources should be declared on food labels despite the suggestion that "highly refined peanut and soybean oils be excluded from the labelling requirements because these two products do not contain sufficient amounts of protein to elicit allergic reactions".<sup>6</sup> There have been contradictory reports on the allergenicity of highly refined peanut oil, as noted below:

*There has been considerable confusion about whether the oils (e.g. of peanut, tree nuts, cottonseed) are allergenic. In the past there was an unsupported assumption that they must be; then an equally unsupported view that oil does not contain protein and therefore they cannot be. In 1997, papers on peanut oils by Hourihane et al and tree nut oils by Teuber et al, showed that unrefined oils were allergenic but refined oils were not. However, a later paper by Olszewski et al (1998) reported the presence of protein allergens in refined peanut oil. The obvious explanation of the contradiction between the results of Hourihane et al and Olszewski et al is that they were using two different samples of "refined" peanut oil, which in turn suggests the conclusion that the unqualified term "refined peanut oil" cannot be assumed to mean non-allergenicity. This further suggests that unless the oil is highly refined, analytically monitored and designated non-allergenic, peanut oil should be treated as allergenic.<sup>7</sup>*

Additionally, it appears that government has limited control over imported foods, which may or may not adhere to food labelling regulations. Rather than state that highly refined peanut oil is 'safe' and unrefined peanut oil is not safe, it may be easier to include the oil source on all labels and leave investigation up to the consumer.

### **Allergenicity of Certain Food Ingredients**

Some foods, such as edible oils, hydrolyzed proteins, lecithin, starch, lactose, flavors, and gelatin, may be derived from sources commonly involved in IgE-mediated food allergies. The suggestion has been made that consumers with allergies to the source material should avoid these ingredients if they contain detectable protein residues.<sup>8</sup>

Anaphylaxis Canada supports the labelling of priority allergens, regardless of source. Sources to include are items found under Annex 2, 3, and 4 in the Canadian Food Inspection Agency (CFIA) Guide to Food Labelling and Advertising, Section II: Basic Labelling Requirements.<sup>9</sup> It is not clear how the issue of cross-contact with allergens, containing relatively small amounts of protein, should be addressed. What we don't want to see is the gratuitous application of a precautionary label (e.g. 'may contain lecithin') if there is not a real concern. Analytical testing, such as enzyme-linked immunosorbent assays (ELISA), combined with input from food scientists, allergists, and manufacturers, would be required to develop a firm recommendation. The goal should be to identify threshold levels that protect the vast majority of allergic consumers.<sup>10</sup>

### **3. Precautionary labels should be used in a responsible way.**

During the past decade, we have witnessed a proliferation of precautionary labels, one of the most popular being the 'may contain...' statement. There are several concerns with this trend:

- Without clear definitions and guidelines, manufacturers have developed several warnings, amongst them: 'may contain...'; 'made in a facility that handles...'; 'processed in a plant that contains...'; 'produced in a factory where peanut is handled'; 'may contain traces of other nuts' (after a reference to peanut in the ingredient list). These are but a few examples.
- There is a widely held view that manufacturers put the warning on to cover themselves from liability or to take shortcuts when cleaning production equipment. This perception has led some allergic consumers to put themselves at risk by ignoring precautionary labels, which are in fact being used in a responsible way by a manufacturer.
- Manufacturers that use precautionary statements unnecessarily, further limit the choices of safe foods for allergic consumers.

To address the above concerns, Anaphylaxis Canada supports the following recommendation on Supplemental Allergen Statements, contained in the Food Allergen Labelling Guidelines. These were developed by the Food Allergy Alliance in June of 2001.<sup>11</sup>

*Food processors that prepare foods potentially exposed to inadvertent contact with Major Food Allergens acknowledge that labelling is not a substitute for good manufacturing practices (GMP).*

*Supplemental allergen statements should be used judiciously only when all four of the following criteria are met:*

- a. The presence of a Major Food Allergen is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product, or other means;*
- b. The risk of presence of a Major Food Allergen is unavoidable even when current GMPs are followed;*
- c. A Major Food Allergen is present in some, but not all, of the product and;*
- d. The presence of a Major Food Allergen is potentially hazardous.*

*If some, but not all, of these criteria are met, food and ingredient manufacturers should consider food allergen control and/or labelling strategies other than supplemental allergen statements.*

*When all four of these criteria are satisfied, the supplemental allergen statement should be placed in close proximity to the ingredient declaration. When using an ingredient that utilizes a supplemental allergen statement, the food processor should carry that supplemental allergen statement forward to the label of its food only when these four criteria are met. Any supplemental allergen statement should be as accurate and conspicuous as possible, to help allergic consumers make a clear decision about whether or not the food is appropriate for them to eat.*

Anaphylaxis Canada has the following additional comments, which would apply to all priority allergens, including sulphite:

- There should be a limit on the number of precautionary warnings.
- A clear definition for each warning should be developed.
- Use of the term 'may contain trace amount of...' should be reviewed, based on comments made in #2 - "Hidden" allergens should be disclosed.

#### **4. Allergens should be placed prominently on the label.**

Given the tendency for consumers to miss an item on a food label, manufacturers could make enhancements to direct more attention to the allergens. The following are ideas for consideration:

- Using bold font for allergens in ingredient lists, precautionary statements, and allergy information would draw attention to their presence.
- Repetition of an item in an allergen statement would also be helpful. For example, in some cereals, soy lecithin is listed in the ingredients. Under the list, **CONTAINS SOY** highlights the fact that this allergen is present. (It prompts the consumer to re-read the ingredient list to find out what 'soy' specifically refers to.)
- Precautionary or allergen information statements should follow the ingredient list in each language, i.e. English warning under English ingredient list. They should not be noted separately from the ingredient list, as they may be missed.
- Packaging should be designed so that ingredient lists and precautionary warnings are not obscured, e.g. precautionary warning is noted under the flap of a package.

#### **5. Allergens should be noted in 'plain' English.**

The use of unfamiliar terms for priority allergens (e.g. casein, albumen) increases the challenge for allergic consumers. This is supported by a recent American study, *Food labels cause confusion for people with food allergies*.<sup>12</sup>

*Researchers concluded that, with current labelling practices, most parents are unable to identify common allergenic foods, and this may be a particular problem for milk and soy. These results strongly support the need for improved labelling with plain English terminology and allergen warnings.*

With a large immigrant population, whose mother tongue is not English, this issue is of equal importance in Canada. Labels in plain English will help allergic consumers make more informed choices, thereby decreasing the risk of potentially life-threatening reactions.

Anaphylaxis Canada generally supports the points outlined by the Food Allergy Alliance in the Food Allergen Labelling Guidelines, Use of Ingredient Terms Commonly Understood by Consumers<sup>13</sup>:

*Ingredient terms commonly understood by consumers for the Major Food Allergens in the product should appear within, or in immediate proximity to, the ingredient declaration of the food label. Examples of acceptable ingredient terms commonly understood by consumers of Major Food Allergens include, "eggs," "fish," "milk," "peanuts," "shrimp," "soy," "walnut," "sesame" or "wheat". The "plain" English names used for the priority list of allergens should be used in ingredient lists and translated into "plain" French also.*

Clarification of a specific food would be helpful, where a food is not commonly known, e.g. Porgy (fish).

## **6. Consumers should be able to easily contact the company for product information.**

Given the potential for food to cause a life-threatening reaction, allergic consumers are being encouraged to contact manufacturers to determine whether a product may be suitable. As mentioned previously, there are over 170 foods, which have been reported to cause an allergic reaction. Clearly, it is important for allergic consumers to have a convenient way to inquire about a product. Increasingly, this is done by phone and email. Contact information should be provided on the package.

Anaphylaxis Canada recommends the following:

- The Canadian Food Inspection Agency's (CFIA) *Guide to Food Labelling and Advertising (Section II, 2.7)*<sup>14</sup> should be amended to include a mandatory telephone number, complete with area code. Where company resources are available, a toll-free number would be helpful.
- The availability of current allergen information on the company website could potentially decrease the volume of telephone and email inquiries about allergen-related concerns.
- Email addresses should be available on company websites.
- Additional labels, such as those put on imported foods to meet bilingual labelling requirements, should not cover up contact information.

## **7. Labels must be legible.**

As avoidance is the only solution to preventing an anaphylactic reaction, allergic consumers depend on labels that are both accurate and easy to read. Unfortunately, there are several inadequacies in current labelling practices, which increase the risk of accidental exposure.

Anaphylaxis Canada recommends the following:

- The section, General Labelling Requirements, in the CFIA's *Guide to Food Labelling and Advertising (Section II, 2.2)*<sup>15</sup> should be amended to a larger font size.
- It is easier to read an ingredient list when it is printed in both upper and lower case lettering as opposed to all upper case letters.
- The background for the ingredient list should contrast well with the print and not be allowed to blend in with a busy or poorly contrasted background. For consideration: Are multi-colored labels a problem for people who are colour-blind?
- Practical consideration should be given to the location of an ingredient list. It should not be obscured or destroyed by opening the product, e.g. ingredient label on salad dressing bottles is destroyed once the cap is removed.
- As mentioned above, bolding of the priority allergens is helpful.

## **8. Criteria should be developed for an allergen management plan.**

Allergic consumers look to manufacturers to have effective allergen management plans in place. Those with a well-entrenched plan will be in a better position to reduce the risk of cross-contact and build brand loyalty. At present, there is not a consistent management plan that has been adopted by the manufacturers and regulatory bodies in Canada.

Anaphylaxis Canada recommends the following:

- Government should look to widely-accepted manufacturing methods and systems as a base for developing a consistent allergen management plan. A couple of examples are:
  - Hazard Analysis and Critical Control Points (HACCP) principles, which reduce the risk of foreign material, microbiological, and chemical contamination.
  - The Food and Consumer Product Manufacturers of Canada (FCPMC) *Allergy Beware 2000: Guidelines - Allergen Management Best Practices*<sup>16</sup>.
- While we support the view that "*Food manufacturers, importers, distributors, and food service establishments should develop an Allergen Prevention Plan to manage allergy risks*"<sup>17</sup>, we believe the plan should be referred to as an Allergen **Management** Plan. Due to variables inherent in the manufacturing process, 'prevention' of cross-contact cannot be guaranteed. Furthermore, there are steps companies can take to eliminate certain allergens from food ingredients, as part of a management plan.
- Consideration should be given to the development of an accreditation process. Companies, which have successfully implemented an allergen management plan, would receive the privilege of using a universal insignia, which represents a 'stamp of approval'. This could be displayed on the package.

## **9. Guidelines should be developed to regulate 'allergen free' claims.**

Government regulations, or at least guidelines, are necessary to protect the anaphylactic consumer against inaccurate labelling and advertising claims. Examples include allergen-free claims such as "*dairy-free*", "*milk-free*", "*peanut-free*", "*nut-free*", and "*egg-free*". Manufacturers and distributors need to meet clearly defined criteria that reflect due diligence. Currently there are no established criteria.

Recommendations to address these issues include:

- An effective allergen management plan, such as FCPMC's *Allergy Beware 2000: Guidelines* could serve as a checklist against which products with an 'allergen-free' claim could be assessed.
- While anaphylactic consumers are often most comfortable with allergen-free facilities (e.g. peanut/nut free plant), this is not always possible. The next best alternative would be a dedicated production line, e.g. no products with peanut/tree nut run on it.
- A claim should be supported by appropriate product packaging so that the claim cannot be compromised, i.e. package should be tamper-proof
- To eliminate confusion, manufacturers should be very clear with their messaging, e.g. '*peanut-free*' does not necessarily mean '*tree-nut free*'. '*Tree-nut free*' does not imply that a product is '*peanut-free*'. What does '*nut-free*' mean? The average consumer does not realize that peanut is a member of the legume family and that peanut and tree nuts are at risk of cross-contact with each other, given the fact that both groups are often processed and/or packaged on the same manufacturing lines. Consideration should be given to whether '*nut-free*' should be allowed.

## **FOOD FOR THOUGHT**

The following represent additional challenges that allergic consumers face. While recommendations are not being offered here, we feel they are worthy of note for future consideration. These should be addressed by government, industry, and allergic consumers alike, in order to close the current gaps.

### **Inconsistency in product labelling creates confusion**

Consumers become accustomed to purchasing products which have been safe for them in past. When the assumption is made that the 'product looks the same, therefore is the same, and safe', mishaps can occur. Examples could include:

- Snacks made in a dedicated plant (i.e. no peanuts/tree nuts). The same product is made in another facility, which is not peanut/tree nut free, and the packaging looks exactly the same. Consumers may miss the precautionary warning on the label in the latter case.
- A Canadian chocolate bar has a long-standing reputation for being 'peanut/tree nut free'. The consumer assumes that the same bar, made in the USA, is safe, but misses the precautionary warning. The bar produced in the US has been co-packed.
- Chocolates produced in snack size may have a warning (often difficult to see unless you are specifically looking for it) while large size format may be safe (produced in nut free facility) and have no warning. This may lead to assumption of safety about the snack size.
- Consumers assume that if an allergen is not listed on a label, then the product is safe. They don't always understand that food labelling regulations differ from country to country and that the precautionary warning is used voluntarily by manufacturers. Imported chocolates are a prime example of products which could put a peanut- / tree-nut allergic consumer at risk.

### **Cross-contact with natural rubber latex**

Natural rubber latex is another allergen of concern. Although its exposure spans beyond food products, direct contact with foods, through gloves used in food handling, has resulted in anaphylactic reactions in the foodservice industry. Latex allergy has increased amongst health care workers who have been exposed in their work environment.

While it is unclear if protein from latex gloves would be present in processed foods, it would be prudent for manufacturers to investigate further how best to reduce the potential for cross-contact of latex in processed foods, and whether latex gloves should be replaced with non-latex gloves to minimize exposure to employees.

For consideration: Rubber bands, placed around fresh vegetables, are an issue for latex allergic individuals. Perhaps there are implications with regard to cross-contact in the food manufacturing sector.



## **SUMMARY**

Food related anaphylaxis is a growing concern in Canada. In a recent survey conducted by the National Institute of Nutrition<sup>18</sup>, it was found that 40% of Canadians read food labels in search of allergen information. This implies that allergic individuals must be able to rely on the accuracy of food labels, not only directly, but also with respect to the interpretation made by caregivers, extended family, friends, institutions and restaurateurs. This fact alone underscores the responsibility of food manufacturers to provide information that is clear and to the point.

While Anaphylaxis Canada supports science-based research in all areas of anaphylaxis, it is clear at this time that science does not yet have all the answers. Where science is lacking, we concur with Health Canada's precautionary approach/principle. However, we believe that any allergen labelling of foodstuffs, based on the precautionary principle should be revised if scientific evidence determines that it is no longer applicable, or the reverse, that other items should be labeled.

With impending changes in nutrition labelling, this is an opportune time to bring representatives from the food industry, government, Anaphylaxis Canada, and medical professionals together, to collaborate on clear guidelines, which will close the gaps in current labelling regulations. Our vision is a safe world for all anaphylactic individuals, until a cure is found.

Thank you for taking this issue seriously and giving consideration to our concerns.

**REFERENCES**

1. *Emerging Problems With Food Allergens*, Taylor SL, *Food, nutrition and agriculture - 26 (2000)* (Food and Agriculture Organization of the United Nations web site)
2. *Food allergy is a matter of geography after all: sesame as a major cause of severe IgE-mediated food allergic reactions among infants and young children in Israel*, Dalal I, Binson I, Reifen R, Amitai Z, Shohat T, Rahmani S, Levine A, Ballin A, Somekh E., *Allergy*. 2002 Apr;57(4):362-5, PMID: 11906370
3. *Emerging Problems With Food Allergens*
4. *Proposed Labelling of Foods Causing Severe Adverse Reactions in Canadians, A Report by a Joint Canadian Food Inspection Agency and Health Canada Committee*, Food and Drug Regulations Review Project 19 Consultation, March 31, 1998.
5. *Emerging Problems With Food Allergens*
6. *Emerging Problems With Food Allergens*
7. *Dealing with Food Allergens*, Seminar 2000, Good Manufacturing Practice: Dealing with Food Allergens in Ingredient and Food Processing, Blanchfield JR., Michigan State University June 15, 2000,
8. *Ingredient and labelling issues associated with allergenic foods*, Taylor SL, Hefle SL., *Allergy*. 2001;56 Suppl 67:64-9. Review, PMID: 11298013 [PubMed - indexed for MEDLINE] (abstract only)
9. *Guide to Food Labelling and Advertising*, Canadian Food Inspection Agency
10. *How Much Is Too Much? Threshold Doses for Allergenic Foods*, Hefle, S and Taylor SL., *Current Allergy and Asthma Reports* 2002, 2:63-66.
11. *Food Allergen Labelling Guidelines*, Food Allergy Issues Alliance, June 2001.
12. *Food Labels Cause Confusion For People With Food Allergies*, New York {American Academy of Allergy, Asthma and Immunology, March 4, 2002
13. *Food Allergen Labelling Guidelines*
14. *Guide to Food Labelling and Advertising*
15. *Guide to Food Labelling and Advertising*
16. *Allergy Beware 2000 Guidelines. Allergen Management Best Practices*, Food and Consumer Product Manufacturers of Canada, FCPMC/FPACC, October 1999.
17. *Common Allergenic Foods and Their Labelling in Canada-A Review*, Canadian Journal of Allergy & Clinical Immunology 1999, 4:3, Zarkadas M, Scott FW, Salminen J, Ham Pong A.
18. *Tracking Nutrition Trends IV; An Update of Canadians' Nutrition-Related Attitudes, Knowledge and Actions, 2001*. Ipsos Reid Study. National Institute of Nutrition.