Annex 2 - Allergen Labelling

PLEASE SEND YOUR RESPONSE TO AUSTRALIA'S CODEX CONTACT POINT - Codex.Contact@agriculture.gov.au BY 29 JUNE 2018

To help inform the development of the CCFL Discussion Paper on this topic, we request Codex members to provide responses to the following questions about current practices, issues, and any potential role for CCFL on this topic. Please enter your name / contact details as requested below also when responding.

Name of Codex Member Country, Member Organisation, or Observer (and e-mail contact details):	**European Union**				
General Questions:					
1. Within your country / region, what is the current practice for allergen labelling? Is the labelling or practice used or proposed (e.g. under development); mandatory/regulatory or voluntary?					
Name of current labelling and/or practice	**Country or Region if applicable**	**Implemented (using) or proposed**	**Mandatory / Regulatory or Voluntary**	**Who developed the labelling? (Government, Industry, other organisation?)**	**Relevant references and/or weblinks. If relevant, what does the label look like on pack? (provide a picture if possible)**
Regulation (EU) No 1169/2011 on the provision of food information to consumers.	European Union	Implemented		European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1530180983115&uri=CELEX:02011R1169-20180101
14 major food allergens are listed ingredients identified in Annex II of Regulation (EU) No 1169/2011 causing allergies or intolerances.	European Union	Implemented	Mandatory		
Declaration of allergenic ingredients or processing aids applies to foods prepacked and non-prepacked.	European Union	Implemented	Mandatory		
Voluntary labelling for gluten free	European Union	Implemented	Voluntary		https://eur-lex.europa.eu/legal-

foods. Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. Gluten free = <20mg/kg Very low gluten = <100mg/kg Voluntary labelling on the unintentional presence of allergens in food. Allergens present in food following unavoidable cross contact – where the risk is real and poses a health risk statements such as “may contain” or “not suitable for...” can be used to inform those with food allergies and intolerances of the risk.	European Union	Implemented	Voluntary		content/EN/TXT/PDF/?uri=CELEX:32014R0828&from=EN

2. Are you aware of existing international guidelines or other relevant work undertaken in other international fora on this topic? If so, please provide relevant reference(s) or website links to access this?

Yes / No	**Details of existing international guidelines or other relevant work in other international fora:**
Yes	In the EU, a guidance document on the provision of information on substances or products causing allergies or intolerances have been recently published. Its purpose is to assist consumers, businesses and national authorities in understanding the new requirements of Regulation (EU) No 1169/2011 related to the indication of the presence of certain substances or products causing allergies or intolerances.

	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.428.01.0001.01.ENG&toc=OJ:C:2017:428:TOC
3. What are the issues that you think need to be addressed by CCFL for this topic? Please give a reason(s) for your answer of why it is important (e.g. there is a gap on [x] in Codex text(s), clarity is needed on [x] information needed for consumer information/choice, etc.).	
Issue(s)	**Reason(s) for answer**
Labelling of the unintentional presence of allergens in foods	The labelling of unintentional presence of allergens due to cross-contamination during the food chain such as "may contain" is not addressed at Codex level. Thus, there are different approaches among the countries in terms of labelling and in terms of conditions of use of such labelling statements. Some of them adopted national legislations on the matter. These different labelling practices, with regard to the unintentional presence of allergens may confuse the consumers and may also lead to obstacles to international trade.
Specific Questions:	

The *General Standard for Labelling of Pre-packaged foods* (CXS 1-1985) (GSLPF) provides a list of foods and ingredients known to cause hypersensitivity (e.g. food allergy, coeliac disease and food intolerance) and that should always be declared.

Extract from the GSLPF

4.2.1.4 The following foods and ingredients are known to cause hypersensitivity and shall always be declared[2].

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or 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; and
- Sulphite in concentrations of 10mg/kg or more.

[2] Future additions to and/or deletions from this list will be considered by the Codex Committee on Food Labelling taking into account the advice provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

4. Is the term 'hypersensitivity' an appropriately descriptive term for these types of adverse health reactions in sensitive populations? Should a definition of the term 'hypersensitivity' be considered for inclusion in the GSLPF?

According to the provisions of point 4.2.1.4 of GSLPF, the food allergens as listed herein are to be always declared on the label "as they are known to cause hypersensitivity". Therefore, the definition of the latter is not, as such, relevant in this context as no assessment of the hypersensitive character of a food has to be made.
However, the interpretation of the term "hypersensitivity" would be crucial for any future addition and/deletion from the labelling list. The term 'hypersensitivity' should therefore be included in the GSLPF. In addition, this would also ensure that the term is understood by the reader, including food business operators.

5. Are there any specific issues with the list of foods and ingredients in the GSLPF that need addressing? For example, are there issues with the grouping of foods and ingredients as listed in the GSLPF?

Cereals containing gluten or tree nuts are not presented consistently across the world. The EU is of the opinion that mentioning the collective terms such as "cereals containing gluten" or "tree nuts" in an allergen declaration would not be an appropriate and efficient way to inform and protect hypersensitive consumers from allergic reactions that specific food can trigger. In the EU, Regulation (EU) 1169/2011 provides that ingredients including allergens have to be designated by their specific name. In this regard, the EU considers imperative to clearly specify in the GSLPF that in case of groups of foods listed in the point 4.2.1.4, their specific type in question (almonds, walnuts or wheat, oats) needs to be declared as an allergen.

Tree nut lists have variability across countries. In the EU we have a defined list for tree nuts: almonds, hazelnuts, walnuts, cashews, pecan, Brazil nuts, pistachio nuts, macadamia or Queensland nuts. The EU considers that the same should be done at Codex level.

6. Are there any foods or ingredients <u>not</u> listed in the GSLPF that in your country/region are now generally recognized as causing hypersensitivity?

The EU list of allergens as listed in Annex II of Regulation (EU) No 1169/2011 has been established on the basis of the scientific opinions[1][2] adopted by the European Food Safety Authority (EFSA). According to the latter, those substances are considered as part of the most common food allergens in the EU and there is ample evidence to support their inclusion into the list. In this context, in addition to allergens included in the GSLPF, the EU list of allergens is complemented by celery, mustard, sesame seeds, lupin, and molluscs and products thereof.

7. What criteria (if any) do you use to identify new foods or ingredients causing hypersensitivity that should be declared in your country/region?

Food allergy refers to an inappropriate immune response to a food constituent, causing the food to provoke an allergic reaction when it is eaten again. Allergic reaction to food can vary from very slight to sever and occasionally fatal, depending on the dose, the individual and other factors. As those factors can change (as for example the cross-reaction with other foods), the obligation to label the allergens in food in the European Union is not linked to any dose/threshold, except for sulphites. The factor which justifies inclusion of certain foods into the EU list of allergens is the scientific evidence that they are likely to provoke allergic reactions to a considerable group of consumers and that they are found in a wide variety of processed foods.

[1] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2004.32/epdf.
[2] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3894/epdf

8. What mandatory/regulatory or voluntary labelling practices (if any) has your country/region implemented to ensure allergen labelling is clear and understandable for consumers (e.g. prescribe or provide guidance on the terms to be used and/or how information is presented)? Is there a further role for Codex in this area? (please give reasons for your response)

In order to ensure that consumers suffering from allergy or intolerance are able to easily identify the substance they are sensitive to, the EU has harmonised the modalities according to which the information about the presence of substances or products causing allergies or intolerances must be provided on foods.

In this regard, Article 21 of Regulation (EU) No 1169/2011 requires the allergens to be declared in the list of ingredients where the name of the substance in question has to be emphasized through a typeset that clearly distinguishes it from the rest of ingredients, for example by means of the font, style or background colour.

In the absence of the list of ingredients, the indication of the allergens has to comprise the word "contains" followed by the name of the food allergen. The allergens declaration is also mandatory for foods offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumers' request or prepacked for direct sale.

Under the Regulation, it is not possible to voluntarily declare the presence of the substances of Annex II used in the food as an ingredient otherwise as foreseen in 21.1 (such as by the statement “contains: milk, wheat flour” provided outside the list of ingredients, or by using of symbols or boxes). The purpose of this harmonization established by the Regulation was to avoid the consumer being confused by different ways of labelling of allergens in food. In this regard, it should be noted that substances listed in Annex II of the Regulation are considered as part of the most common allergens present in the EU. Nevertheless, also other food ingredients can trigger allergic reactions by certain groups of consumers. Taking this into account, it is important that such consumers always check the list of ingredients.

Furthermore, a guidance document on the provision of information on substances or products causing allergies or intolerances has been recently published. Its purpose is to assist consumers, businesses and national authorities in understanding the new requirements of Regulation (EU) No 1169/2011 related to the indication of the presence of certain substances or products causing allergies or intolerances

The EU considers that any guidance at Codex level on how the information on the allergens should be provided on the label would be very useful and beneficial for consumers.

9. Do you have a process in your country/region for exempting from labelling foods known to cause hypersensitivity? If so, what criteria do you use to evaluate and determine whether to exempt from labelling foods or ingredients derived from a food known to cause hypersensitivity?

In order to ensure better information for consumers and to take account of the most recent scientific progress and technical knowledge, the European

Commission has to systematically re-examine and, where necessary, update the list in Annex II. The update of the list in Annex II may consist in adding a substance to the list or removing a substance from that list. In this context, the interested parties can communicate to the European Commission evidence establishing that products derived from substances listed in Annex II are not likely, under certain circumstances, to trigger adverse reactions in individuals. Such evidence is further evaluated by European Food Safety Authority. On the basis of the scientific opinion of the latter, the EU list of allergens can be amended accordingly.

Following the above-mentioned procedure, the following exemptions have already been established for : wheat based glucose syrups including dextrose; wheat based maltodextrins; glucose syrups based on barley; cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin; fish gelatine used as carrier for vitamin or carotenoid preparations; fish gelatine or Isinglass used as fining agent in beer and wine; fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources; whey used for making alcoholic distillates including ethyl alcohol of agricultural origin and lactitol;

10. Does your country/region allow for advisory labelling regarding certain allergens present unintentionally that cause hypersensitivity (statements such as: “may contain [name of allergen]” or “produced on equipment that processes [name of allergens]”)? If so, what are the criteria for the use of these statements? Is the use of these statements voluntary or mandatory?

Regulation (EU) No 1169/2011 requires the provision of allergen information on both prepacked and non-prepacked foods when allergens are intentionally incorporated in foods, namely when they are ingredients. The presence of allergens when they are intentionally incorporated in a food is not subject to any threshold (except for the sulphur dioxide and sulphites). Even traces of allergens when they are ingredients must be labelled.

The EU legislation does not contain any specific provisions concerning the information on the possible and unintentional presence in food of substances or products causing allergies or intolerances. Such information may be provided voluntarily by the food business operator. The Regulation foresees that the Commission shall adopt implementing acts to ensure that information on the possible and unintentional presence in food of substances or products causing allergies or intolerances does not mislead or confuse consumers (Article 36.3(a)). Such act has not yet been adopted.

Many food business operators opt to use precautionary allergen warnings to alert allergic consumers on the possibility of, and consequently the risks from, the inadvertent presence of allergenic constituents. In the absence of EU rules, it is the responsibility of national competent authorities to ensure that such warnings comply with the general requirements for voluntary information.