



Comparison of international food allergen labeling regulations

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ABSTRACT

Food allergy is a significant public health issue worldwide. Regulatory risk management strategies for allergic consumers have focused on providing information about the presence of food allergens through label declarations. A number of countries and regulatory bodies have recognized the importance of providing this information by enacting laws, regulations or standards for food allergen labeling of “priority allergens”. However, different governments and organizations have taken different approaches to identifying these “priority allergens” and to designing labeling declaration regulatory frameworks. The increasing volume of the international food trade suggests that there would be value in supporting sensitive consumers by harmonizing (to the extent possible) these regulatory frameworks. As a first step toward this goal, an inventory of allergen labeling regulations was assembled and analyzed to identify commonalities, differences, and future needs.

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1. Introduction

Food allergy is a significant public health issue that affects up to 3–5% of adults and 8% of children worldwide (Gupta et al., 2011; Sicherer, 2011). Unlike for other foodborne hazards, the risk management options available to allergic consumers are limited because the hazard is a food, something that is both nutritious and desirable for the general population, rather than an added component or contaminant in the food. This means that regulatory risk management strategies for food allergic consumers have focused on communication in the form of label declarations. The development of labeling regulations for food allergens has been complex because of the number of foods that are allergens, the range of sensitivities in the allergic population, and the variety of ways that allergenic foods and their derivatives are used as ingredients.

Food allergy is an immune-mediated sensitivity to food proteins (Boyce et al., 2011). There are several types of immune-mediated sensitivities and they are classified according to the type of antibody involved and whether there is a cell-mediated component. The IgE-mediated immediate reactions are of greatest public health concern because they may result in rapid-onset severe or fatal reactions. The development of a food allergy is a two step process (Sicherer and Sampson, 2010). The first step, sensitisation, leads to the production of IgE antibodies specific to one or more proteins in a food. The second step, elicitation, occurs when a previously sensitized individual is re-exposed to the same food or food proteins. Binding of the preformed IgE antibodies to the target proteins triggers a cascade of events that leads to the signs and symptoms of an

allergic reaction. While many of the molecular and cellular events involved in both sensitisation and elicitation have been described, many important questions remain such as why some individuals develop food allergies and others do not, why sensitisation may not occur until after repeated exposure to the same food, and why some foods are more likely to trigger allergies than others. This means that there is no effective way to predict who will develop food allergies, to prevent individuals from becoming sensitized, or to address sensitisation as a public health issue. Therefore, public health and legislative efforts have focused on providing information to individuals with food allergies to help them avoid foods that might provoke an allergic reaction.

Allergic reactions may manifest as a variety of signs and symptoms that can involve the digestive, respiratory, cardiovascular, or cutaneous organ systems (Boyce et al., 2011). Reaction severity varies from mild (such as a few small hives) to severe (such as systemic shock). Reactions involving multiple organ systems are generally called anaphylaxis. Reaction severity depends on the sensitivity of the individual, the level of exposure (amount of food consumed), and modifying factors such as the presence of other conditions (e.g., uncontrolled asthma) or the use of medications such as steroids or antihistamines. Clinical studies have shown that the range of sensitivity in the allergic population can encompass many orders of magnitude (Taylor et al., 2010). This means that the same exposure might result in a mild reaction in one individual, a severe reaction in another, and death in a third. Food processing and cooking can affect the relative ability of a food to trigger a reaction in an unpredictable manner. Because there are so much uncertainty regarding each individuals sensitivity and reaction severity, any exposure to protein from a food allergen is considered to be of public health significance.

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Until a cure or effective treatment for food allergy becomes available, sensitive consumers must rely on avoidance to prevent reactions. Successful avoidance depends on the public having complete and accurate information on the substances in a food, information obtained from food labels. A number of countries and international bodies have recognized the importance of providing this information by enacting laws, regulations, or standards for food allergen labeling. Because over 200 foods have been shown to be allergenic (Hefle et al., 1996), governments and regulatory agencies have recognized the need to focus allergen labeling regulations on a limited set of “priority allergens.” Different governments and organizations have taken different approaches (technically and historically) to identifying these “priority allergens.”

The importance of food allergy as a public health issue has been known for many years. For example, one justification that was advanced for requiring ingredient labeling in the 1938 United States (US) Food, Drug, and Cosmetics Act was the need to protect sensitive consumers (Derr, 2006). This need became more acute in the 1980s and 1990s as the number of uses for food derivatives and extracts increased, leading to the presence of “hidden” allergens in many foods.

To address these issues, a working paper on food allergens was presented to the Codex Committee on Food Labeling in 1993, followed by a Food and Agriculture Organization (FAO) Technical Consultation on Food Allergens in 1995 (The Codex Alimentarius Commission was formed by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts such as codes of practice, and is recognized under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures as the international standards organization for food safety.). These efforts led to the adoption of a list of substances of concern in 1999 as part of the Codex General Standard for the Labeling of Prepackaged Food (Codex (Codex Alimentarius), 2001).

In the United States, increased awareness of the importance of allergen labeling led the Food and Drug Administration (FDA) to issue a Notice to Manufacturers in 1996 (FDA, 1996) asking that they declare all allergens in the ingredient list, even if they were found in flavors or processing aids which did not otherwise need to be declared on the label. The allergens of concern identified in this letter were those previously given as examples of foods that “commonly cause an allergic response” in the 1992 policy statement on foods derived from new plant varieties (FDA, 1992). In 2001 FDA issued a “Dear Colleague” letter (FDA, 2001a), a Statement of Policy (FDA, 2001b), and an Inspection Guide (FDA, 2001c) all aimed at improving allergen labeling through control and reduction of cross-contact. (Cross-contact is the transfer or an allergen or protein from an allergen from one food to another.)

International recognition of food allergy as an important public health issue and the need to provide information to protect sensitive consumers resulted in the enactment of Directive 2003/89/EC (European Parliament, 2003) and the US Food Labeling and Consumer Protection Act (FALCPA) (US Code, 2004). Both of these identified lists of foods or groups of foods that were considered to be “priority allergens” and required that these allergens be identified in plain language on the labels of foods that contain these allergens as ingredients. A number of other countries then adopted allergen labeling regulatory frameworks, many of which were based on the Codex or European Union (EU) standards.

Despite extensive international communication and scientific collaboration on allergen issues, there are a number of significant differences among the different regulatory frameworks that have emerged. Identifying these differences is an important first step in developing a uniform, feasible, and enforceable regulatory approach to food allergens that is protective of consumers worldwide.

The increasing volume of international food trade suggests that there would be value in harmonizing (to the extent possible) the foods subject to allergen labeling regulation. As a first step in this process, an inventory of allergen labeling regulations was assembled and analyzed to identify commonalities and differences.

2. Allergen labeling regulatory frameworks considered

Nineteen laws, directives, regulations, rules, and ministerial statements on food allergen labeling were identified through an extensive search of regulatory databases, agency and government web sites, literature citations, and references in other regulatory documents (Table 1). Because the exact legal status of each differs depending on the specific governmental structure involved, these are referred to as regulatory frameworks. Codex standards are considered to be equivalent to a national regulatory framework. To the extent possible, primary sources (or direct translations of primary sources) were used for this analysis. However, in some cases, information from secondary authorities was used because the primary source was not available. These secondary sources are identified in Table 1. In many instances it was not possible to review historic information or explanatory material because only the current versions of relevant documents are available. Of the 19 regulatory frameworks identified, six directly use or cite the Codex standard and three directly use or cite the EU standard (see Table 1). These nine frameworks need no further discussion.

3. Results

Food allergen labeling regulatory frameworks differ significantly around the world. Each jurisdiction identifies different priority allergens and it is often not clear what criteria were used to develop these lists of priority allergens. In addition, the standards for adding and removing allergens from the regulations differ.

The foods that are currently identified as priority allergens in the remaining ten regulatory frameworks are shown in Table 2. Between five and 13 allergens are identified in the various lists, with five of the lists containing eight foods. Five foods (wheat/cereals, eggs, milk, peanuts and crustacean shellfish) are common to all ten of the lists. Soy and fish occur in nine (although Korea includes a single species of fish), and tree nuts are listed in eight.

In many cases, neither the regulatory framework nor the supporting documents are clear as to what criteria were used to determine which foods should be listed. For example, the US FALCPA states that the “major food allergens” “account for 90 percent of food allergies.” It is not clear if this is intended to mean 90% of individuals with food allergy or 90% of allergic reactions. The Hong Kong regulatory framework has a similar statement that the eight foods listed have been “identified to be responsible for 90% of the food allergic reactions.” In neither case are data or references given explaining on how this figure was derived or why 90% is considered an appropriate level of public health concern.

EU Directive 2003/89 established a list of “common food allergens” that were identified based on a 1995 report by the Scientific Committee on Food.¹ The committee report does not explain how this list was developed, and the EU list of allergenic foods differs somewhat from the committee list. While the Codex standard simply describes the Codex list as “those foods and ingredients that are known to cause hypersensitivity,” this list was developed after several rounds of discussion at Codex meetings and a review by a FAO expert consultation. The expert consultation suggested that three specific criteria should be used “to select the foods causing

¹ EU Directive 2003/89 listed the allergens of concern in Annex IIIa. EU Regulation No. 1169/2011 of October 2011 places this list in Annex II.

Table 1
Food allergen regulatory frameworks.

Jurisdiction	Source
Codex Alimentarius	Codex General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 2010)
Argentina	Argentine Food Code Section 235 Seventh (Information from WTO Notification G/TBT/N/ARG/252)
Australia/New Zealand	Australia New Zealand Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations
Barbados	Barbados National Standard Specification for Labeling of Prepackaged Foods BNS 5: Part 2: 2004 (Second Revision)
Canada	Regulations Amending the Food and Drug Regulations (1220 – Enhanced Labeling for Food Allergen and Gluten Sources and Added Sulfites) – Canada Gazette 145 (4) February 16, 2011
Chile	Amendment to Article 107 of the Food Health Regulations, Decree No. 977/96 (Information from WHO Notification G/TBT/N/CHL/95)
China	General Rules for the Labeling of Prepackaged Foods GB7718–2011 (Information from USDA GAIN Report CH110030)
European Union	Regulation No. 1169/2011 and Annex II; European Commission Directive 2007/68/EC and Annex IIIa; European Commission Directive 2003/89/EC and Annex IIIa, Regulation No. 1169/2011 and Annex II
Hong Kong	Food and Drugs (Composition and Labeling) (Amendment) Regulation 2004 Labeling Guidelines on Food Allergens, Food Additives and Date Format.
Japan	Standards and Evaluation Division, Department of Food Sanitation, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare; FAQs on Labeling System for Foods Containing Allergens
Korea	Korean Food and Drug Administration (Information from USDA ARS GAIN Report KS1102)
Mexico	Official Standard for General Labeling Specification of Pre-Packaged Foods and Non-Alcoholic Beverages (Information from USDA GAIN Report MX0505)
Mongolia	Technical Regulation on Trading and Supplying of Specified Import Goods and Products Only with the Labels Which Appear in Mongolian Language in the Domestic Market
Papua New Guinea	Food Sanitation Regulation 2007
Philippines	Rules and Regulations Governing the Labeling of Prepackaged Foods Products Distributed in the Philippines (Amending Administrative Order No. 88-B s. 1984) (Information from WTO Notification G/TBT/N/PHL/128)
St. Vincent and The Grenadines	Standard for Labeling of Pre-Packaged Foods, SVGNS 1 Part 3: 2000 (Rev. 2009)
Switzerland	Ordinance of the Federal Department of Home Affairs on Food Labeling and Advertising of Foods (Information from WTO Notification G/TBT/N/CHE/106)
Ukraine	Technical Regulations on Rules for Marking of Food Products (Information from WTO Notification G/TBT/N/UKR/52)
United States	Food Allergen Labeling and Consumer Protection Act of 2004 ^a

^a FALCPA applies to products regulated by the Food and Drug Administration. The labeling of most meat and poultry products is regulated by the Food Safety and Inspection Service in the Department of Agriculture and the labeling of most alcoholic beverages is regulated by the Alcohol and Tobacco Tax and Trade Bureau in the Department of the Treasury. Both of these agencies have developed policies to encourage allergen labeling consistent with the requirements of FALCPA.

Table 2
Allergenic foods.^a

	Codex ^b	European Union ^c	Australia/New Zealand	Canada	China	Hong Kong	Japan	Korea	Mexico	United States
Wheat/Cereals	X	X	X	X	X	X	X ^d	X ^e	X	X
Eggs	X	X	X	X	X	X	X	X	X	X
Milk	X	X	X	X	X	X	X	X	X	X
Peanut	X	X	X	X	X	X	X	X	X	X
Fish	X	X	X	X	X	X	X	X ^e	X	X
Crustaceans	X	X	X	X	X	X	X ^d	X ^e	X	X
Soy	X	X	X	X	X	X	X	X	X	X
Tree Nuts	X	X	X	X	X	X	X	X	X	X
Sesame		X	X	X						
Shellfish/Mollusks		X		X						
Mustard		X		X						
Celery		X								
Lupine		X								
Other							X ^d	X ^e		

^a As of January 1, 2012 based on the sources listed in Table 1.

^b The following countries use CODEX wording in their regulatory frameworks: Barbados, Chile, Papua New Guinea, Philippines, St. Vincent and The Grenadines. The wording for the Papua New Guinea uses the term “shellfish” instead of “Crustacean.” It is not clear if this is intended to include Molluscan shellfish. Mongolia cites the CODEX standard by reference.

^c The following countries use the EU Annex IIIa wording in their regulatory frameworks: Argentina, Switzerland, Ukraine.

^d Shrimp and crab are the only Crustaceans listed. Grains includes wheat and buckwheat. “Other” includes foods for which labeling is recommended but not required: abalone, squid, salmon roe, oranges, kiwifruit, beef, walnuts, salmon, mackerel, soybeans, chicken, bananas, pork, matsutake mushrooms, peaches, yams, apples, gelatin.

^e Mackerel is the only fish, crab and shrimp are the only Crustacean listed. Grains includes wheat and buckwheat. “Other” includes pork, peaches, and tomatoes.

the majority of reactions,” but it also indicated that the available data were inadequate to apply two of these criteria (a credible cause-effect relationship and prevalence) and it did not explain how the third (systemic reactions) could be used to identify foods causing the majority of reactions (JECFA, 2000).

The Canadian regulatory framework does not directly state how the Canadian list was developed, but the accompanying regulatory impact analysis says that Health Canada started with the list in the Codex standard and added three other foods to “meet the needs of the Canadian population” (Canada, 2011). Health Canada has also

developed a document describing the factors that would be considered in determining whether to add a new food to the list (Health Canada, 2010), but it appears that only one of the three additional allergens (mustard) was evaluated using this process.

An explanatory document from the Japanese Ministry of Health, Labour, and Welfare indicates that their list was developed on the basis of a literature review (Japan, 2010).

In general, it seems that the eight allergens that occur in most lists are perceived to be responsible for a large majority of food allergies worldwide. The differences between the lists probably

Table 3
Food groups.

	Codex	European Union	Australia/ New Zealand	Canada	China	Hong Kong	Japan	Korea	Mexico	United States
Cereals	Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains	Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains	Same as Codex	Wheat or triticale Plus “gluten” as protein from barley, oats, rye, triticale, wheat or a hybridized strain	Grain and products containing gluten protein (For example wheat, rye, barley, spelt, or cross-breeding products)	Same as Codex	Wheat, buckwheat	Wheat, buckwheat	Cereals containing gluten	Wheat
Fish								Mackerel		Examples: bass, flounder, cod
Crustaceans					Examples: shrimp, lobster, crab		Shrimp, crab	Shrimp, crab		Examples: shrimp, crab, lobster
Tree Nuts		Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pistachio nuts, walnuts		Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts						Examples: almonds, pecans, walnuts

reflect differences in the criteria used to determine which foods to include and in the cultural dietary patterns. Any future efforts to coordinate these lists should consider how to develop explicit and broadly applicable criteria for determining which food allergens are of significant public health concern.

One of the most important concerns for sensitive consumers is that a food allergen might be “hidden” in a processed food. This can occur when an ingredient derived from an allergenic food is described using a technical or scientific term (such as “casein” instead of milk or “ovalbumin” instead of egg) or by using a broad, uninformative term (such as textured vegetable protein instead of soy). Therefore, one of the major goals of all of the food allergen regulatory frameworks has been to ensure the use of plain language in the ingredient list. For example, FALCPA states that allergen-derived protein containing ingredients must be declared using the name of the food sources. The Canadian, EU, and Mexican regulatory frameworks also explicitly indicate that plain language or common names should be used. All of the other regulatory frameworks imply that plain language labels should be used in that they use the common names of the foods in the lists of allergens of concern.

All of the allergen labeling regulatory frameworks integrate the allergen declaration into preexisting ingredient declaration labeling formats. However, the US and Canadian regulatory frameworks also address the use of a “contains” statement. In both cases, all food allergens must be declared in the “contains” statement if one is used. The Chinese regulation mentions both the ingredient list and a “prompt” that accompanies the ingredient list without further clarification.

Although, on the surface, the identities of foods that have been listed as priority allergens appear to be clear and straightforward, there are unexpected potential complications. For example, none of the lists is specific as to the species source of the “egg” or “milk”. In some cases, other legal documents define standards of identity (or equivalent) that limit the scope of the terms “milk” and “egg”. For example, US regulations define “milk” as being cows’ milk (21CFR131.110) and “egg(s)” as hens’ eggs (21CFR160.115). This is probably highly protective of sensitive consumers both because these are the most commonly consumed species of milk and egg. In addition, foods using other forms of milk (such as goat milk) or egg (such as quail egg) are either likely to be labeled as such for marketing reasons or are subject to other labeling requirements. In contrast, the use of protected geographic names or appellation sys-

tems may not provide all sensitive consumers with sufficient information, particularly for foods in international commerce, if the appellation does not include the common name of the food source. This is a significant issue because the medical literature indicates that there is a considerable amount of cross-reactivity between species since these allergenic proteins have been evolutionarily conserved. It appears that the expectation in the EU is that milk and eggs from all species are included (Hattersly, 2009).

All of the allergen lists include cereal grains, although the number of species included and their descriptions differ (Table 3). In the US only wheat is included, while Japan and Korea include wheat and buckwheat. The EU, Codex, Australia/New Zealand, and Hong Kong specify “cereals containing gluten” followed by a list that identifies the included species. It is unclear whether the use of gluten in the definition of the cereals of concern is intended to protect consumers with Celiac disease in addition to allergic consumers. Celiac disease is a form of gluten sensitivity that has an immunological component, but it has a different etiology from IgE-mediated allergies. Gluten sensitivity also differs from food allergy in that it is primarily a chronic problem that does not cause immediate life threatening reactions. Canada clearly distinguishes these two forms of sensitivity since it has a list of priority allergens including wheat and triticale, while a second list defines “gluten” as being protein from wheat, triticale, barley, oats, rye, and hybridized strains. It is not clear why a list of allergenic foods should identify the grains of concern as those that contain gluten when there is little evidence for widespread allergy to grains other than wheat and buckwheat. An alternate approach to providing protection for consumers with Celiac disease that is being widely implemented is to define the appropriate use of the term “gluten free.”

Several of the foods that are identified in most allergen lists are actually groups of foods (e.g., fish, tree nuts, and shellfish). Table 3 compares the wording used to describe these food groups in different regulatory frameworks. Eight of the ten lists do not address the fact that fish is a food group, six do not address crustaceans as a group, and seven do not address tree nuts as a group. Korea only requires labeling of one species of fish, while Japan and Korea each require labeling of only two species of Crustaceans (shrimp and crab). The EU limits the list of tree nuts to eight named species and Canada to nine named species. The US FALCPA cites three species of tree nut as examples but does not include a complete list of tree nuts. In all the regulatory frameworks that address tree nuts, the “nut” produced by the species listed represent several different

botanical or anatomical structures. This suggests that the intention of these regulatory frameworks is to use the term “tree nut” in the culinary or common sense, rather than in a technical sense. This is consistent with the goal of providing plain language labeling for sensitive consumers. Canada and the US are the only regulatory frameworks that specify that the individual species within each group must be identified on the food label for all the food groups. The US regulatory framework does this through a direction to use the “name of the specific type” of tree nut, fish, or Crustacean. The Canadian regulatory framework uses two approaches. For tree nuts it does not use the group term “tree nut,” but instead lists the nine species of concern individually. For Crustaceans, shellfish, and fish, it requires the use of the name of the particular type. Several other regulatory frameworks imply that individual species of tree nuts should be labeled, but do not indicate that this applies to the other food groups.

One of the major public health goals of allergen labeling regulations is to ensure that the presence of ingredients derived from allergenic foods (as opposed to the foods themselves) is declared using terms that can be understood by consumers (that is, by using the names of the source foods). To that end, six of the labeling regulations contain language that explicitly includes such ingredients in the labeling requirement. Four of them (EU, China, Hong Kong, Mexico) refer to “products of” the food allergens without defining what this means. The US definition of a “major food allergen” includes any “ingredient that contains protein derived from” one of the identified foods, while Canada uses similar language to include “any protein that is derived from” the listed foods within the definition of a food allergen.

4. Exemptions

Allergenic foods can be used as the source material for the manufacture of a large number of ingredients and food additives. The processes used to make these ingredients can result in removal, modification, or degradation of the proteins in the food so that an ingredient derived from an allergenic food may no longer be a hazard for sensitive consumers. The EU and US regulatory frameworks acknowledge this possibility by providing mechanisms for requesting exemptions from the labeling requirement for modified ingredients.

In the US, ingredients may become exempt from the labeling requirements through either a petition or notification process. In both cases the submission is explicitly required to include “scientific evidence (including the analytic method used)” to demonstrate that the ingredient meets the applicable standard. The standard for granting an exemption through the petition process is that the ingredient “does not cause an allergic response that poses a risk to human health.” There are two standards for obtaining an exemption through the notification process; either the ingredient “does not contain allergenic protein” or it has been previously determined that it “does not cause an allergic response that poses a risk to human health” as part of a premarket approval process (such as the food additive petition process). To date, no exemptions have been obtained using either process, primarily due to shortcomings in the scientific evidence that has been submitted (Luccioli and Fasano, 2008).

The 2003 EU Directive that established the allergen labeling regulatory framework contained a provision exempting ingredients for which it has been “scientifically established that it is not possible for them to cause adverse reactions.” The 2007 Directive that implemented amendments to the allergen list described the standard as “scientifically established that they are not likely, under specific circumstances, to trigger adverse reactions.” The 2011 Regulation states that the “Commission shall systematically

re-examine the list in Annex II by means of delegated acts” but does not indicate what standard will be used. Previously, the responsibility for determining whether an ingredient met the 2003 or 2007 standards was explicitly given to the European Food Safety Authority (EFSA). The evaluation of individual submissions has been carried out by the EFSA Panel on Dietetic Products, Nutrition, and Allergies. It appears that each submission has been evaluated on a case-by-case basis considering both biochemical and clinical data. To date, the panel has approved 13 applications for ingredients derived from four allergenic foods (grains, fish, soy, milk). The published summaries of the evaluations for those applications that have been denied indicate that, in most cases, the denial was the result of data gaps that prevented the panel from reaching a conclusion.

The Codex standard indicates that future changes to the allergen list in the standard would be considered by the FAO/WHO Joint Expert Committee on Food Additives (JECFA). The only time that JECFA has considered food allergens was in 1998, early in the process of developing the labeling standard, when it determined that the data available at the time did not support exemptions for peanut and soy oils.

5. Additions

Some of the regulatory frameworks recognize the need to require labeling of additional allergenic foods as eating patterns change around the world and as our understanding of the epidemiology of food allergy improves. The Codex labeling standard delegates consideration of future additions to the allergenic food list to JECFA. However, it does not indicate who is responsible for initiating such reviews or what process to use.

Also as previously discussed, the EU regulatory framework calls for systematic re-examination of the list of food allergens in Annex II. Under the previous Directives, two additional food allergens (lupin and mollusks) were added to the list in 2007 at the same time that the exemptions were added. Interestingly, both of the documents that EFSA published describing the deliberations of the Scientific Panel on Dietetic Products, Nutrition, and Allergies for these foods contain reviews of scientific evidence related to the allergenicity, but no specific recommendations. Both state that the Panel considered the actual decision as to whether or not to include lupin or mollusks in the Annex to be “a risk management task which is outside the remit of the Panel.” This means that the criteria that were used to make the decision to include these foods were never articulated.

Canada is the only jurisdiction that has published and used a clearly articulated and detailed set of criteria for adding new foods to the list of priority allergens. These criteria include evidence of a “credible cause-effect relationship” establishing that the food causes allergies, reports of “severe systemic reactions,” and data on prevalence. Consideration is also given to potential exposure in the Canadian population and to the possibility that the food might occur as a “hidden allergen” in foods. Canada has also described the process for systematic data collection, for assessing the strength-of-evidence, and for evaluating the severity of clinical adverse reactions to be used in these evaluations. These criteria were applied to the evaluation of mustard, garlic, and onions as potential priority allergens of concern and were found to support the addition of mustard to the list, but not garlic and onion. Both of the systematic reviews (garlic and onions were evaluated together) have been made available on the Health Canada web site.

Although FALCPA does not include a mechanism for adding foods to the list of major food allergens in the US, it does permit the FDA to require labeling of a “spice, flavoring, coloring, or incidental additive” that is a food allergen. This served as one of

the bases for the regulation requiring labeling of the color additives Cochineal extract and carmine (21 CFR 73.100 (d) (2)).

6. Advisory and “free from” labels

All of the regulatory frameworks described above are intended to provide consumers with information about allergens when they occur in foods as ingredients; that is, when they are intended components of the final food product. Allergens may also become unintended components of a food when manufacturing processes and controls are not adequate to prevent cross-contact between allergen-containing and non-allergen-containing foods or ingredients. In those cases, manufacturers often add an advisory or precautionary statement to the food label. None of the allergen labeling regulatory frameworks address such labeling. A few regulatory authorities have cautioned that advisory labeling should not be seen as an alternative to Good Manufacturing Practices. The UK Food Standards Agency (Food Standards Agency, 2006) and Health Canada (Health Canada, 2011a) have provided guidance to industry on the use of wording of precautionary labels. Health Canada has also completed a set of consultation sessions on precautionary labeling and will use the results of these consultations to update their policy (Health Canada, 2011b).

None of the allergen labeling regulations set standards for the use of terms such as “free from” or “does not contain” in relation to food allergens. An increasing number of jurisdictions have, or are developing, regulations or policies on the use of the term “gluten free.” In most cases, these efforts have been focused on defining threshold levels of residual gluten in processed foods and the appropriate terminology to describe foods below these threshold values.

7. Sulfite labeling

Many of the allergen labeling regulatory frameworks also include sulfite in the list of agents that require labeling. Although sulfite sensitivity is not an allergy (i.e., it is not immune-mediated) the signs and symptoms experienced by sensitive individuals are similar to those for allergic reactions. Interestingly, sulfite is the only hazard identified in these regulatory frameworks with an explicit regulatory threshold (10 mg/kg). However, none of the regulatory thresholds that include sulfite on the list of agents along with food allergens explains why this threshold is considered appropriate.

8. Conclusions

Food allergens are a unique public health issue in that the hazard for sensitive individuals is a food rather than a contaminant or additive. Further, the sensitive population is unusually diverse demographically with a wide range of sensitivities. Internationally, public health authorities and regulatory bodies have recognized that accurate and complete food labels are the only effective tool for risk management available to the sensitive consumer at this time. The various regulatory frameworks that have been developed in response to this realization share many common features but also differ in important specifics, including the lists of priority allergens and the processes for modifying these lists. As food products and culinary practices become increasingly international it will be important to develop scientific criteria and approaches for reconciling these differences.

At this time, the most critical need is for a risk ranking framework that can be used to identify which foods should be considered to be allergens of concern. Although differences in the patterns of sensitivity from country to country make it unlikely

that a single list of allergens will be appropriate for all jurisdictions, it is important that a consistent risk assessment framework be used to develop each list. This will also facilitate a systematic identification of important data gaps and information needs. For example, while a great deal of effort has been devoted to characterizing distributions of sensitivities in food allergic populations, very little is known about the dietary patterns for these individuals. Similarly, while substantial work has been done on detecting and measuring allergens in foods, there are only a few studies on the prevalence and levels of undeclared allergens in a wide variety of foods.

Conflict of interest statement

The author declares that there are no conflicts of interest.

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