Complementary Medicines Australia *submission to the* FSANZ: Plain English Labelling 2nd call for submissions

27 February 2020

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Contents

Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to comment on the second round of feedback regarding the Food Standard Australia New Zealand (FSANZ) consultation on Plain English Allergen Labelling (PEAL). CMA represents stakeholders across the value chain – including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. Many stakeholders manufacture, distribute and supply both foods and complementary medicines.

CMA's members supply both complementary medicines that are listed on the Australian Register of Therapeutic Goods as well as a wide variety of products that are regulated under food regulations. In particular, complementary medicines include a number of ingredients of natural origin, and therefore are more closely aligned in allergen content with foods than other types of pharmaceuticals. CMA supports the responsible and meaningful communication of the presence of allergens in complementary medicines, foods and other consumer goods. Our members take the regulatory reporting and labelling responsibilities of allergens seriously, and we work to develop methods that are consistent between industry members for the reliable reporting of allergens.

In the 2015/2016 re-development of the TGA's labelling requirements to create the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*, the TGA and its stakeholders went to some lengths to further harmonise with FSANZ requirements. There are increasing calls for the harmonisation of allergen declarations between differently regulated products and industries. As CMA represents members with products in both categories, we review allergen proposals with these harmonisation efforts in mind. Harmonisation is supported wherever possible to benefit ease of use and health outcomes, although it is known that there are some different considerations between the product types in terms of:

- Materials/ingredients commonly used
- The use of proprietary ingredients, where the sponsor of the goods does not have full access to ingredient lists
- The expectations of consumers
- The packaging type and style, in particular, medicine labels are often much smaller than typical food labels.

Harmonisation therefore offers some benefits, in that consistent expectations for some allergen terminology (such as crustaceans) reduces red-tape and confusion for the industry sector as well as reducing confusion and misunderstandings by consumers. In other areas, harmonisation creates significant challenges for industry, particularly as it relates to the ability to identify particular allergens (some ingredients such as maltodextrin can vary in the cereal origin) and label space in particular can be a significant challenge. Our submissions on allergens take these benefits and challenges into consideration.

FSANZ Proposal

CMA notes that feedback from the March 2018 submission were considered amongst other stakeholder comments and is therefore proposing to amend the Code to require the following when arriving at the following proposed amendments:

1. The separate declaration of:
   - molluscs;
   - individual tree nuts: almond, brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut ;
   - wheat, barley, rye, oats or spelt or their hybrids .
2. The use of mandatory specified terms of the allergen source when declaring allergens.
3. For packaged foods:
   - The declaration of allergens in the statement of ingredients using bold font and in a separate emboldened allergen summary statement.
   - The use of the mandated specified term 'Gluten' in the allergen summary statement if present from wheat, barley, rye, oats or spelt or their hybrids
   - The use of the mandated specified term 'Tree nut' in the allergen summary statement if individual tree nuts are declared in the statement of ingredients.

With the options being:

Option 1: Maintain the status quo (i.e. no change to allergen declaration requirements).

Option 2: Declare allergens using mandatory specified terms in bold font.

Option 3: Declare allergens using mandatory specified terms in bold font, with additional requirements to declare in the statement of ingredients as well as in a separate allergen summary statement., where:

FSANZ's assessment is that allergens are to be declared in the statement of ingredients using a bold font that provides a distinct contrast to ingredient names, and in a font size no less than that used for other ingredient names. An allergen summary statement is to be provided and displayed in bold font, and:

- include the prefix 'Contains', followed by a list of the allergens present
- appear directly below and be distinctly separated from the statement of ingredients
- be printed in the same font type and size as declarations in the statement of ingredients.

FSANZ is proposing for the draft variation to take effect on the date of gazettal, with the following transitional arrangements:

- A two year transition period followed by a 12-month stock-in-trade period.
  - The two year transition period will allow any relevant food to be sold as long as the food complies with either the existing requirements in the Code, or the amendments arising from Proposal P1044.
  - The subsequent 12-month stock-in-trade period will allow a food packaged and labelled before the end of the above transition period to continue to be sold for up to 12 months after the above transition period ends.

CMA response to 2nd call

Options 1, 2 or 3

1. **CMA is aligned with Option 2** (Declare allergens using mandatory specified terms in bold font) for this class of allergens as the precise source of the allergen can be clearly identified by the consumer.

2. **CMA does not support Option 3** (same as Option 2, but with additional requirements to declare in the statement of ingredients as well as in a separate allergen summary statement).

   This will create labelling challenges for foods, greater red tape, and more potential for accidental error and recall, than simply implementing Option 2.

   Option 2 is neat and succinct for industry and consumers, however, allergens are highlighted for consumers.

   The addition of another allergen statement summary also creates significant challenges to harmonisation between foods and TGA listed medicines sought by consumer groups, as almost all listed medicines will not have the label space available to include a separate allergen summary statement. This will likely prevent harmonisation and create confusing differences between various consumer goods.

Fish, Molluscs and Crustacea

3. **CMA supports** that fish, crustacea and molluscs are to be declared separately on packaging of goods for sale.

   Judging by the risk assessment conducted by FSANZ this approach significantly reduces risk to consumers and is consistent allergen declaration for non-prescription medicines which are detailed in Schedule 1 of the *Therapeutic Goods Order No. 92- Standard for Labels of Non-Prescription Medicines* (TGO 92), and is supported by a questionnaire that is used by raw materials suppliers and provided to manufacturers and sponsors. CMA is also aligned with the resolution to declare all fish under the moniker “fish” without distinguishing finfish, and to declare crustacea and molluscs without simultaneously declaring fish (unless fish is also present).

4. **CMA notes** that it is critical from an industry ingredient management point of view, and to avoid errors that would affect consumers, that the FSANZ and TGA definitions of these substances are the same. TGO 92 definitions:

- **Fish** includes freshwater fish, diadromous fish and marine fish, including shark.
- **Crustacea** include various species of aquatic animals which have an inedible chitinous outer shell. These include but are not limited to crab, crayfish, lobster, prawn and shrimp.
- **(Mollusc** no definition – not currently required).

Gluten and gluten containing grains

In section 5.6.2 the argument proposes separate declaration of gluten and wheat due to their individual allergenic profiles. This is different to allergen declaration in TGO 92 for medicines, where gluten only is required for declaration. A disparity like this between foods and medicines has the potential to be confusing for consumers. However we acknowledge the evidence from the safety review identifying the distinct allergenic potential of wheat.

Section 5.6.2 contains the following commentary which has an unclear intent:

> "Based on this evidence, FSANZ is proposing (for food required to bear a label) to require the use of the term 'gluten' in the allergen summary statement, and the use of specific cereal names 'barley', 'rye', 'oats', and 'spelt' in the statement of ingredients (along with 'wheat' – see Section 5.6.1 above). These requirements apply when these cereals or one of their hybrids is present (e.g. the use of triticale in a food would require 'wheat' and 'rye' in the statement of ingredients, and 'wheat' and 'gluten' in the allergen summary statement). These requirements will enable information to be provided for both fast searches, as well as additional detail on the individual cereals.
>
> FSANZ is proposing not to require allergen declarations for barley, rye, oats and spelt (and their hybrids) if these cereal ingredients do not contain gluten (e.g. due to processing or breeding techniques to remove gluten proteins). In this situation, the cereal names may still be declared voluntarily or as a means of using a true and accurate ingredient name, although the requirements for formatting allergen declarations would not apply to the cereal name. This reflects the findings of the safety risk assessment (Supporting Document 3), in that gluten (rather than the individual cereals) is the substance of concern for individuals with Coeliac disease and Dermatitis herpetiformis."

These two paragraphs are not clear and would benefit from an example and imply that foods typically contain gluten do not require an allergen statement if the specific raw material has had gluten removed, clarity is required as to what detection limit is considered suitable for gluten to not be declared, and also as to whether the term 'gluten-free' is suitable for use on packaging in these circumstances.

If the individual declaration of grains is considered necessary in the context of foods:

5. **CMA notes** it likely impractical to apply this rule to ingredients in both foods and therapeutic goods, such as maltodextrin, whose source can vary depending upon the particular supplier and availability at any given time.

6. **CMA notes** declaration each individual cereal sources on therapeutic goods is both impractical and likely unnecessary in comparison to foods. This presents another significant harmonisation challenge where consumers expect that labels may or should be harmonised.

Tree nuts

Section 5.5.2 proposed that the singular term "tree nut" be employed to reduce confusion of multiple tree nut ingredients where there may only be one source. This is echoed in section 5.5.4. It also states that in instances where a statement of ingredients is not required to be displayed, that the individual tree nuts must be declared by name.

Similarly to cereal grains, If the individual declaration of tree nuts is considered necessary for foods:

7. **CMA notes** that for tree nuts in particular, cross-contamination considerations are of a particular concern. If a facility for foods or therapeutic goods process a variety of materials for a variety of tree nuts, and this is expected to be reflected in allergen declarations **as it is for therapeutic goods**[1] – the individual declaration is not going to be possible in such circumstances. The declaration of tree nuts as an unspecified group, where the individual nut is not or cannot be identified, must remain an option for both food businesses, and harmonisation purposes.

Conclusion

Critical considerations are:

- The practical implementation of any proposals in manufacturing facilities
- The avoidance of unnecessary and excessive red-tape
- Harmonisation of allergen definitions between foods and medicines
- The avoidance of confusing requirements for industry in how statements are required – any resolution must be crystal clear to avoid inadvertent errors and the costs of unnecessary recalls;
- Providing suitable flexibility in situations where individual grains or nuts cannot be elucidated
- Awareness of label size limitations
- Awareness of harmonisation challenges with medicines, especially as it relates to label sizes and practical considerations are of paramount concern.

We have attached a copy of our most current industry Allergens questionnaire for reference.

We appreciate the opportunity to provide a submission to this consultation. Please do not hesitate to contact us, we are able to consult with our stakeholders on specific technical matters and provide information and answers to specific or general questions about industry implementation considerations within the complementary health (food and medicinal) product industry.

[1] See Section 1.5.9 – What substances must be declared – Guidance to TGO 91 and TGO 92, V 2.1 July 2019 https://www.tga.gov.au/book-page/1-using-orders#s15

Raw Material Questionnaire
Allergens and Substances of Concern Information

Introduction

This questionnaire is developed for raw material suppliers to provide information to manufacturers and sponsors of non-prescription medicines. The questionnaire collects information on allergens, substances of concern and other substances, that may be present within raw materials for which there are Australian regulatory requirements. Use of the questionnaire helps ensure compliance with these requirements.

Complementary Medicines Australia (CMA) and Consumer Healthcare Products Australia (CHP Australia) have jointly developed this questionnaire in consultation with member companies.

1. Company and Contact Details

1.1 Company Name:

This document was completed by:

Signature

Name:

Title:

Date:

2 Product Information

2.1 Raw Material Code:

Raw Material Name:

3 Declarable Substance Information

Substance[1]		Substance used in the manufacture or is a known component of the raw material[2]	Quantity of substance in the raw material[3]	Source and description[4]
Major allergens	Celery derived substances[5]			
	Cereal grain derived substances[6]			
	Crustacean derived substances[7]			
	Dairy derived substances[8]			
	Egg derived substances[9]			
	Fish derived substances[10]			
	Gluten			
	Lupin derived substances[11]			
	Mollusc derived substances[12]			
	Mustard derived substances[13]			
	Peanut derived substances[14]			
	Pollen[15]			
	Propolis			
	Royal jelly			
	Sesame derived substances[16]			
	Soy derived substances[17]			
	Sulfites[18]			
	Tree nut derived substances[19]			

Substances of concern	**Antibiotics**[20]				
	Benzoates[21]				
	Ethanol				
	Hydroxybenzoic acid esters[22]				
	Phenylalanine[23]				
	Potassium[24]				
	Sodium[25]				
	Sorbates[26]				
	Sugars	**All**[27]			
		Galactose			
		Lactose			
	Sugar alcohols[28]				
	Tartrazine				
	Artificial sweeteners	All[29]			
		Aspartame			
		Saccharin[30]			
		Sucralose			
Other Substances	Colours	Natural[31]			
		Synthetic/nature identical[32]			
	Flavours	Natural[31]			
		Synthetic/nature identical[32]			
	Fragrances	Natural[31]			
		Synthetic/nature identical[32]			

Notes:

1 Provides a description of the substance classified into three categories - major allergens, substances of concern and other substances. The list of allergens and substances of concern is derived from Schedule 1 of the Therapeutic Goods Administration (TGA) Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines, Food Standards Australia New Zealand (FSANZ) Food Standards Code Standard 1.2.3 Information Requirements - Warning Statements, Advisory Statements and Declarations, European Union Commission Directive 2007/68/EC and US Federal Register Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).

Substances included in Schedule 1 of the Therapeutic Goods Administration (TGA) Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines are indicated in **bold**.

2 Identifies if the substance is an ingredient or used in the manufacture of the raw material (including as a processing aid) or is a known component of an ingredient. A response of yes, no or unknown should be provided for every substance.

3 Provides the quantity present of the specified substance. A response should be provided for every substance in the form of a discrete quantity (for example 10 mg/g), a limit (for example not more than 10 ppm), not detected (in this case the limit of detection (LOD) and limit of quantification (LOQ) should also be stated) or Unknown.

4 Provides information on the source of the specified substance, for example lecithin derived from soy.

5 Includes celeriac, celery seed oil, celery leaf, celery seed and all substances derived from celeriac (*Apium graveolens* var. *rapaceum*) and celery (*Apium graveolens*).

6 Includes barley (*Hordeum vulgare*), einkorn (*Triticum boeoticum*, *Triticum monococcum*), emmer (*Triticum dicoccum*), kamut (*Triticum turanicum*), oats (*Avena sativa*), rye (*Secale cereale*), spelt (*Triticum spelta*), triticale (*Triticale hexaploide*), wheat (*Triticum durum*), their hybridised strains and all substances derived from cereal grains.

7 Includes chitin, chitosan, crab, crayfish, krill, lobster, prawns, shrimp, and all substances derived from fresh water and marine crustaceans.

8 Includes bovine colostrum, bovine lactoferrin, casein, caseinates, hydrolysed milk protein, lactose, lactic acid, milk, whey and all substances derived from dairy.

9 Includes egg lecithin, egg albumin, egg yolk, egg white and all substances derived from eggs.

10 Includes cod liver oil, fish gelatin, fish oil, isinglass, omega-3 marine triglycerides, omega-3 acid ethyl esters and all substances derived from freshwater fish, marine fish including sharks and diadromous fish.

11 Includes Australian sweet lupin (*Lupinus angustifolius*), Andean lupin (*Lupinus mutabilis*), white lupin (*Lupinis albus*), plants in the genus *Lupinus* and all substances derived from lupins.

12 Includes green lipped mussel oil, green lipped mussel powder, octopi, oysters, squid, squid oil, concentrated omega-3 marine triglycerides - squid and all substances derived from molluscs.

13 Includes mustard seed, mustard seed oil and all substances derived from mustard (*Brassica juncea*), (*Brassica nigra*) and (*Sinapis alba*).

14 Includes arachis oil, peanut flour and all substances derived from peanuts (*Arachis hypogaea*).

15 Pollen includes plant materials with reasonable cause to suspect pollen is present, such as flowering plant tops that are likely to include pollen, unless it is likely that the pollen has been removed.

16 Includes sesame oil, sesame seed and all substances derived from sesame (*Sesamum indicum*).

17 Includes lecithin, soy bran, soy fibre, soy isoflavones, soy oil, soy protein, soy sterols, tocopherols and all substances derived from soy (*Glycine max*).

18 Includes bisulfites, metabisulfites, potassium metabisulfite, sodium metabisulfite, sodium sulfite, sulfites and sulfur dioxide, including when present as a residue, for example in gelatin.

19 Includes almond (*Prunus dulcis*), black walnut (*Juglans nigra*), brazil (*Bertholettia excelsa*), cashew (*Anacardium occidentale*), chestnut (*Castanea sativa*), hazelnut (*Corylus avellana*), macadamia (*Macadamia ternifolia*), pecan (*Carya illinoinensis*), pistachio (*Pistacia vera*), walnut (*Juglans regia*) and all substances derived from tree nuts.

20 Includes all residual antibiotics.

21 Includes benzoic acid and its simple salts, for example calcium benzoate, sodium benzoate and potassium benzoate. More complex esters such as methyl benzoate are not included.

22 Includes ethyl hydroxybenzoate, methyl hydroxybenzoate, propyl hydroxybenzoate, sodium ethyl hydroxybenzoate, sodium methyl hydroxybenzoate and sodium propyl hydroxybenzoate. Does not include salicylates.

23 Includes substances naturally high in protein, containing phenylalanine, for example aspartame, soy (*Glycine max*) and other legumes in the family Fabaceae, spirulina (*Arthrospira platensis*, *Arthrospira maxima*) and those where the raw material processing causes concentration of phenylalanine content

24 Includes potassium ascorbate, potassium chloride, potassium bicarbonate, potassium salts and all substances containing potassium.

25 Includes sodium ascorbate, sodium chloride, sodium bicarbonate, sodium salts and all substances containing sodium.

26 Includes sorbates such as potassium sorbate and sorbic acid. Does not include polysorbates.

27 Includes fructose, galactose, glucose, honey, invert sugar, lactose, maltose, sucrose and all substances defined as monosaccharides and disaccharides.

28 Includes erythritol, glycerol, isomalt, lactitol, maltitol, mannitol, polydextrose, sorbitol, xylitol and all substances defined as sugar alcohols.

29 Includes aspartame, cyclamates, saccharin, sucralose and all other substances defined as artificial that have a functional role in sweetening.

30 Includes saccharin calcium and saccharin sodium.

31 Natural substances should meet the definition of natural, as included in ‘Therapeutic goods advertising: Ensuring 'natural' claims are not misleading’. This generally includes substances that are derived from a form found in nature (algae, animal, bacteria, fungi, plant, marine or mineral sources), applying outlined ‘minimal’ processing/manufacturing steps and without chemical identity changes.

32 Synthetic substances do not meet the definition of natural, as included in ‘Therapeutic goods advertising: Ensuring 'natural' claims are not misleading’. This generally includes synthetically modified substances, such as derivatives or salt forms of a natural substance, and synthesised substances that are nature identical.

References:

Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines
- https://www.legislation.gov.au/Search/labels%20non-prescription

TGA interpretative guidance: Medicine labels: Guidance on TGO 91 and TGO 92
- https://www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92

Therapeutic goods advertising: Ensuring 'natural' claims are not misleading
- https://www.tga.gov.au/therapeutic-goods-advertising-ensuring-natural-claims-are-not-misleading

Food Standards Australia New Zealand (FSANZ) Food Standards Code Standard 1.2.3 Information Requirements - Warning Statements, Advisory Statements and Declarations
- https://www.legislation.gov.au/Search/food%20warning%20advisory

European Union Commission Directive 76/768/EEC
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01976L0768-20120823

European Union Commission Directive 2007/68/EC
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02007L0068-20101231

US Federal Register Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)
- http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm

Document Revision
This questionnaire should be updated when any information changes or every three years.

Document Revision History		
Date	**Version**	**Changes**
16/01/2012	1	First issue.
4/08/2014	2	Introduction updated to reflect name change from CHC to CMA.
25/06/2018	3	Name Change. Revision to reflect the TGO 92 and associated guidance (Version 1.1) including changes to Risk Analysis Key. Removal of most substances not included in legislation. Division into allergens and other substances of concern.
28/10/2019	4	Removal of risk analysis key used in previous versions and improvement of presentation and usability to reflect TGO 92 and updated TGA guidance. Addition of artificial sweeteners, colours, flavours and fragrances. Introduction updated to reflect name change from ASMI to CHP Australia.