Complementary Medicines Australia *submission to the Food Standards Australia New Zealand consultation:*

Proposal P1044 - Plain English Allergen Labelling (PEAL).

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Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to comment on 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 supports the responsible and meaningful communication of the presence of allergens in foods and other consumer goods. Our members take the regulatory reporting and labelling responsibilities of allergens extremely seriously, and we work to develop methods that are consistent between industry members for the reliable measurement and recording of allergens.

The materials used in foods in Australia are frequently used in complementary medicines in Australia and in international foods and dietary supplements. While international food harmonisation is desirable where possible, it is also very important to aim for systems that harmonise between domestic regulatory agencies in the food and therapeutic sectors because these consumer goods have the same Australian audience.

In the latest 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. Any TGA review in the future will inevitably examine the need to adopt FSANZ changes that are implemented through this review. In this respect we encourage communication between FSANZ and the TGA's Labelling Review area (labellingreview@health.gov.au), because changes in food labelling widely affect the allergen labelling expectations of consumers generally.

Although foods are a separate regulatory category with some different needs and considerations, there is a close connection between the categories for both consumers and industry. Consumers exist in an environment with an increasing amount of digital messages as well as regulatory advisory statemens, including the TGA Advertising area which is currently increasing the number of mandatory statements. This increasingly busy environment emphasises the importance of creating a reliable system for consumers across different product types to benefit ease of use and better health outcomes. This is particularly true where the interface between packaged food products with permitted health claims and TGA regulated complementary medicines becomes less distinct. Products are increasingly indistinguishable by consumers. Ingredients are shared across categories. A relatively harmonised system assists suppliers of materials that regularly cross both categories to reduce overall red-tape, and reduce the possibility of administrative confusion or errors between different classification types and terminologies.

Response to Consultation questions

3.1 Clarifying terminology for fish, crustacea and mollusc declarations

1. **Do you agree there should be a separate declaration requirement in Standard 1.2.3 for molluscs?**

   CMA has an industry questionnaire to record allergen content. The questionnaire is used by ingredient suppliers and provided to product manufacturers and sponsors. Our document, which is currently in the process of being updated, allows for differentiation between crustacea and molluscs. Therefore, it appears that the differentiation on label would be feasible to implement.

   A difference of allergenicity between the two food categories appears to support a separate declaration requirement. However, we note that the TGA's *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines* only differentiates between fish and crustacea for complementary medicine labels. This creates a difference in allergen labelling in Australia. Consumers who are not aware of the difference between TGA and FSANZ regulated products are likely to develop the expectations that molluscs are declared on labels generally. We encourage harmonisation of labels where practicable and suggest there should be a discussion between the regulatory agencies if FSANZ prefer to proceed with this change.

2. **How should finfish be declared on food labels? Should Standard 1.2.3 require a declaration of 'fish' or 'finfish'?**

   For continued alignment between labels and regulatory agencies, we believe it would be less confusing for consumers if FSANZ remain consistent with TGA product labelling which is 'fish'. It will also reduce labelling complexities for industry members when there is consistency of terminology across product types.

   For those with fish allergies, the FSANZ website could have a consumer information statement to clarify and define the term for affected consumers.

3. **What amendments should be made to Section S10—2 of Schedule 10 (if any) to prevent inconsistencies between ingredient labelling requirements and allergen declaration requirements for finfish, crustacea and molluscs?**

This question relates to the naming and classification of different aquatic allergen groups. Clarity needs to be available to industry members on how to define and group, as well as consumers on how to recognise each grouping. We support the grouping method proposed by FSANZ and would not support the naming of individual species.

For your reference, this is how our proposed industry document classifies the three groups:

Fish: Includes cod liver oil, fish gelatin, fish oil, isinglass, omega-3 marine triglycerides, omega-3 acid ethyl esters and all ingredients derived from fresh water fish, marine fish including sharks and diadromous fish.

Crustacea: Includes chitin, chitosan, crab, crayfish, krill, lobster, prawns, shrimp, and all ingredients derived from fresh water and marine crustaceans.

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

3.2 Clarifying terminology for tree nut declarations

4. **Do you agree with FSANZ's preliminary view that the nine individual tree nuts associated with food allergy should be required to be specifically declared?**

We support the continued use of 'tree nuts' as the allergen statement. This harmonises with other Australian requirements.

While recognising the argument around individual nut allergies – for foods, the individual nuts are almost always individually declared within the main ingredient list. However, for those who wish to broaden the audience of their product to consumers who do not have nut cross-allergenicity, we support the ability of sponsors to provide an additional and voluntary truth in labelling statement to distinguish between individual nuts for consumers if desired. For example, contains tree nuts (brazil nuts).

3.3 Terminology issues for the declaration of wheat and cereals containing gluten

5. **Do you support the approach of clarifying the original intent of Standard 1.2.3 by requiring wheat and its hybrids to always be declared irrespective of the gluten content in a food?**

   We would not support a statement that requires naming of *individual* wheat varieties or hybrids. If a separate declaration of wheat and its hybrids is required for allergen purposes, we support a succinct label statement referring to wheat and/or its hybrids as a named group.

   For reference, our industry document currently includes a category for cereals, which is grouped for FSANZ purposes:

   Cereal grain derived ingredients: 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 ingredients derived from cereal grains.

6. **Would clarifying the intent of Standard 1.2.3, so that individual sources of gluten-containing cereals are declared provide adequate information about the presence of gluten in a food for gluten intolerant consumers?**

   Gluten intolerant consumers need to be advised of the presence of gluten, that can be tested for in products. Currently, our industry document contains the following content for gluten declaration in complementary medicines and foods where applicable:

   Gluten: Gluten, when present at ≥ 20 mg/kg.

   Gluten is a simple label declaration that is short and succinct for labelling purposes and determinable by testing methods. It is applicable across both foods and complementary medicines in Australia, therefore harmonised. It provides the required information to the consumer. Naming individual sources of gluten-containing cereals requires the separation of the cereals within industry documentation, creating a great deal of red-tape and introducing complexity that could lead to inadvertent errors. Some processed ingredients may come from variable cereal sources depending upon the availability of the source material at the time. We do not see there would be a significant consumer advantage to naming the individual cereals when the presence of gluten can be confidently identified.

7. **Are there other approaches (if any) that could be used for declaring 'cereals containing gluten', which would provide information for both wheat allergic and gluten intolerant consumers?**

   As per the above, we support a simple statement for gluten. For cereals, we support an approach that sufficiently protects consumers against allergenic problems of significant risk in the population but which allows for a grouped category (or categories) so that industry are able to maintain achievable quality control documentation processes. We support statements that are adequately informative for the population at risk but are also succinct as possible for labelling considerations.

3.4 Potential approaches for introducing PEAL

(Questions 8 – 11 for consumer group submitters).

12. **How do you make mandatory allergen declarations on your product labels? For example, listing source allergens in brackets after the ingredient they relate to within the statement of ingredients or including a 'contains' statement. Why did you choose the method you use?**

    Many members of CMA have product ranges across both foods and TGA regulated complementary medicines. Because complementary medicines do not declare the excipient ingredients it is not possible to then include it within an ingredient list, consequently these products almost always have the 'contains' statement.

    The line for consumers between 'functional' foods and complementary medicines becomes increasingly complex and therefore blurred in part due to the health claims now available for foods (many turmeric based products exist in both categories, for example). It is pragmatic to have a similar approach between differently regulated but similar products.

13. **Which of the potential approaches outlined for applying PEAL to allergen declarations (if any) would you support?**

    a) The Code requires the specific source of an allergen to be declared but the terminology is not prescribed.

    b) The Code prescribes the terms that must be used for each type of allergen declaration.

    As per the rest of this submission, we prefer the option that is most harmonised to improve outcomes. The TGA labelling order better reflects option b), where a particular term is used but allergens can be grouped under that category, for example, 'crustacea'.

3.5 Placement of allergen declarations on food labels

14. **Should the location of the allergen declaration(s) be mandated on the label (e.g. in a separate 'contains' statement or in the statement of ingredients)? If so, where on the label should this information be located?**

    We support consumer testing to determine the minimum effective method to safely relay allergen information to consumers.

    We note that the complementary medicines regulated by the TGA almost always contain a separate 'contains' statement, and that therefore this method is familiar to consumers. Succinct or grouped statements are preferred because long 'contains' statements cause label space difficulties for smaller packages.

    A particular location is not currently prescribed for TGA labelling purposes but we recognise it may be necessary for foods if consumer testing indicates so. If a particular location is prescribed, there should be a process to allow for an ability for a sponsor to apply for an exception in rare circumstances that prevent the prescribed location being possible (for example, very small packages), in which case an alternate suitable location can be approved by the regulator. This is similar in nature to the TGA's Section 14 provisions to allow an exception to a standard (such as a particular requirement within the TGA's labelling order).

Conclusion

CMA appreciates the opportunity to provide a submission to this consultation. We support the FSANZ approach to creating clearer plain English allergen labelling. We recognise that foods have unique needs that sometimes will require separate allergen labelling requirements from complementary medicines, but recognising that consumer expectations as well as industry processes are often shared, we encourage the same or similar wherever possible.

We are always available to you at technical@cmaustralia.org.au to consult with our stakeholders and provide information and answers to specific or general questions about industry implementation considerations within the complementary health (food and medicinal) product industry.