

Comments from the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources.

Due 15 January 2016

General Comments:

The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments) welcome the opportunity to comment on the issues raised in the Consultation Paper W1070 – Plain English Allergen Labelling.

Overall the departments support the need to provide sufficient information for people with allergies given the potentially severe consequences of consumer misinterpretation of allergen risk due to unclear food labels. Allergen labelling requirements should be concise and not open to interpretation, businesses and consumers should not have to rely on guidance about how to make or read allergen declarations, and consumer education should accompany any change to labelling requirements. If an allergenic component is present, the food or source of ingredient should be labelled in a consistent format using names that are easily understood by consumers.

The departments believe precautionary allergen statements need to be considered alongside “contains” statements. The Code is silent on precautionary allergen statements, such as ‘may contain nuts’. These can be important to assist food sensitive consumers to identify food allergens, but they should be limited and only used when there is a likelihood an allergen could actually be present. Many allergen sufferers report they are confused by current precautionary allergen statements on food products and the broad use of these, irrespective of true risk, may reduce consumer confidence in the information¹. This may lead consumers to take risks during food purchases, such as ignoring the statements. The use of precautionary statements should be limited to identifying allergens that are potentially present when the product is reviewed as part of a robust systemically analysis by the manufacturer or producer.

Inappropriate labelling has been shown to be an issue for allergy sufferers, with a 2010 study showing that almost half (47%) of accidental allergen exposures were attributed to inappropriate labelling². However, the recall/ complaints database at the Department of Health and Human Services suggest that errors relating to poor production methods can also be a common cause of anaphylaxis. It should also be recognised that many severe and fatal anaphylactic cases may not be directly related to packaged foods, therefore, any proposed variation to change the Food Standards Code (the Code), such as a change to food labelling requirements, would need to be accompanied by a detailed impact analysis that considers risk management options.

FSANZ should seek guidance from relevant food industry and industry bodies on the most cost effective way to achieve effective labelling to ensure no undue costs relating to labelling and Quality Assurance systems are placed on businesses. If changes are proposed to the allergen labelling requirements in the Code, FSANZ should consider giving priority to those that are currently causing the greatest concern for allergic consumers. A transition period should also be included to reduce the impact on the food industry.

¹ Zurzolo, G. et al. (2013). Perceptions of precautionary labelling among parents of children with food allergy and anaphylaxis. *Med J Aust* [online]. **198** (11): 621-623. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23919711>

² Sheth, S. et al. (2010) Role of food labels in accidental exposures in food-allergic individuals in Canada. *Annals of Allergy, Asthma & Immunology* [online]. **104**(1):60-5. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20143647>

The departments also recommend that any proposed changes to allergen labelling in the Code should be supported by a communication strategy to ensure consumers are aware of the changes that have occurred. This will be particularly important if precautionary allergen statements are included in any proposed changes. This information will assist in clarifying allergen labelling and empower consumers to select suitable foods without making risky purchases.

While this paper is related to allergen labelling, there are significant parallel issues which impact on the ability of food authorities and food manufacturers to make consistent risk management decisions regarding complaints or food recalls about alleged allergens in foods, or to ensure compliance with labelling requirements. In particular, a lack of clear data on allergen threshold levels, the lack of validated methods for identifying a specific allergen in a wide range of different food matrices and the capacity to identify low levels of allergens in packaged products make it difficult for a consistent decision to be made. This is a major problem especially if threshold levels of specific allergens are determined to be at low levels. Until validated methods have been developed for the full range of suspected allergens in different food matrices, risk management decisions from authorities or manufacturers will continue to be difficult and inconsistent.

Questions in the Consultation Paper:

Fish Questions:

1. *Are the current requirements to declare fish and fish products in Standard 1.2.3 clear on what foods/ingredients must be captured by the declaration? If not, please explain the problems associated with declaring these foods and ingredients on food labels.*

Fish (defined as finfish), crustaceans and molluscs should all be declared as specific allergens as it is known they are allergenically distinct from each other. However, the Code is currently unclear with regards to declaration of fish. The departments expect a declaration of *fish* to mean *finfish* and the Code should be clear and unambiguous each and every time there is a requirement relating to a food or class of food.

The problems caused by the broad commodity definition in Chapter 2 of the Code were first raised by Victoria in the early stages (2010) of the development of proposal P1025 - Code Revision. The review of terminology used in the Code was identified by jurisdictions and industry as a matter that needed to be progressed through ongoing Code reform.

In the case of Standard 1.2.3 the problem could be addressed by replacing the word *fish* with *finfish* under Standard 1.2.3 – 4 (1)(b) (iv) of the Code, or by taking the approach under Standard 1.4.1 – 2(2), which states:

- (2) *In this Standard and Schedule 19, a reference to a particular food is to the food as described in Schedule 22.*

However, the departments would prefer to review **all** requirements in the Code currently that use the broad definition of *fish* with a view to either expand or contract the terminology as appropriate. This would ensure clarity regarding precisely what food was subject to a requirement. The broad definition of *fish* could then be deleted from Standard 2.2.3 and replaced with an edited version of, or reference to, the definitions of foods and classes of foods in Schedule 22; i.e. *fish, molluscs and crustacea*.

2. *Do food manufacturers understand that the allergen declaration requirement for*

fish and fish products includes finfish, crustacea and molluscs?

The departments do not hold the relevant information to be able to answer this question and it is recommended FSANZ directs this question to food manufacturers/processors, and relevant peak groups representing manufacturers/processors. FSANZ should also direct this question to fish-allergic and shellfish-allergic consumers to help inform FSANZ's consideration of responses from manufacturer/ processors' groups.

3. *Is the term 'fish' being used to refer to molluscs and/or crustacea in a 'contains' statement (even if a mollusc or crustacean ingredient is specifically declared in the ingredient list)?*

The departments do not hold the relevant information to be able to answer this question. However, the Department of Health and Human Services does record complaints related to allergens and does not have any complaints on record about the way that "fish" is declared on products. It is recommended that FSANZ directs this question to food manufacturers/processors and relevant peak groups representing manufacturers/processors and to fish-allergic and shellfish-allergic consumers as part of this consultation.

Questions: Gluten – containing cereals

The Code should treat cereal allergies distinctly from coeliac disease so that both of these conditions are adequately recognised. That is, cereals that are common allergens, such as wheat, should be declared as separate allergens to gluten. Therefore, declarations should be clear and any allergen statement should be consistent with the ingredients list or marketing claims.

4. *Are manufacturers regularly declaring 'gluten containing cereals' in a 'contains' statement, with the specific cereal/s declared in the ingredient list? Is this information helpful for consumers with a cereal-specific allergy, or does it create difficulties for them in making correct food choices?*

The departments have seen products from large manufacturers which do declare the specific cereals in the ingredients list along with the words "contains gluten containing cereals" and then lists the cereals in addition to those already identified in the ingredients list. For people with coeliac disease, gluten intolerance or an allergy to the cereals listed in the table to Clause 4 of Standard 1.2.3, this information is unlikely to "create difficulties"; on the contrary it enables informed choice.

Other issues that have been identified include using an advisory statement to declare gluten and not state the specific cereal when there are multiple cereals listed in the ingredients list. The departments recommend that FSANZ directs these questions to food manufacturers and consumers with coeliac disease or gluten intolerance.

5. *Are there instances where food labels omit the mandatory declaration for 'cereals containing gluten' because the cereal ingredients happen to contain no detectable gluten?*

Whilst data is limited regarding the labelling practices of gluten related claims or cereal declaration there is anecdotal evidence via complaints that some manufacturers may be confused or unclear of the declaration requirements. There have been incidents where manufacturers have declared a gluten free statement on food products when the cereal or wheat is declared in the ingredients list or somewhere else on the same label. This practice has the potential to mislead consumers or in some cases the consumer could

misinterpret the information.

6. *Are there instances where manufacturers are declaring the presence of 'gluten' (not 'gluten-containing cereals') along with a declaration of the specific cereal elsewhere on the label? If so, then can you comment on why this labelling practice is occurring, and whether it is/is not useful information for consumers with a cereal allergy?*

Whilst the departments do not directly have evidence, the Department of Health and Human Services has seen the practice on food products. Providing it is done consistently and clearly, it provides useful information for those with coeliac disease or gluten intolerance, and for those with allergies to cereals containing gluten. However, we do not have any evidence of how this practice of labelling affects consumers with allergies not related to gluten.

7. *Are you aware of food products that declare the name of a cereal on their labels but also declare that they are 'gluten free'? Would such information be unclear to consumers with a cereal-specific allergy, and if so, how?*

The Department of Health and Human Services has received complaints pertaining to the presence of oats in a product (usually porridge) which also claims to be gluten free. On other occasions, gluten free claims on products that declare a cereal such as wheat in the ingredients list to comply with the Code, have led to analysis which has revealed no detectable gluten. This labelling can be confusing for consumers, and often results in food regulators having to go to the expense of analysis, however they are unlikely to present a health risk.

Questions: Tree nuts

8. *Do food manufacturers understand which tree nuts must be declared on food labels as a means of meeting the tree nut declaration requirements in Standard 1.2.3?*

All common tree nut allergens should be specifically included in the allergen declaration requirements. We believe the Code does not clearly define "tree nuts" which may potentially cause manufacturers to misinterpret the declaration requirements. However, our complaints database system does not highlight this as being a systematic failure in the legislation.

We recognise however that having to state the specific tree nut might be difficult to manage and enforce because manufacturers or authorities might have difficulties in identifying a particular tree nut or in some cases be unable to analyse for a particular tree nut. FSANZ should direct this part of the consultation to food manufacturers, industry bodies and potentially food laboratories.

9. *Which tree nuts are clinically significant for individuals with a tree nut allergy? Has there been any clinical evidence since 2010 to further clarify the types of tree nuts implicated in tree nut allergies in Australia and New Zealand?*

The departments do not hold any further relevant information. It is recommended that FSANZ direct this question to clinicians and allergen specialists as part of this consultation.

10. *Are manufacturers declaring the presence of tree nuts using the broader term 'tree nuts' in addition to the declaration of the specific tree nuts elsewhere on the label (e.g. a 'contains tree nuts/nuts' statement, with the specific nuts listed in the ingredient list)?*

Would such an arrangement on a food label assist or hinder tree nut-sensitive consumers in making a correct food choice?

The departments do not hold the relevant information to be able to answer this question and recommend that FSANZ direct the first question to food manufacturers, and the second to nut-allergic consumers as part of this consultation. However, if there was a consistent protocol for declaring nuts (and consumers were educated about this) that required a generic “contains nuts” statement with specific nuts identified in the ingredients list, the departments believe this would be useful for consumers. Any proposed changes should undergo consumer testing with both allergic and non-allergic consumers. While consumers with allergies may be well educated to navigate the information on food labels, other consumers who may not be educated may still be required at times to buy and prepare food for those with allergies. Allergen labelling needs to be easily understood by all consumers.

Precautionary allergen statements

Research shows that the majority of precautionary statements on food and drink items are for tree nuts^{3,4} and that only a minority of products carrying precautionary labels for tree nuts actually include specific tree nuts in the ingredients list¹.

Although cross-contamination is a common means by which allergic consumers experience accidental exposure to an allergen, research shows that the likelihood of cross-contamination of products carrying precautionary statements is minimal. A 2011 study revealed that most products containing precautionary statements (including for tree nuts) in the Australian market contained no detectable levels of allergen irrespective of whether the allergen in question was listed in a precautionary statement⁵.

The effect of consuming food allergens by food sensitive individuals is variable, as evidence shows that allergen threshold levels below which reactions are not provoked in allergic individuals do exist⁶. There is a possibility that food manufacturers could include precautionary statements based on mean consumer threshold levels of some allergens, however this process could be cost prohibitive for businesses.

Precautionary labels and specific ingredient listing of tree nuts may offer a variable level of assistance/hindrance to food sensitive consumers, as some studies reveal that people with food sensitivities are increasingly ignoring advisory statements on food labels^{7,8,9,10}.

³ Zurzolo, G. et al. (2013) Precautionary allergen labelling following new labelling practice in Australia. *Journal of Paediatrics and Child Health* [online]. **49**(4): 306–310. Available from: <http://onlinelibrary.wiley.com/doi/10.1111/jpc.12138/full>

⁴ Koplin, J. Osborne, J. and Allen, J. (2010) Prevalence of allergen avoidance advisory statements on packaged processed foods in a supermarket. *Med. J. Aust* [online]. **193**: 426–427. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20919979>

⁵ Zurzolo, G. et al. (2013) Foods with precautionary allergen labeling in Australia rarely contain detectable allergen. *J Allergy Clin Immunol Pract* [online]. **1**(4): 401–3. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24565547>

⁶ Taylor, S. L. et al. (2002) Factors affecting the determination of threshold doses for allergenic foods: How much is too much? *Journal of Allergy and Clinical Immunology* [online]. **109**(1):24–30. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/11799361>

⁷ Noimark, L. Gardner, J. and Warner, J. O. (2009) Parents' attitudes when purchasing products for children with nut allergy: a UK perspective. *Pediatr. Allergy Immunol* [online]. **20**: 500–504. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19538437>

⁸ Barnett, J. Muncer, K. and Leftwich, J. et al. (2011) Using ‘may contain’ labelling to inform food choice: a qualitative study of nut allergic consumers. *BMC Public Health* [online] **11**: 734–743. Available from: <http://bmcpublikealth.biomedcentral.com/articles/10.1186/1471-2458-11-734>

⁹ Zurzolo, G. et al. (2014) *The Role of Precautionary Labelling for Food Allergens and the Care of Children with Food Allergies*. Victoria University, St Albans campus, Victoria, Australia. Available from: <http://vuir.vu.edu.au/25921/>

¹⁰ Hefle, S. L. et al. (2007) Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. *J. Allergy Clin. Immunol* [online]. **120**: 171–176. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/17544097>

while large numbers of allergen-sensitive consumers continue to avoid all foods carrying allergen advisory statements^{6,8}, sometimes on advice from medical professionals^{1,7}.

Given that the risk of cross-contamination of food allergens (in products containing precautionary statements) is low, the threshold tolerance of consuming food allergens by food sensitive individuals is variable, and the level of assistance/hindrance of precautionary statements varies between consumers, it is recommended that food manufacturers should:

- a) retain precautionary labelling for tree nuts, when tree nuts are included as an ingredient, or there is a potential risk of cross-contamination by tree nuts; and
- b) specify the types of tree nut/s in the ingredient list; and
- c) specify the types of tree nuts which may be included due to cross-contamination.

Questions: issues associated with terminology

11. Is the use of unfamiliar or unrecognisable terminology for allergen declarations common practice, and/or creating difficulties with the identification of allergens in foods?

The Department of Health and Human Services does not have data on the prevalence of the use of 'unfamiliar terminology' to declare the presence of food allergens. However, it could be a potential problem and the department does on occasion receive complaints. For example, one incident indicated a milk-based ingredient was listed as "WPI" instead of "whey protein isolate" in a formulated supplementary sports food, which had the potential to mislead consumers. The recent national undeclared milk in coconut milk products issue highlighted the declaration of milk as "sodium caseinate" in a small number of products; however there was no evidence to suggest that milk-allergic consumers had been consuming this. It is not known if this reflects a low incidence of this occurring, or if this reflects an informed allergic public.

It is recommended that FSANZ conducts a survey of allergic consumers via groups through relevant organisations such as Allergy & Anaphylaxis Australia to find out more about their understanding and consumption practices.

However, whilst Standard 1.2.3 mandates what needs to be declared, it does not mandate how, which has resulted in differing views between Australian and New Zealand food regulators. This is not ideal and could lead to difficulty in convincing a food company that a recall is required. This is something that should be reviewed, particularly in light of the outcomes of the national meetings which took place late last year as a result of the coconut milk products issue. The allergen labelling requirement in Standard 1.2.3 should include a requirement to use a common name of the allergen in the declaration. Consultation with relevant allergy groups would indicate the preferred allergen names for labelling purposes.

12. Do 'contains' statements assist with identifying the presence of an allergen especially in the context of less familiar or less recognisable terminology being used in allergen declarations?

The departments believe that 'contains' statements do assist with identifying the presence of an allergen. However, if the Code is amended to clarify **how** allergens should be declared, this could remove the confusion and need for "contains" statements. Any labelling system should highlight the allergen, such as bold type, or in some cases an allergen statement that highlights all allergens present in the food.

In consideration of the challenges faced by consumers and medical professionals to identify allergens using current terminology, as well as the wide variation of consumer interpretation of precautionary statements, it is recommended that FSANZ sets requirements for improved terminology of advisory labels as follows:

- a) regulated wording of precautionary allergen statements, based on plain-English terminology
- b) precautionary allergen statements to be applied on all products that include a food allergen in the ingredients, or if there is a potential risk of cross-contamination by a food allergen
- c) food manufacturers to use regulated allergen assessment methods to test for contamination by food allergens

Currently in the Australian and overseas markets, there is a wide range of allergen declarations with inconsistent terminology being used on foods and drink items to alert consumers to the potential risk of allergens¹¹. Studies into consumer perceptions and understanding of allergen declarations reveal that food sensitive consumers in Australia and overseas were unable to identify common allergenic food ingredients¹², did not understand this type of labelling⁷, and believed that words in some ingredient lists were too technical or hard to understand and this was a serious obstacle for managing an allergy¹³. The hindrance of inappropriate labelling for food sensitive individuals is highlighted in a 2010 study, with almost half (47%) of accidental allergen exposures being attributed to inappropriate labelling¹⁴, while a 2013 study of anaphylactic youth, discovered that almost half (43%) of the participants desired more information on food labelling¹⁵. This evidence shows a clear need for improved, plain-English labelling requirements to assist food sensitive consumers in identifying allergens.

The Royal Children's Hospital in Melbourne publicly disseminates patient information sheets that highlight the difficulty in interpreting precautionary allergen statements. Specifically, the hospital advises that *the wording of these statements makes it very difficult to determine your level of risk and a product that does not contain the statement may be no safer than a product that does*⁷. There have been different practices reported about how medical professionals are advising patients in relation to precautionary labels, as some services are recommending complete avoidance of all foods with precautionary labels, whereas other services support continued consumption of foods already eaten safely even if precautionary labels are present¹.

Mandatory allergen declarations have been identified as an important strategy for allergen management¹⁶, yet consumers' interpretation and response to 'may contain' statements are based not only on the detail of the labelling, but also external factors such as the nature of the product, the perceived trustworthiness of the producer and on the previous experience of the nut allergic individual⁶. The wording used in 'may contain' statements also influences people's decision to buy these products, as consumers have been reported to associate the degree of risk with the wording on precautionary labels. For example, more patients were avoiding products labelled as 'may contain nuts'

¹¹ Allergen Bureau. (2009) *VITAL Q & A for Consumers*. Available from: <http://www.allergenbureau.net/vital/vital-qaas>

¹² Preeti, Joshi. (2002) Interpretation of commercial food ingredient labels by parents of food-allergic children. *Journal of Allergy and Clinical Immunology* [online]. **109** (6): 1019–1021. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12063534>

¹³ Vierk, K. A. et al. (2007) Prevalence of self-reported food allergy in American adults and use of food labels. *J. Allergy Clin. Immunol* [online]. **119**: 1504–1510. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/17451802>

¹⁴ Sheth, S. et al. (2010) Role of food labels in accidental exposures in food-allergic individuals in Canada. *Annals of Allergy, Asthma & Immunology* [online]. **104**(1): 60–5. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20143647>

¹⁵ Worth, A. et al. (2013) Living with severe allergy: an Anaphylaxis Campaign national survey of young people. *Clinical and Translational Allergy* [online]. **3**(1):2. Available from: <http://www.ctajournal.com/content/3/1/2>

¹⁶ Ju, S. Park, J. et al. (2015) Attitudes and preferences of consumers toward food allergy labeling practices by diagnosis of food allergies. *Nutr Res Pract* [online]. **9**(5): 517–522. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4575965/>

compared with 'may contain traces of nuts'^{5,17}.

The confusion within the community and with medical professionals about how to identify allergens and interpret precautionary statements strongly supports the need for improved labelling with clear, plain-English terminology. Given the widespread confusion about allergen labelling, any changes need to be accompanied by an education strategy targeted at both consumers and medical professionals.

¹⁷ Zurzolo, G. et al. (2013). Perceptions of precautionary labelling among parents of children with food allergy and anaphylaxis. *Med J Aust* [online]. **198** (11): 621-623. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23919711>