

29 November 2019
[103–19]

Second Call for Submissions – Proposal P1044

Plain English Allergen Labelling

FSANZ has assessed a proposal requiring mandatory food allergen declarations to be made clearer and in plain English, and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 27 February 2020

Executive summary

Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations of the *Australia New Zealand Food Standards Code* (the Code) requires mandatory declaration of the presence of certain foods or substances in food which can cause severe allergic and other reactions (for simplicity, these substances will be collectively referred to as ‘allergens’). However, the Standard does not mandate how these declarations should be made or the terminology to use when making allergen declarations.

Previous reviews by Food Standards Australia New Zealand (FSANZ) have identified issues in the clarity and consistency of allergen declarations. Inconsistent and unclear allergen declarations can make it more difficult for food-allergic consumers (and their caregivers) to make safe food choices. At the worst extreme, a consumer is unable to identify the presence of an allergen in a food, resulting in potentially fatal reactions such as anaphylaxis. Other consequences include the unnecessary exclusion of foods due to the uncertainty about the presence of an allergen, greater effort to search for allergen information, and a lack of confidence in allergen labelling.

The lack of explicit requirements in the Code on how to declare allergens also creates uncertainty for industry in complying with these requirements, and for regulators in enforcing the Code.

The purpose of this proposal therefore is to consider variations to the Code to make allergen information clearer and more consistent for consumers particularly through the use of plain English allergen labelling (PEAL).

In 2018, FSANZ released for public consultation a First Call for Submissions on Proposal P1044. A summary of submissions received is provided in Supporting Document 1.

Since the First Call for Submissions, FSANZ has done further risk assessment work to inform possible changes to allergen declaration requirements, including:

- a literature review of consumer awareness, understanding, attitudes and behaviour in relation to food allergen labelling (Supporting Document 2)
- an updated safety risk assessment (Supporting Document 3).

Based on submitter comments and the findings of the risk assessment, FSANZ has considered the following three regulatory options:

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.

From assessing the costs and benefits of each option (Supporting Document 4), FSANZ’s assessment is that on balance, Option 3 provides the greatest net benefit and is therefore the preferred option.

FSANZ is therefore proposing to amend the Code to require the following:

- 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
- the use of mandatory specified terms of the allergen source when declaring allergens.
- 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.

The above amendments have been prepared into draft variations to the Code as provided at Attachment A

The draft variation will take effect on the date of gazettal and includes transitional arrangements. Details of these amendments are provided in the draft Explanatory Statement at Attachment B of this draft report.

This proposal is being assessed as a Major Procedure involving two rounds of public consultation. Information received in response to this second consultation will inform FSANZ's decision to approve, reject or amend the draft variation under subsection 63(1) of the *Food Standards Australia New Zealand Act 1991* (Cth).

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Supporting documents

The following documents informed the assessment of this proposal and are available on the FSANZ website:

- Supporting Document 1 – Summary of submissions
- Supporting Document 2 – Consumer behaviour literature review
- Supporting Document 3 – Safety assessment
- Supporting Document 4 – Consideration of costs and benefits

1 Introduction

1.1 Reasons for preparing this proposal

Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations of the *Australia New Zealand Food Standards Code* (the Code) requires mandatory declaration of the presence of certain foods or substances in food which can cause severe allergic and other reactions (for simplicity, these substances will be collectively referred to as ‘allergens’). However, the Standard does not mandate how these declarations should be made or the terminology to use when making allergen declarations.

In two previous reviews, FSANZ identified issues which can lead to unclear allergen declarations. The first review *W3 – Review of the regulatory management of food allergens* (the W3 Review) (FSANZ 2010) identified a lack of clarity with the requirements to declare fish, crustacea and molluscs; tree nuts; and cereals containing gluten. FSANZ conducted a second review *W1070 – Plain English Allergen Labelling* (W1070 review) in 2015 to explore how terminology was being used to declare allergens (FSANZ 2016a). The W1070 Review concluded there is no consistency in how allergens are declared, due to variability in the terminology used across different foods, making identification of allergenic ingredients unclear.

The result of unclear and inconsistent allergen declarations is that labelling information is difficult for food-allergic consumers (and their caregivers) to use in making safe food choices. At the worst extreme, a consumer is unable to identify the presence of an allergen in a food, resulting in potentially fatal reactions such as anaphylaxis. Other consequences include excluding foods unnecessarily due to the uncertainty about the presence of an allergen, greater effort to search for allergen information, and a lack of confidence in allergen labelling.

The lack of explicit requirements in the Code on how to declare allergens also creates uncertainty for industry in complying with these requirements, and for regulators in enforcing the Code.

Voluntary guidance exists for industry on how best to declare allergens, which may address some of the clarity and inconsistency issues for consumers. However, although this guidance has been in place for over a decade, food producers and/or importers do not always follow or apply it in a consistent manner.

Therefore, the purpose of this proposal is to consider variations to the Code that may be necessary to address the above risks to food-allergic consumers. In particular, FSANZ is considering variations to the Code to make allergen information clearer and more consistent for consumers through the use of plain English allergen labelling (PEAL) and requirements for the presentation of this information.

1.2 Procedure for this Proposal

This proposal is being assessed as a Major Procedure involving two rounds of public consultation. In 2018, FSANZ released for public consultation a First Call for Submissions¹. A total of 42 submissions were received and are summarised in Supporting Document 1. This report takes into account these submissions and details further work undertaken by FSANZ since that time, including:

¹ <http://www.foodstandards.gov.au/code/proposals/Pages/P1044PlainEnglishAllergenLabelling.aspx>.

- a review of the literature on consumer understanding, attitudes and behaviour in relation to food allergen labelling (Supporting Document 2)
- a revised safety assessment (Supporting Document 3)
- the development of regulatory options and consideration of the costs and benefits (Supporting Document 4).

This Second Call for Submissions includes a draft variation containing amendments to the Code at Attachment A. Following the second round of public comment, the FSANZ Board will consider whether to approve, reject or amend the draft variation under subsection 63(1) of the *Food Standards Australia New Zealand Act 1991* (Cth) (the FSANZ Act). If the draft variation is approved, it will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) for their consideration.

1.3 Scope

Proposal P1044 is considering changes to allergen declaration requirements in the Code for all food for sale, including food not required to bear a label.

In the First Call for Submissions, FSANZ excluded the format of allergen declarations (e.g. use of bold font) from the scope of this proposal. However, on the basis of submitter comments and the findings of the consumer behaviour literature review (see Section 4.1 below), FSANZ has included formatting issues in its assessment and the draft variation.

Proposal P1044 will not be considering the introduction of declaration requirements for new allergens into the Code or exemptions from declaring existing allergens.

Issues relating to the unintended presence of food allergens will not be considered, such as the use of precautionary allergen labelling (PAL) statements, e.g. 'May be present: allergen x, allergen y...'. This is because the issues involved with PAL are substantially different to those relating to mandatory allergen declarations.

2 Background

2.1 Relevant standards

2.1.1 Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations

Section 1.2.3—4 of Standard 1.2.3 lists certain foods or substances which must be declared when present in food as: an ingredient or as an ingredient of a compound ingredient; a substance used as a food additive (or an ingredient or component of such a substance); or a substance or food used as a processing aid (or an ingredient or component of such a substance or food). Although a declaration of these foods or substances is required, there is no requirement (besides those for general legibility of labelling information) about where or how declarations are to be made on a food.

The foods and substances requiring mandatory declaration are: added sulphites (when present in amounts of 10 mg/kg or more), cereals containing gluten, crustacea, egg, fish, milk, peanuts, soybeans, sesame seeds, tree nuts, and lupin. Subsection 1.2.3—4 also includes some exemptions from the declaration requirements, where FSANZ has assessed certain ingredients as safe for allergic individuals (e.g. in relation to milk, alcohol distilled from whey).

2.1.2 Standard 1.2.1 – Requirements to have labels or otherwise provide information

Where a food for sale must bear a label under section 1.2.1—6 of *Standard 1.2.1 – Requirements to have labels or otherwise provide information*, declarations of the presence of allergens must be placed on the label of the food.

Where a food for sale does not have to bear a label under section 1.2.1—6 (e.g. food for sale in an assisted service display cabinet), Standard 1.2.1 requires the declaration of the presence of allergens to either:

- accompany the food or be displayed in connection with the display of food where the food is sold from a vending machine (subsection 1.2.1—9((2) and paragraph 1.2.1—9((3)(d)), or
- else, either be displayed in connection with the display of the food or provided to the purchaser on request (subsection 1.2.1—9(6) and paragraph 1.2.1—9(7)(b)).

Allergen information must be declared on the label of packaged food sold to caterers (section 1.2.1—12 and paragraph 1.2.1—15(c)). If the food sold to caterers is not required to bear a label, then allergen declarations must be provided to the caterer with the food. Subsection 1.2.1—16 also permits a statement of ingredients to be provided either on a label or in documentation for the food.

Division 4 of Standard 1.2.1 requires that for all other foods, information is to be provided to enable a purchaser to comply with any compositional, labelling or declaration requirement of the Code. This would include information that enables the declaration of allergens.

2.1.3 Standard 1.2.4 – statement of ingredients

Standard 1.2.4 – Information requirements – statement of ingredients sets out the requirements for the declaration of ingredients in a statement of ingredients. Ingredients must be declared using either a name by which the ingredient is commonly known, a name describing the true nature of the ingredient, or a generic name for the ingredient listed in section S10—2 of *Schedule 10 – Generic names of ingredients and conditions for their use*.

The table to section S10—2 contains a list of permitted generic names along with conditions for the use of certain generic names. Some of these conditions provide the terminology to be used when certain generic names are used for ingredients that potentially contain allergens. These generic names and their conditions are:

- ‘cereals’ and ‘starch’—the specific name of the cereal must be listed if the cereal or source of the starch respectively, is wheat, rye, barley, oats or spelt or a hybridised strain of one of these cereals
- ‘nuts’—the specific name of the nut must be declared
- ‘fish’—if the food is crustacea, the specific name of the crustacea must be declared
- ‘fats’ or ‘oils’—the specific source name must be declared if the source of the oil is lupin, peanut, sesame, or soybean (unless the soybean oil has been degummed, neutralised, bleached or deodorised).

Section S10—2 also includes permitted generic names for ‘milk protein’, ‘milk solids’, and ‘cheese’, however none of these generic names have conditions relevant to allergen declarations.

2.2 Voluntary food industry guidelines

The Australian Food & Grocery Council (AFGC) and the Allergen Bureau have developed a *Food Industry Guide to Allergen Management and Labelling* (Food Industry Guide), which has also been adopted by the New Zealand Food & Grocery Council for use by the New Zealand food industry. The Food Industry Guide was first released in 2007 to assist the food industry in making allergen declarations, and includes recommendations relating to their format, terminology and location. The Food Industry Guide was recently revised and updated (AFGC and Allergen Bureau 2019).

2.3 International and overseas regulations

FSANZ has considered the international and overseas standards and regulations of Codex Alimentarius, the European Union, Canada and the United States of America for allergen labelling. FSANZ's consideration of these requirements is included as part of the risk management at Section 5 of this report. These international and overseas regulations are:

- CODEX STAN 1-1985 General Standard for the Labelling of Prepackaged Foods (the Codex Standard)
- European Union Regulation 1169/2011 on the provision of food information to consumers
- Canadian Food and Drug Regulations (C.R.C., c. 870)
- United States Code Title 21 Food and Drugs, Chapter 9 – Federal Food, Drug and Cosmetic Act, which incorporates the requirements in the Food Allergen Labelling and Consumer Protection Act 2004 (US FALCPA).

3 Stakeholder views

A First Call for Submissions was released for public comment from 1 March to 10 May 2018. In total, 42 submissions were received. Details on the submissions can be found in Supporting Document 1, along with a summary of the comments made. An overview of the main issues raised in the submissions is provided below.

3.1 Consistency

Many submitters highlighted consistency in how allergens are declared is important for consumers to identify the presence of allergens and make safe food choices. That is, the information should be presented in a consistent manner, use consistent terminology, and be applied to the same labelling elements (e.g. statement of ingredients, use of allergen summary statement²) across all foods.

3.2 Terminology

In general, submitters supported the introduction of PEAL, recognising some change to the Code is required; i.e. the status quo was seen as untenable. Most submitters supported mandatory plain English terms to be used for each allergen declaration. In support of providing flexibility, several industry submitters preferred a generic requirement to use plain English for declarations, which would not mandate the specific terms to be used. When commenting on what constitutes the most meaningful terminology for allergen declarations, all submitters indicated this needed to be a reference to the source allergen. However, views regarding the best terms to use when referring to the source allergen varied. Some submitters considered 'gluten' or 'gluten containing cereals' to be the source for gluten

² A statement that summarises the allergens present in the food, and usually begins with the word 'Contains'.

intolerance/Coeliac disease as well as or instead of the individual cereal, and milk-allergic individuals refer to their allergy as being to 'dairy' rather than 'milk'.

3.3 Location

Many submitters supported requiring a consistent location for the display of allergen declarations on labels. Comments were split on whether this location should be the statement of ingredients or an allergen summary statement, although there was a preference for allergens to be declared in an allergen summary statement as a minimum. When commenting on the use of an allergen summary statement, some submitters mentioned this statement should also be placed in close proximity to, and preferably below, the statement of ingredients.

3.4 Format

In respect to the presentation of allergen declarations, a number of submitters requested FSANZ reconsider the exclusion of formatting from the scope of Proposal P1044. There were calls for boldening of allergen declarations in the statement of ingredients, along with the boldening of an allergen summary statement. There were also comments that formatting requirements could be based on the Food Industry Guide.

3.5 Specific allergens

There was strong support for having declaration requirements in the Code for wheat (separate from cereals containing gluten) and molluscs (separate from fish). Submitters stated separate declarations would allow wheat-allergic and mollusc-allergic consumers to more effectively identify foods that were not suitable for them. Submitters also noted there was a substantial body of scientific evidence in support of separate wheat and mollusc declarations.

In respect to 'cereals containing gluten', there was strong support from submitters for the term 'gluten' to be declared, given the importance and recognition of this term by individuals with Coeliac disease or Dermatitis herpetiformis. Comments varied on how a requirement to declare 'gluten' could be achieved, with a slight preference for mandating 'gluten' in an allergen summary statement combined with a declaration of the specific cereal name in the statement of ingredients.

There was also support for a requirement to declare individual tree nuts separately. However, a number of industry submitters commented that the collective term 'tree nuts' should be permitted in the allergen summary statement, along with individual tree nuts declared in the statement of ingredients. In contrast, several allergy support groups commented the term 'tree nuts' should not be used on food labels.

4 Risk assessment

To inform risk management considerations for possible changes to allergen declaration requirements, including the introduction of PEAL, FSANZ has:

- undertaken a literature review of consumer awareness, understanding, attitudes and behaviour in relation to food allergen labelling (Supporting Document 2)
- provided an updated safety risk assessment (Supporting Document 3).

The sections below provide a summary of the findings of the consumer behaviour literature review and safety risk assessment.

4.1 Consumer behaviour literature review

FSANZ prepared a literature review on consumers' awareness, attitudes, understanding and behaviours related to allergen labelling. The full literature review, including the methodology used, is available at Supporting Document 2.

The literature review examines the evidence relating to allergen declarations. This includes aspects of these declarations such as boldening of allergens in a statement of ingredients. For the purpose of the literature review, food-allergic consumers includes people with self- and medically-diagnosed food allergy or intolerance.

4.1.1 Consistency

To determine the safety of their food, food allergic consumers (as well as those purchasing food for them) appeared to rely heavily on the statement of ingredients of commercial food products. Consumers in Australia, New Zealand and internationally have reported several obstacles to accurate label reading and interpretation. Strong and consistent themes in consumer preferences for the delivery of allergen information were identified. Consumers appeared to desire allergen information to be presented in a clear, consistent manner, so as to enable quick identification and comprehension of the information they require to make informed and safe food choices.

4.1.2 Location

To reduce the time required to identify allergens, consumers in four international studies expressed a desire for a brief allergen summary statement. This would provide a short summary of any allergens present in the product separately from (but in close proximity to) the statement of ingredients, either just above or adjacent to it. Current voluntary allergen summary statements are often located below the statement of ingredients, with consumers reporting frequently missing them when placed in this location. Research suggests repetition of consistent allergen information in different locations on a label aids in identification and comprehension. Fifteen studies found location of allergen information played a significant role in ease of identification.

4.1.3 Terminology

Twenty eight studies identified terminology issues as an impediment to allergen identification and comprehension of allergen information. In particular, complex (technical) terminology used for certain allergens, such as 'casein' for milk or 'ovalbumin' for egg, may not be generally recognised by consumers. This may be especially true for children, those shopping for food allergic consumers, or food allergic consumers recently diagnosed or from culturally and linguistically diverse (CALD) backgrounds. Further, the use of vague or ambiguous terms such as 'nut', without reference to the specific nut may cause food allergic consumers to unnecessarily restrict certain foods from their diet, thereby limiting dietary variety.

Throughout the literature, consumers in English-speaking countries expressed a preference for the adoption of plain English language to be consistently used when listing mandatory allergens. The use of the same, simple and specific terms across different products and in different locations on the package of the same product (e.g. both in the statement of ingredients and an allergen summary statement) is desired, and has been shown to enhance allergen identification and result in appropriate precautionary action (i.e., not purchasing/consuming the unsafe food).

4.1.4 Formatting

Twenty studies identified formatting issues such as small text in the statement of ingredients, the use of an extensive statement of ingredients, poor colour contrast between the background and font colour, shiny packaging and inconsistent location of allergen information as potential barriers to allergen identification and comprehension of allergen information. Such labelling issues may cause frustration in consumers, as the result often means increased time spent examining product labels and/or contacting the manufacturer (or some other form of research). Consumers are also unaware of the current voluntary nature of some allergen labelling elements (e.g. the emboldening of allergens, the presence of an allergen summary statement) and if these elements are not present, they may incorrectly assume the food is free from allergens and is safe to consume.

Consumers reported frustration at how ingredients of concern are often buried in an extensive statement of ingredients, making their identification laborious and difficult. For this reason, consumers expressed a preference for the font of allergens to be altered to stand out from other listed ingredients. This included a preference for emboldening of text and the use of a different 'warning' colour (e.g. red).

As with the allergens listed in the statement of ingredients, consumers expressed a desire for the allergen summary statement to be emboldened, and ideally placed within a textbox. This is seen to grab attention more rapidly than if the information was presented solely as text, and is consistent with current studies examining effective warning labels and the use of borders. Some consumers also expressed a desire for the percentage amount of each allergen to be placed in brackets after the allergen is listed in the statement of ingredients to enable them to assess the risk e.g. 'almonds (10%)'.

Thirteen of the studies included in the review found a consumer preference for the introduction of a universal allergen symbol labelling system. Ten studies found food allergic consumers believed symbols would aid in allergen identification. Three studies found symbols actually increased the accuracy and speed with which food allergic consumers and/or those shopping for them were able to identify allergens. However, consumers acknowledged several obstacles surrounding the introduction of a symbol-based system, noting logistical difficulties such as managing the number of mandatory allergens to be declared, how to represent less well-known allergens (e.g. lupin), and whether the presence of a symbol indicates the presence or absence of an allergen.

4.1.5 Cereals containing gluten

The review examined consumer preferences for terminology concerning cereals containing gluten, as this issue emerged as a separate topic in stakeholder submissions during the 2016 W1070 – Plain English Allergen Labelling project. There was limited literature on this topic, however the four studies identified as being suitable for inclusion in the review suggested gluten-intolerant consumers, individuals with Coeliac disease / Dermatitis herpetiformis, or those purchasing for them appeared to rely on the inclusion of the word 'gluten' somewhere on the label. This is in addition to the source of the cereal still being identified in the statement of ingredients, as the consumer desire for specificity extends to gluten containing cereals. Specifying the allergen source conveys to consumers that the allergen content of the food product has been assessed and considered by the manufacturer.

The inclusion of the word 'gluten' seems to be less necessary for individuals with Coeliac disease and/or with Dermatitis herpetiformis, who are more experienced food label readers and appear more adept and comfortable with identifying whether gluten is present based solely on examination of the statement of ingredients. Nevertheless, these consumers still

express frustration at increased time spent shopping due to label reading, and therefore the inclusion of the word 'gluten', ideally on the front of the pack, may still offer some benefit.

The search did not find any research examining consumers with specific cereal allergies (e.g. wheat). One could reasonably expect that such individuals would be in a similar situation to those allergic to specific nuts (for whom not specifying the type of nut would result in unnecessary restriction of certain foods).

4.2 Safety risk assessment

In the First Call for Submissions, FSANZ included an assessment of safety issues relating to food allergy associated with fish, crustacea and molluscs; tree nuts; and cereals including advice from FSANZ's Food Allergy and Intolerance Scientific Advisory Group (FAISAG)³.

Details of the safety risk assessment, which has been updated following the First Call for Submissions, can be found in Supporting Document 3. A summary of the findings of this assessment is provided below.

Three mollusc classes (bivalves, gastropods and cephalopods) have been confirmed in cases of food allergy. Although there are few published data specifically regarding the prevalence of mollusc allergy in Australia and New Zealand, the FAISAG advised FSANZ that mollusc allergy is of clinical significance in the two countries.

There is some evidence of cross-reactivity or co-sensitisation between molluscs and crustacea based on serological testing, self-reporting and clinically diagnosed allergy. However based on available data the extent of clinically relevant cross-reactivity is likely to be relatively low.

FAISAG previously advised FSANZ that nine tree nuts are important allergens: almonds, Brazil nuts, cashews, hazelnuts, macadamias, pecans, pine nuts, pistachios and walnuts. Clinically defined food allergy, clinical cases or positive responses to oral food challenges in Australia and/or New Zealand have been reported for all of these tree nuts. Clinical reactions to more than one tree nut have also been reported in up to one third of tree nut allergic individuals, and the incidence of reactions to multiple nuts may be even higher based on the advice and assessment of available literature by FAISAG.

There is little evidence relating to the allergenicity of less commonly consumed tree nuts, and FAISAG considered the available information did not indicate a need to amend its previous advice on tree nuts of clinical significance in Australia and New Zealand. However given these nuts are currently unlikely to be widely used in processed foods and may only be consumed by small numbers of individuals, there is some uncertainty about whether these tree nuts would be likely to be significant allergens under conditions of more widespread use.

Food allergy to wheat, barley, rye and oats is IgE-mediated and distinct from gluten intolerance. Several studies have reported positive allergic responses to food challenges with barley, rye and/or oats in children or adults, and in most of these studies individuals were confirmed as not having coexisting coeliac disease. Gluten and non-gluten proteins have been identified as allergens in barley. There is little data on the prevalence of allergy to these cereals in Australia and New Zealand. The FAISAG advised FSANZ they do see cases of rye and barley allergy, but these are not common. Oat allergy is very rare and problems are usually due to cross-contamination with other cereals.

³ FAISAG provides expert advice to FSANZ on a range of matters related to food allergy and intolerance to help assess and manage risk to allergic consumers. Information on the membership of the FAISAG is available at: <http://www.foodstandards.gov.au/science/expertise/Pages/Food-Allergy-and-Intolerance-Scientific-Advisory-Group.aspx>.

5 Risk management

5.1 Principles

FSANZ has established a risk management framework based on three principles (see Table 1 below) to guide consideration of the risk management approach as discussed in the following sections. The first principle reflects FSANZ's priority objective of addressing the risk to public health and safety in the context of Australia and New Zealand. The second and third principles reflect the findings of the consumer behaviour literature review, which found consistency and clarity in allergen information are important for consumers in using allergen information. These principles also reflect submitter comments on the need for allergens to be clearly and consistently declared.

Table 1: Risk management principles

Principle	Outcome
Public health and safety risk	Allergen declarations need to address the specific public health and safety risk to allergic consumers in the Australian and New Zealand populations.
Consistency	Allergens are declared consistently, in respect to location, format and terminology used.
Clarity	Allergen declarations provide consumers and caregivers with clear and readily understood information that allows them to identify allergens quickly and make safe food choices.

5.2 Presentation of allergen declarations

5.2.1 Location

As noted in Section 2.1.1, the Code does not specify where allergen declarations must be made on the label of packaged foods. However, FSANZ has observed that allergen declarations are generally made in the statement of ingredients or in an allergen summary statement. In some instances, both labelling elements are used.

A lack of consistency on the location of allergen declarations was identified both in the W1070 review and in the First Call for Submissions as a contributor to the variability of allergen information. FSANZ therefore sought views in the First Call for Submissions report on whether the location of allergen declarations should be mandated, and if so, where on the label this information should be located.

Most submitters supported mandating the location of allergen declarations on food labels, but were split on whether this location should be the statement of ingredients or an allergen summary statement. To this point, some submitters commented that consumers use the two label elements in different ways, with the allergen summary statement used for simple, fast allergen searches, and the statement of ingredients for more detailed ingredient and allergen searches.

FSANZ's consumer behaviour literature review (Supporting Document 2) included a specific area of research on how consumers respond to information in different parts of the food label. Consistency in the location of allergen information across different labels aids in identification and comprehension of food allergens. The findings also show an allergen

summary statement reduces the time required to identify allergens, and this statement is easier to identify and read compared to identifying allergens in the statement of ingredients.

The Food Industry Guide recommends a format that includes an allergen summary statement, and many products manufactured in Australia and New Zealand include this voluntary label element. However, despite the Food Industry Guide recommendations for using specific terminology for allergen declarations, FSANZ has previously observed inconsistencies in the terminology used between the allergen summary statement and the statement of ingredients (FSANZ 2016a). Therefore, in the absence of any requirements being set for the use of an allergen summary statement, differences in terminology and presentation across different food products is likely to be perpetuated.

Internationally, the Codex Standard specifies allergens to be declared in the list of ingredients. However, some overseas food regulations mandate where allergens are to be declared on a food label, although there is no uniform approach. For example, the US FALCPA and Canadian regulations require declarations in either an allergen summary statement or the statement of ingredients. The European Union requires allergen declarations in the statement of ingredients and explicitly prohibits the use of an allergen summary statement, except when a statement of ingredients is not provided (due to exemptions).

Based on the above information, FSANZ's is proposing to mandate the declaration of allergens in the statement of ingredients and also require an allergen summary statement on food labels. Declaration of allergens in the statement of ingredients is relatively common practice, therefore consumers are already familiar with seeking information from this location. Additionally, requiring the declaration of allergens in a statement of ingredients across all packaged foods will increase the consistency of allergen information.

Mandating the use of an allergen summary statement would result in the consistent use of this statement across foods, and certainty that the absence of an allergen summary statement means there are no allergens being declared for a food.

To further ensure consistency, it is necessary to consider where a mandated allergen summary statement would be placed in relation to the statement of ingredients. FSANZ notes most food labels with an allergen summary statement place it below the statement of ingredients (NSWFA 2018), an approach which is also recommended in the Food Industry Guide. This approach aligns with mandatory and voluntary approaches used overseas. Furthermore, the consumer behaviour literature review identified a preference by food allergic consumers for some method of differentiating the allergen summary statement from other labelling information (e.g. the statement of ingredients) to assist allergen identification.

Therefore, FSANZ is proposing a requirement for the allergen summary statement to be located directly below and distinctly separated from, the statement of ingredients. However, FSANZ is not proposing to specify the size of the separating space, as this would be difficult to implement on different packaging sizes and shapes.

FSANZ is also aware some stakeholders consider there is a need to mandate the use of a symbol on the front of a food package, warning consumers about the presence of an allergen. FSANZ's consumer literature review has identified that such a symbol could assist in identifying the presence of allergens, but also identified significant difficulties with its use that would counteract these benefits (see Section 4.1.4 and Supporting Document 2). Further, the use of an allergy symbol on the front of pack may be of limited value given it would appear on most packaged foods, and consumers would still need to refer to the ingredient list for additional allergen information specific to their needs.

5.2.2 Format

5.2.2.1 *Font size and type*

The consumer behaviour literature review (Supporting Document 2) included specific research questions relating to how consumers respond to the format and presentation of allergen information on food labels. The findings show food allergic consumers lose the ability to identify allergens within a statement of ingredients if the relevant allergen-containing ingredient names are not distinguished from the surrounding text. Bold font, larger font size, and the grouping of similar information all assist allergen food-allergic consumers or those purchasing for them to identify allergens.

The Codex Standard does not include any specific provisions for the format of allergen declarations in the list of ingredients. European Union regulations require declarations to 'be emphasised from the surrounding text'. The United States of America and Canada do not place any requirements on the font type including bolding of allergen declarations. These two countries do, however, require an allergen summary statement to be displayed with the same font size as used in the statement of ingredients.

The Code contains generic requirements for the legibility of information on food labels; i.e. any word must be in English; and any word, statement, expression or design written or set out on a label must be legible and prominent so as to contrast distinctly with the background (subsection 1.2.1—24(1)). Although these general requirements apply to allergen declarations, they do not require allergen declarations to be displayed differently or in a contrasting manner to any surrounding text on the label itself.

Therefore, FSANZ is proposing a requirement for allergen declarations to be made using bold font to make them clearer and easier to locate on a label, especially in amongst large amounts of labelling information (e.g. a long statement of ingredients). This use of bold font will extend to the entirety of the allergen summary statement to help distinguish it from the statement of ingredients. Bold font has also become a commonplace voluntary measure for declaring allergens on food labels (it is a recommendation of the Food Industry Guide), and therefore mandating a bold font should not significantly impact those food manufacturers who are already following the voluntary guidance.

In response to the First Call for Submissions, some submitters commented the font size and legibility of allergen declarations should be given further consideration because some of the current labels are difficult to read.

FSANZ is of the view the existing generic legibility requirements in the Code are sufficient to ensure allergen declarations are presented in a size which can generally be read by consumers. However, FSANZ's proposal to co-locate allergen declarations in the statement of ingredients and in a separate allergen summary statement means there is the potential for the allergen summary statement to be displayed in a (smaller) font size, which would cause it to lose prominence compared with the statement of ingredients. Having the allergen summary statement displayed prominently is important for the clear identification of allergen information.

Therefore to ensure both elements are presented similarly, FSANZ is proposing for allergens to be declared in the statement of ingredients in a font size no less than the other text in the statement of ingredients, with the font size for text in the allergen summary statement to be the same as the declarations made in the statement of ingredients.

5.2.2.2 Prefix for the allergen summary statement

Currently there is variation in the prefix used for an allergen summary statement. For example, FSANZ notes the Food Industry Guide recommends a 'Contains' prefix. However, a food label survey by the NSW Food Authority (NSWFA 2018) reported 84% of labels with an allergen summary statement had used this prefix. Other prefixes reported included 'allergy advice', 'allergens', or 'warning product contains'.

FSANZ notes consistency in the use and presentation of the allergen summary statement was identified in the consumer behaviour literature review as important for food-allergic consumers. Mandating the prefix will increase consistency in the presentation of the allergen summary statement. FSANZ therefore is proposing for the allergen summary statement to begin with 'Contains' followed by a list of the allergens present in the food. This reflects the most common approach currently used voluntarily by industry.

5.2.2.3 Use of parentheses

Currently, the Food Industry Guide recommends declaration of allergens in the statement of ingredients by the allergen source in parentheses after the ingredient name, if the name itself does not refer to the allergen (e.g. 'semolina (wheat)'). Similarly, some overseas allergen labelling regulations (e.g. Canada, United States of America) require the use of parentheses when declaring allergens as part of ingredient names. Several submitters requested this practice be mandated in the Code.

However, FSANZ is not proposing to mandate the use of parentheses, because the use of bold font will allow consumers to identify allergens in the statement of ingredient. Additionally, based on the existing voluntary approach, it is likely manufacturers will continue to use parentheses to declare allergens, when the allergen source is not in the ingredient name.

FSANZ is therefore of the view that the food industry is best placed to manage how mandatory specified terms are displayed as part of ingredient names. Additionally, not mandating the use of parentheses will provide manufacturers with the flexibility to effectively implement allergen information on their product labels.

5.2.2.4 Colour

Some submitters suggested allergens should be declared using a different colour from the surrounding text to further highlight the information. However, while the consumer behaviour literature review identified colour differentiation as a potential means of improving the identification of allergens, this was in the context of one of many strategies that could be used to assist food allergic consumers (e.g. emboldened text). Therefore, FSANZ does not consider there is a need to specify the colour that must be used for allergen declarations.

5.2.3 Summary

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.

5.3 Terminology

5.3.1 Mandating PEAL terms

In the First Call for Submissions, FSANZ proposed two potential approaches for applying PEAL to the existing allergen declaration requirements. These were for the Code to either require the specific source of an allergen be declared using mandatory specified terms, or not.

The majority of submitters supported the use of mandatory specified terms because they would:

- result in standardised, consistent and clear terminology for allergen declarations
- decrease consumer confusion and make identification of allergens easier for food allergic consumers
- improve the ability of food allergic consumers to understand allergen information, and so decrease unnecessary food avoidance
- make allergen labelling simpler and easier for individuals with limited allergy knowledge (e.g. carers) and those with English as their second language
- align with Canadian and United States of America regulations.

Some industry submitters preferred an approach which applies a generic requirement to use plain English rather than mandatory specified terms. In their view, PEAL is already used in allergen declarations in a consistent manner, and the naming of source allergens is best addressed through industry codes of practice. A generic requirement was also seen as having the least impact on food manufacturers, as it would allow for flexibility in label information and reduce the need to update labels.

Internationally, there is no consistent approach for using specific terminology when declaring allergens. The Codex Standard and European Union regulations do not specify the terms that must be used, whereas the United States of America and Canada provide lists of the specific terms to be used for declaring allergens (and some of these terms differ between the two countries).

Since the First Call for Submissions, FSANZ's consumer behaviour literature review (Supporting Document 2) has specifically investigated the subject of terminology for allergen declarations. The findings show consumers receive a benefit from declarations using terms that are simpler and less technical, while being specific to the allergen. The use of consistent terminology enhances allergen identification and results in appropriate precautionary action (i.e. avoiding the purchase and consumption of unsafe food).

Consistency is an important consideration. Of the two approaches proposed at First Call for Submissions, only the mandating of specific terms will ensure allergens are declared consistently on an individual food, and between different foods. A generic requirement to use PEAL could result in food manufacturers using different terms when declaring the same allergen. The W1070 Review demonstrated that this practice already occurs.

FSANZ is therefore proposing allergens be declared using mandatory specified terms (each called 'required name' in the draft variation at Attachment A) when making allergen declarations. Further discussion about specifying terms for particular allergens is provided in Sections 5.3.2 – 5.6.3 below, with a list of specified terms provided in Section 5.7.

5.3.2 Synonyms

Although not discussed in the First Call for Submissions, submitters requested FSANZ give consideration to permitting some specific terms that, while not a direct reflection of the allergen source, were considered sufficiently similar and well understood. In particular, there were some comments supporting use of the synonym 'dairy' or the common name of the ingredient (e.g. cream, cheese, yoghurt etc.) for milk declarations.

FSANZ has considered this issue, and notes the following:

- Canada permits the use of 'soya' and 'soybean' as alternatives to 'soy'. FSANZ is not aware of any overseas regulation (which mandates specific terms for allergen declarations) permitting the use of 'dairy' as a term for milk declarations.
- The consumer behaviour literature review identified that consumers in the United States of America have a preference for the term 'dairy' over 'milk', although the latter term is mandated. However the term 'dairy' can also create confusion over the presence of milk in a food, especially in respect to claims such as 'dairy free'.

FSANZ considers the terminology used for allergens should always reflect the source allergen, and synonyms which are not the name of the source allergen should not be used. Such an approach will ensure a high level of consistency, as no variations in the terms will be permitted. A single term that reflects the source of the allergen will also be clearer and therefore easier for consumers to comprehend.

This approach means alternative terms for milk such as 'dairy', or the name for a milk product (e.g. 'butter'), should not be used as a declaration for milk allergens given these alternative terms have the potential to cause consumer confusion (they can be used as ingredient names, but an additional declaration of 'milk' would be required with the name). However, FSANZ is proposing an exception in relation to 'soy'; 'soya' and 'soybean' can be used for soy declarations in the statement of ingredients. This is because the terms 'soya' and 'soybean' are very similar terms to soy and are recognisable as referring to the allergen as they incorporate the term 'soy'. However, FSANZ considers the allergen summary statement should always declare 'soy', as this is the simplest and most accurate summary term for this allergen.

5.3.3 Summary

FSANZ's assessment is for allergens to be declared using specified terms (referred to as 'required names' in the drafting at Attachment A).

The use of synonyms will not be permitted for allergen declarations except in the case of soy, where 'soya' and 'soybean' will be alternatives to the specified term 'soy' for use in the statement of ingredients.

5.4 Declaring fish, crustacea and molluscs

5.4.1 The definition and reference to 'fish' in the Code

The Code includes a definition for 'fish' at subsection 1.1.2—3(2) of *Standard 1.1.2 – Definitions used throughout the Code*:

Fish means a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish, but not including amphibians or reptiles.

This definition and the use of the word 'fish' in Standard 1.2.3 is causing confusion and a lack of clarity on how fish, crustacea and molluscs should be declared. In the First Call for Submissions, FSANZ canvassed how finfish could be declared and asked if Standard 1.2.3 should require a declaration of 'fish' or 'finfish'.

There were diverse submitter responses on this issue, with strong arguments put forward for each term. Submitters in support of a declaration of 'finfish' said the term is very clear and explicit as to what it covers. They mentioned that declaring 'finfish' would also help to educate consumers in the reading of allergen information on labels. Submitters in support of retaining the term 'fish' mentioned it is what the general public commonly associates with finfish, and 'finfish' is not used in everyday speech. 'Finfish' is also not used in overseas or other domestic legislation.

FSANZ considers use of the term 'fish' is appropriate given it clearly represents the specific source of the allergen in question, harmonises with international and overseas regulation, and reflects current industry practice in Australia and New Zealand.

FSANZ is also proposing that the definition for 'fish' in Standard 1.1.2 should not apply to Standard 1.2.3. This definition refers to 'shellfish' and is intended for compositional and identification purposes (by *Standard 2.2.3 – Fish and fish products*). Redefining 'fish' in Standard 1.1.2 could therefore have unforeseen regulatory and enforcement implications. By not applying the definition of 'fish' to allergen declaration requirements, the ordinary meaning of fish will instead apply (which FSANZ considers does not include crustacea and molluscs).

5.4.2 Clarifying mollusc declaration requirements

Standard 1.2.3 includes requirements to declare 'fish' and 'crustacea', however it does not include a separate requirement to declare molluscs. Additionally, the definition of 'fish' in Standard 1.1.2 (see above) was not developed for the purpose of allergen declarations, and it could capture molluscs and crustacea as 'shellfish' in addition to finfish. Under Standard 1.2.3 currently, molluscs would therefore need to be declared, but could be declared as 'fish'.

At First Call for Submissions, FSANZ assessed the allergenicity of molluscs and whether molluscs could be considered as an allergen distinct from 'fish' and 'crustacea'. FSANZ's safety assessment determined cross-reactivity and co-allergy between molluscs and crustacea is likely to be relatively low, meaning individuals who are allergic only to one of these foods do not need to avoid the other (see Supporting Document 3). The majority of submitters to the First Call for Submissions supported these findings.

Based on the findings of the safety assessment, FSANZ considers there is a need for a separate declaration requirement for molluscs (and their products) in Standard 1.2.3 of the Code. This separate declaration requirement (in combination with mandatory specified terms for allergen declarations) will ensure mollusc-allergic consumers have access to information that is specific to their allergy, and increase the food choices for both them and fish allergic consumers.

FSANZ also received submissions requesting the introduction of consistent definitions for crustacea and molluscs across the Code. Similar to the approach for the definition of 'fish' in Section 5.4.1 above, FSANZ intends that the ordinary dictionary definitions for these terms will apply. In proposing this approach, FSANZ notes section S22—2 in *Schedule 22 – Foods and classes of foods* contains fish, crustacea and mollusc groups with an explanation of what comprises these groups. However this section is intended to categorise foods for assigning agricultural pesticide permissions, and is not intended for allergen declaration purposes.

5.4.3 Summary

FSANZ's assessment is:

- not to apply the definition for 'fish' in Standard 1.1.2 to the requirements for the declaration of allergens in Standard 1.2.3
- that fish, crustacea and molluscs are to be separately declared when they are present in a food for sale.

5.5 Declaring tree nuts

5.5.1 Individual tree nut declarations in the statement of ingredients

Standard 1.2.3 requires tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*, to be declared when present in a food for sale. 'Tree nuts' are not defined for the purposes of this Standard, and so the Code is unclear about which individual tree nuts are captured by the term 'tree nuts'. This creates uncertainty for the food industry about what tree nuts should be declared and what to declare for 'tree nuts'. The reference to 'nuts' in section S10—2 may also be adding to this uncertainty.

Section S22—2 also groups a number of individual tree nuts under the heading of 'tree nuts', however this section is intended to categorise foods for assigning agricultural pesticide permissions, and is not intended for allergen declaration purposes.

As part of the W3 Review (FSANZ 2010), the FAISAG gave advice on the tree nuts of public health significance with respect to food allergy for Australia and New Zealand. These (nine) tree nuts are: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut. At First Call for Submissions, FSANZ's safety risk assessment identified reports in the scientific literature of clinically defined food allergy, clinical cases or positive responses to oral food challenges in Australia and/or New Zealand for all nine of the tree nuts previously identified as being important allergens. Submitters were asked to comment on FSANZ's preliminary view that the nine individual tree nuts should be specifically declared, and if this approach offers sufficient clarity with regard to which tree nuts/nuts should be declared. In response, there was strong submitter support for individual tree nut declaration requirements.

Submitters mentioned individual declaration requirements would allow for easier identification of tree nuts in foods resulting in safer food choices, as well as increasing the available food choices. Also, it was mentioned that individual tree nut declaration requirements would bring Australia and New Zealand in line with overseas regulations, and provide manufacturers with clarity on how to declare tree nut ingredients. There were a few submitters who did not support the proposed individual tree nut declaration requirements, on the basis individual tree nuts are always individually declared within the statement of ingredients, and 'tree nuts' is a well understood term.

Given the safety assessment findings and strong submitter support, FSANZ is proposing a requirement for the individual declaration of the nine tree nuts mentioned above in the statement of ingredients of packaged foods. These requirements, in combination with mandating specified terms for allergen declarations, would enable individuals with allergies only to certain tree nuts to safely choose from a broader range of foods. The approach would also be consistent with the general approach taken by European Union, the United States of America and Canada for declaring tree nuts.

5.5.2 Use of the term ‘tree nut’

As part of the W1070 Review (FSANZ 2010), FSANZ identified problems associated with the use of the collective term ‘tree nuts’ in the allergen summary statement. Ordinarily, information should be available in the statement of ingredients on the specific tree nut, however the qualitative label survey of the W1070 Review found this was not always the case.

Although the use of the term ‘tree nut’ in the allergen summary statement was not considered at First Call for Submissions, a number of industry submitters suggested the collective term ‘tree nuts’ should be permitted in the allergen summary statement, with the individual tree nut declarations being made in the statement of ingredients. In contrast, several allergy support organisations commented the term ‘tree nuts’ should not be used (anywhere) on food labels.

The consumer behaviour literature review shows food allergic consumers and their caregivers find a brief allergen summary statement to be useful as an alert for the presence of allergens, and a trigger to scrutinise the statement of ingredients more thoroughly.

On this basis, FSANZ considers there is a case to include the term ‘tree nut’ in an allergen summary statement, in association with a requirement to declare the specific tree nut(s) in the statement of ingredients. This approach would allow for a quick label search by food allergic consumers to identify the presence (or not) of tree nuts using the allergen summary statement, with the statement of ingredients providing allergy-specific information for more detailed searches. The requirement to use ‘tree nut’ will also shorten the allergen summary statement compared to listing out individual tree nuts, and so assist the food industry in managing label space.

‘Tree nut’ (singular) is proposed instead of ‘tree nuts’ (plural) to accommodate the situation where only one tree nut may be present in the food. The use of ‘tree nuts’ could mislead a food allergic consumer to search for more than one nut in the statement of ingredients, whereas the reverse is unlikely to occur.

This approach would ensure ‘tree nut’ and individual tree nut terms are declared consistently on all foods in the same place on a label and in the same manner. Note if the food is not required to have a statement of ingredients on the label, then it must declare using the individual tree nut terms, and cannot meet these declaration requirements using the term ‘tree nut’ (see Section 5.7 below).

5.5.3 The exemption for coconut

Under Standard 1.2.3, a tree nut declaration is not required for the presence of coconut from the fruit of the palm *Cocos nucifera* in a food. However, a public health submitter argued coconut should be captured as a tree nut for declaration because sensitisation to tree nut is correlated with coconut. Four studies were cited in support of this position (Teuber et al. 1999; Nguyen et al. 2004; Stutius et al. 2010; Polk et al. 2016).

FSANZ undertook a literature search to identify additional studies relating to coconut and food allergy. A risk assessment was undertaken of the available evidence and is described in Supporting Document 3. FSANZ has assessed that, based on the available evidence, coconut allergy is rare with a limited number of clinical cases reported in the scientific literature, and therefore the risk of coconut allergies in individuals allergic to tree nuts is very low.

FSANZ also notes the current exemption for coconut at subparagraph 1.2.3—4(1)(b)(ix) of the Code is intended to clarify that the declaration requirement for ‘tree nuts’ (and their products) does not apply to coconut. Several submitters requested Standard 1.2.3 should retain this exemption for coconut if the standard includes declaration requirements for the

nine identified tree nuts. However, it is FSANZ's view that this exemption will be made redundant if the requirement to declare specific tree nuts is adopted, and so we are proposing to remove it from the Code.

5.5.4 Summary

FSANZ's assessment is that each of the following nine tree nuts implicated in food allergy are to be declared: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut.

For packaged foods:

- the specific individual tree nuts must be declared in the statement of ingredients, whereas the term 'tree nut' must be used in the allergen summary statement.
- when a statement of ingredients is not required to be displayed for the food, the specific individual tree nuts must be declared by name.

5.6 Cereal declaration requirements

The declaration requirements in Standard 1.2.3 do not distinguish between cereals associated with allergies and cereals that are only associated with conditions related to the consumption of gluten (Coeliac disease and Dermatitis herpetiformis). Instead, subparagraph 1.2.3—4(1)(b)(i) states: *cereals containing gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains* (or products of these foods) must be declared when present in a food for sale.

The current wording of the 'cereals containing gluten' declaration requirement does not make it clear what needs to be declared. The wording could be interpreted to mean the individual cereals must be declared (wheat, rye, barley, oats, spelt and their hybrids), which was the original intent of subparagraph 1.2.3—4(1)(b)(i). However this requirement could also be interpreted as permitting the words 'cereals containing gluten' as a means of declaring the presence of these cereals, and FSANZ notes there are products labelled with these types of declarations (FSANZ 2016a). There are also labels displaying 'gluten' in the allergen summary statement.

FSANZ has investigated how to improve clarity in the declaration requirements for cereals as detailed in the following sections.

5.6.1 Wheat declaration

Previously, FSANZ confirmed wheat is a food allergen of clinical significance for the Australian and New Zealand populations, and has been implicated as the cause of severe adverse reactions in Australia and New Zealand⁴. FSANZ reaffirmed the clinical significance and adverse health outcomes associated with wheat allergy during the W3 Review (FSANZ 2010), and more recently during *Proposal P1031 – Allergen Labelling Exemptions* (FSANZ 2016b).

The safety assessment for this proposal also identified that hybrid strains of wheat and other cereals such as triticale (a hybrid of wheat and rye) share antigenic potential with wheat. Members of the FAISAG have also noted patients with wheat allergy are advised to avoid hybrids of this cereal. Details on the safety assessment for wheat can be found in Supporting Document 3.

⁴ Proposal P161 – The Review of the Declaration of Specific Labelling Statements on Packed Food

At First Call for Submissions, FSANZ proposed the separation of a declaration for wheat and wheat hybrid strains from other declaration requirements for cereals containing gluten (i.e. from barley, rye, oats and spelt), irrespective of the presence of gluten in the food.

The comments received supported this change. Submitters mentioned a separate wheat declaration will allow wheat-allergic consumers to obtain labelling information applicable to their condition, and it was important for them to avoid the proteins in wheat rather than the gluten fraction. It was also mentioned that always declaring 'wheat' will reduce unnecessary food avoidance by wheat-allergic consumers.

Based on the safety assessment and support from submitters, FSANZ is proposing to require the declaration of 'wheat' in all instances where wheat or wheat hybrid cereals are present in a food (unless there is an existing exemption from declaring wheat, for example certain glucose syrups made from wheat starch).

5.6.2 Declaring cereals containing gluten

At First Call for Submissions, FSANZ identified there could be alternative methods for declaring the presence of gluten in a food, which may be clearer to gluten intolerant consumers than a declaration of the individual cereals, specifically whether the terms 'cereals containing gluten' or simply 'gluten' would be helpful.

Submitters were asked if declaring the individual sources of gluten-containing cereals would provide adequate information about the presence of gluten, and if there are other approaches for declaring cereals which would assist individuals with a cereal allergy as well as those who have conditions related to the consumption of gluten. As noted in Section 3 of this report, submitters expressed support for declaring the term 'gluten' somewhere on the label. However submitters were divided on how this could be achieved.

Some submitters supported a declaration for 'gluten' without the specific cereal source, as the declaration of the individual cereal is insufficiently clear for individuals with gluten intolerance or Coeliac disease. However, most submitters were in support of the declaration of 'gluten' or 'cereals containing gluten', but only if there was also a declaration of the individual cereal source on the label. A number of industry submitters also argued for 'gluten' or 'cereals containing gluten' to be used in the allergen summary statement with individual cereals named in the statement of ingredients. A smaller group of submitters argued 'gluten' or 'gluten-containing cereals' should not be used for cereal declarations.

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.

For wheat declarations, FSANZ is proposing to apply a similar declaration requirement to the one for the presence of gluten. However, based on the outcomes in Section 5.6.1, the term 'wheat' must always be used because of its separate role in food allergies. Therefore the term 'wheat' must be declared in the statement of ingredients, and both 'wheat' and 'gluten' must be declared in the allergen summary statement. If the wheat ingredient has been processed or bred to remove gluten, then only 'wheat' would be required in bold font in both locations.

FSANZ's proposed approach will result in both 'gluten' and individual gluten-containing cereals being declared on all foods consistently in the same location and in the same manner. Consumer education will assist in helping consumers to become familiar with these label changes.

Note that for foods not required to bear a label or a statement of ingredients, a declaration of the individual cereal names will be required but not 'gluten' (see Section 5.7 below). A declaration of gluten may however be provided voluntarily in addition to the individual cereal names.

5.6.3 Summary

For foods required to bear a label, FSANZ's assessment is that:

- 'wheat' is to be declared in the statement of ingredients and the allergen summary statement when wheat or wheat hybrids are present
- 'barley', 'rye', 'oats' and 'spelt' are to be declared in the statement of ingredients when both these cereals or their hybrids are present, and the food contains gluten
- 'gluten' is to be declared in the allergen summary statement if gluten from wheat, barley, rye, oats, or spelt, or their hybrids is present.

5.7 Generic ingredient names

5.7.1 Fish and crustacea

The table to section S10—2 in the Code sets out conditions for the use of generic ingredient names. This section permits the use of the generic name 'fish' and includes the condition that 'if crustacea, the specific name of the crustacea must be declared'. In addition there is a separate existing requirement to declare crustacea in Standard 1.2.3.

At First Call for Submissions, FSANZ asked how section S10—2 could be clarified to prevent inconsistencies between ingredient labelling and allergen declaration requirements for finfish, crustacea and molluscs. Most submitters supported amending the Code to include separate generic ingredient names for fish, crustacea and molluscs. One industry submitter advocated removing the 'fish' generic ingredient name provision altogether. Some submitters expressed support for FSANZ's approach not to mandate individual species names as part of declaration requirements.

FSANZ is of the view Standard 1.2.4 should not use ingredient names which do not reflect the source name of the allergens present within ingredients. In this respect, the existing generic name 'fish' can remain and is suitable as an allergen declaration for fish; no further elaboration of the individual fish species is needed as fish-allergic individuals are allergic to all fish. However, FSANZ does not consider there is a need to permit new, separate generic ingredient names for 'crustacea' and 'molluscs', given these terms will be mandated for the purposes of allergen declarations.

Similarly, the condition in the table to section S10—2 to declare ‘the specific name of the crustacea’ is to be removed, given ‘crustacea’ is will be a separate declaration to fish in Standard 1.2.3, and crustacea-allergic individuals are allergic to all crustacea. Instead, FSANZ has determined that Standard 1.2.4 (section 1.2.4—4) is to be amended to require ingredient names in a statement of ingredients be subject to the new allergen declaration requirements in Division 3 of Standard 1.2.3. This amendment clarifies what has to be declared for allergens in respect to the ‘fish’ generic ingredient name.

5.7.2 Nuts

There is a condition in the table to section S10—2 for the specific name of the nut to be declared when using the generic ingredient name ‘nuts’. Several submitters requested FSANZ replace the generic ingredient name ‘nuts’ with ‘tree nuts’, or alternatively list out the individual tree nuts in that table.

Because FSANZ is proposing that the mandatory specified terms for nine tree nuts and peanut (a legume) are to be used for allergen declarations, the existing permission to use the generic name ‘nuts’ in the statement of ingredients would end up being inconsistent with the intent of the new allergen declaration requirements. ‘Nuts’ can refer to any nut whether they are associated with an allergy or not. Even though the Code currently requires the specific name of the nut to be declared with the generic name ‘nuts’ (table to section S10—2), its use is not in keeping with the general premise of using PEAL, which is to refer to the specific allergen source of the tree nuts and peanut listed for declaration. FSANZ therefore considers the generic name ‘nuts’ and its condition of use should be removed from the table to section S10—2.

As a result of removing the generic ‘nuts’ ingredient name permission, all nut ingredients would need to be listed individually in the statement of ingredients consistent with the requirements in Standard 1.2.4. However, FSANZ’s approach to bold allergen declarations will distinguish the nine tree nuts and peanut from other nuts in the statement of ingredients.

The use of ‘tree nut’ as a generic ingredient name in the statement of ingredients would be inconsistent with the purpose of PEAL, in the same way that would occur with the use of ‘nuts’. However, FSANZ does consider the term ‘tree nut’ to be useful as a concise term for the allergen summary statement (see Section 5.5.2 above).

5.7.3 Cereals, starch and fats/oils

The table to section S10—2 permits the use of ‘cereals’, ‘starch’, and fats/oils as generic ingredient names. FSANZ is not proposing to remove the permission to use these generic ingredient names, as they could be used for cereal/starch/fat/oil ingredients that are not derived from listed allergens in Standard 1.2.3. Instead, FSANZ is proposing to remove the conditions for cereals, starch, and fats/oils generic ingredient names. This would ensure the mandatory specified terms are used with these generic names, without duplicating requirements in different standards of the Code. To make it clear, the draft variation at Attachment A includes an amendment to Standard 1.2.4, requiring ingredient names in a statement of ingredients to be subject to the new allergen declaration requirements in Division 3 of Standard 1.2.3.

5.7.4 Cheese, milk protein and milk solids

The table to section S10—2 contains permissions to use the generic ingredient names ‘cheese’, ‘milk protein’ and ‘milk solids’. Under amendments in the draft variation prepared by FSANZ which mandate specified terms for allergen declarations, ‘milk’ would also need to be used in the ingredient list if the generic name ‘cheese’ is used (e.g. cheese (milk)). However

the generic ingredient names 'milk protein' and 'milk solids' already include the name 'milk', and so would not require any further clarification.

5.7.5 Summary

FSANZ's assessment is that the Code be amended to:

- remove the generic name 'nuts' and its condition from the table to section S10—2
- remove existing conditions for the generic names 'cereals', 'fats' or 'oils', 'fish' and 'starch' that relate to allergen declarations
- add a provision in Standard 1.2.4 to require the use of ingredient names in a statement of ingredients be subject to the allergen declaration requirements of Standard 1.2.3.

5.8 Foods not required to bear a label or display a statement of ingredients

Standard 1.2.1 allows for foods for sale in certain circumstances to be exempt from bearing a label (e.g. food displayed in an assisted service display cabinet). These foods must still provide allergen declarations, either by displaying in connection with the display of the food, or providing to the purchaser on request (subsection 1.2.1—9(6)).

Also, the requirement for a statement of ingredients does not apply to standardised alcoholic beverages and food for sale in small packages (subsection 1.2.4—2(3) of Standard 1.2.4), although allergen declarations are still required for these foods.

Allergens must be declared for food sold to caterers, which are required to bear a label (paragraph 1.2.1—15(c)). However, where food sold to caterers do not have to bear a label, section 1.2.1—13 allows the allergen declaration information for the food to be provided to the caterer with the food.

FSANZ is not proposing to change these requirements. However for consistency, FSANZ considers the same mandatory specified terms required for the statement of ingredients on packaged foods should be used for these declarations. Alternative terms required for the allergen summary statement, such as 'gluten' and 'tree nut', will not apply (see Table 2 below). While the consumer behaviour research has shown 'gluten' and 'tree nut' are useful prompting terms to include in the allergen summary statement, there is an underlying need to ensure the declaration of individual tree nuts and cereals, even if a statement of ingredients is not present. Therefore the use of mandatory specified terms for individual tree nuts and cereals in allergen declarations on foods not required to bear a label or display a statement of ingredients will ensure consistency of information for allergic consumers.

While 'gluten' and 'tree nut' terms will not be required for these foods, they could still be used voluntarily, provided the individual cereals/tree nut terms are also declared.

It should be noted that the presentation and format requirements for allergen declarations in the statement of ingredients and allergen summary statement (e.g. emboldened text) (as discussed in Section 5.2) will not apply to food not required to bear a label, food sold to caterers, and food not required to display a statement of ingredients.

FSANZ's assessment is to apply the requirement to use the mandatory specified terms required for a statement of ingredients (on food required to bear a label) to foods that are:

- not required to bear a label,
- exempt from displaying a statement of ingredients
- sold to caterers.

5.9 List of specified terms

Using the risk management outcomes from Sections 5.2-5.8 above, FSANZ is proposing a list of the mandatory specified terms to be used for declaring allergens as shown in Table 2 below.

Table 2: Mandatory specified terms ('required names') for allergen declarations

Allergen declaration		Mandatory specified term	
		For all declarations (except in the allergen summary statement)	For declarations in the allergen summary statement
Added sulphites in concentrations of 10 mg/kg or more		sulphites	sulphites
Wheat and its hybrids		wheat	wheat, gluten (when gluten is present)
These cereals and their hybrids (when gluten is present)	Barley	barley	gluten
	Oats	oats	
	Rye	rye	
	Spelt	spelt	
Milk		milk	milk
Egg		egg	egg
Fish		fish	fish
Crustacea		crustacean	crustacean
Mollusc		mollusc	mollusc
Sesame seed		sesame	sesame
Lupin		lupin	lupin
Soybean		soy, soya or soybean(s)	soy
Peanut		peanut	peanut
Almond		almond	tree nut
Brazil nut		Brazil nut	
Cashew		cashew	
Hazelnut		hazelnut	
Macadamia		macadamia	
Pecan		pecan	
Pine nut		pine nut	
Pistachio		pistachio	
Walnut		walnut	

5.10 Summary of the risk management approach

Based on FSANZ's assessment, the proposed risk management approach is summarised below:

- Allergens be declared in the statement of ingredients using bold font and in a separate emboldened allergen summary statement.
- Allergens be declared in the statement of ingredients in a font size no less than that used for other ingredient names.
- The allergen summary statement is to:
 - include the prefix 'Contains', followed by a list of allergens present
 - appear directly below and be distinctly separated from the statement of ingredients
 - be printed in the same font type and size as allergen declarations made in the statement of ingredients.
- Mandatory specified terms are to be used when declaring allergens. In the statement of ingredients, 'soya' and 'soybean' will be permitted alternatives to the specified term 'soy'.
- To clarify that the definition for 'fish' in Standard 1.1.2 does not apply to the declaration of allergens.
- Require separate declarations when the following food or substances are present in a food for sale:
 - molluscs
 - the nine tree nuts implicated in food allergy: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut in the statement of ingredients, with the term 'tree nut' for declaring in the allergen summary statement
 - wheat in the statement of ingredients and the allergen summary statement when wheat or wheat hybrids are present
 - 'barley', 'rye', 'oats' and 'spelt' in the statement of ingredients when these cereals or their hybrids are present, and the cereal contains gluten
 - 'gluten' in the allergen summary statement if gluten from wheat, barley, rye, oats or spelt or their hybrids is present.
- Remove from the table to section S10—2:
 - the generic name 'nuts' and its condition for use
 - existing conditions for the generic names 'cereals', 'fats' or 'oils', 'fish' and 'starch' that relate to the 'specific name' or 'specific source name' of an allergen.
- Include in Standard 1.2.4 a requirement that the use of ingredient names in a statement of ingredient are subject to the allergen declaration requirements in Standard 1.2.3.
- Apply the requirement to use mandatory specified terms (as proposed for the statement of ingredients on foods required to bear a label) to foods that are not required to bear a label, exempt from displaying a statement of ingredients; or sold to caterers.

6 Risk Communication

6.1 Communication Strategy for Proposal P1044

Consultation is a key part of FSANZ's standards development process. FSANZ has prepared a communication strategy for this proposal, which includes targeted communication with key stakeholders and the preparation of information for the broader community. FSANZ will work with key consumer groups and other interested stakeholders on ensuring consumers (in particular) are informed about the amendments in the draft variation if they are approved. FSANZ will continue to engage with the Allergen Collaboration⁵ on Proposal P1044.

All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are notified about the availability of reports for public comment.

6.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international and overseas standards (see Section 2.3 above). However, the draft variation prepared by FSANZ to amend the Code, which contains new requirements for the declaration of allergens in food, may have an effect on trade because there are amendments which are additional to and/or different from requirements in other countries. Therefore, a notification under Australia's and New Zealand's obligations to the WTO Technical Barriers to Trade Agreement has been made to enable other WTO members to comment on the amendments in the draft variation.

7 FSANZ Act assessment requirements

7.1 Section 59 of the FSANZ Act – Assessing a proposal

7.1.1 Paragraph 59(2)(a) – Consideration of costs and benefits

Paragraph 59(2)(a) of the FSANZ Act requires FSANZ to have regard to whether the costs arising from a food regulatory measure developed for this proposal would outweigh the direct and indirect benefits to the community, government and industry that arise from the measure.

The Office of Best Practice Regulation (OBPR) has exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed (OBPR reference number 25283). This is due to the OBPR being satisfied the proposed regulatory change is likely to have a minor economic impact.

Although a formal RIS is not required, FSANZ has given detailed consideration to the costs and benefits associated with Proposal P1044, which is provided as a separate document to this report (Supporting Document 4).

⁵ See <http://www.foodstandards.gov.au/consumer/foodallergies/collaboration/Pages/default.aspx>.

FSANZ has considered two options to address the issues of clarity and consistency, in addition to the status quo. The options are:

1. Maintain the status quo (i.e. no change to allergen declaration requirements).
2. Declare allergens using mandatory specified terms in bold font.
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

FSANZ's assessment from analysis of available literature and consultations is that Option 3 (mandatory specified PEAL terms, format and location) will, on balance, have the greatest net benefit and is therefore the preferred option. This option, of those considered, most ensures the relevance and effectiveness of allergen declaration requirements in assisting consumers to avoid potentially harmful products.

However, information received through this call for submissions consultation process may result in FSANZ arriving at a different conclusion.

Questions for submitters

1. What proportion of foods are likely to be affected by the change?
2. Is there likely to be a material difference in costs between Options 2 and 3? If yes, why?
3. Is there likely to be a material difference in the benefit to consumers between Options 2 and 3?
4. Is Option 2 or 3 sufficient for consumers to make quick and reliable assessments of foods?
5. What would be an appropriate duration of time for stock in trade provisions?
6. Do you expect to have any notification⁶, education⁷, permission⁸, purchasing⁹, record keeping¹⁰, enforcement¹¹, publication and documentation¹², procedural¹³, delay¹⁴, labelling¹⁵ or any other costs associated with the proposed changes to the Food Standards Code?
7. Any views in relation to unintended consequences associated with Option 2 or 3.

⁶ **Notification** - businesses face costs when they have to report certain events to a regulatory authority, either before or after the event has taken place.

⁷ **Education** - businesses face costs when keeping up to date with regulatory requirements.

⁸ **Permission** - businesses face costs when applying for and maintaining permission to conduct an activity.

⁹ **Purchasing** - businesses face costs when having to purchase a service (advice) or a product (materials or equipment) to comply with a regulation.

¹⁰ **Record keeping** - businesses face costs to keep statutory documents up to date.

¹¹ **Enforcement** - business costs when cooperating with audits, inspections and regulatory enforcement activities.

¹² **Publication and documentation** - businesses face costs when having to produce documents for third parties.

¹³ **Procedural** - businesses face non-administrative costs imposed by some regulations.

¹⁴ **Delay** - businesses face costs when administrative delays result in expenses and loss of income.

¹⁵ **Labelling** - declaring the presence of allergens on labels or displaying or providing information to consumers about the presence of allergens where a label is not required.

7.1.2 Paragraph 59(2)(b) – Whether there are other measures that would be more cost-effective than a food regulatory measure

There is a voluntary guideline in place (Food Industry Guide) which provides an alternative to regulating the use of PEAL on food labels and has been implemented for over ten years. However, FSANZ has considered the guideline as a part of Option 1 (status quo), and concluded that while it is well established, its recommendations are not universally adopted. As such, FSANZ is of the view there are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of this proposal.

7.1.3 Paragraph 59(2)(c) – Any relevant New Zealand standards

In assessing this proposal, FSANZ has had regard to paragraph 59(2)(c) of the FSANZ Act, which requires FSANZ to have regard to any relevant New Zealand standards. FSANZ notes that Standard 1.2.3 applies in both Australia and New Zealand and is not aware of any relevant New Zealand only standards for allergen labelling.

7.1.4 Paragraph 59(2)(d) – Other relevant matters

Other relevant matters are considered below.

7.1 Section 18 of the FSANZ Act – FSANZ Objectives

7.2.1 Paragraph 18(1)(a) – Protection of public health and safety

FSANZ has assessed the scientific evidence relating to the safety aspects of allergy and intolerance to molluscs, crustacea, tree nuts, and cereals (including gluten content), and prepared a consumer behaviour literature review that identified consistency and clarity of allergen information is important for food allergic consumers (or those who purchase foods for them) to make safe food choices. Based on this, FSANZ has prepared a draft variation to the Code to clarify existing, and introduce new requirements to increase the consistency and clarity of allergen information to enable food allergic consumers make safer food choices.

7.2.2 Paragraph 18(1)(b) – The provision of adequate information relating to food to enable consumers to make informed choices

In our assessment, FSANZ has identified a number of amendments to the Code that will make allergen declarations clearer and more consistent for food allergic consumers (or those who purchase foods for them) to better assist them to make informed choices. These amendments relate to mandating the terminology, format and location of allergen declarations.

7.2.3 Paragraph 18(1)(c) – The prevention of misleading or deceptive conduct

FSANZ has not identified any issues relevant to this objective.

7.2.4 Subsection 18(2) considerations

The need for standards to be based on risk analysis using the best available scientific evidence

FSANZ has used the best available scientific evidence to develop proposed changes to allergen declarations as set out in FSANZ's consumer behaviour literature review (Supporting Document 2) and safety risk assessment (Supporting Document 3). Scientific evidence used in previous FSANZ reviews (W3 and W1070) has also been considered.

The promotion of consistency between domestic and international food standards

FSANZ has considered relevant international and overseas standards and regulations for allergen declarations. The relevant Codex Standard does not include provisions for mandatory specified terms or presentation of allergen declarations. Amendments in the draft variation prepared by FSANZ to mandate the format and use of specific terminology of allergen declarations are similar to approaches used elsewhere. However, there is no consistency at an international level in the presentation or wording of allergen declarations.

The desirability of an efficient and internationally competitive food industry

FSANZ does not anticipate any significant impact on efficiency and international competition. However, a notification has been made to enable WTO members to comment on the draft variation to the Code (see section 6.2).

The promotion of fair trading in food

This proposal has considered approaches to make the allergen declaration requirements in the Code clearer, which will provide clarity and certainty for the food industry on how to make allergen declarations and thereby promote fair trade.

Any written policy guidelines formulated by the Forum on Food Regulation

There are no written policy guidelines which apply to this proposal.

8 Implementation

8.1 Transition periods

FSANZ is proposing not to apply the standard transition arrangements that are specified in Section 1.1.1—9 of the Code (located in Standard 1.1.1 – Structure of the Code and General Provisions). These arrangements are for a 12-month stock-in-trade period to apply to variations to the Code.

Instead, 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, as long as the food complies with either existing requirements in the Code, or the amendments arising from Proposal P1044.

In either case, a food will have to comply fully with either version of the Code; it will not be able to comply with only part of the amendments during that transition period.

These transitional arrangements have been included for the draft variation because the proposed changes will be affecting a broad range of foods, including those with a longer shelf life.

8.2 Education

If the draft variation is approved, FSANZ intends to prepare communication and education materials related to the introduction of the new allergen labelling requirements.

FSANZ recognises the education of food allergic consumers as well as the food industry will be important for the introduction of the proposed changes to labelling information, and to its use in making safe allergen-based food choices. FSANZ intends to work with food allergy and intolerance support groups, health professionals, and food industry representative organisations on education strategies which can support the introduction of the new allergen labelling requirements.

Education will occur during the transition period, so consumers and the food industry can adjust to the new allergen information arrangements before amendments to the Code come into full effect.

9 Draft Variations

FSANZ has prepared a draft variation to the Code which is based on the preferred regulatory option (Option 3) and is provided at Attachment A. A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

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Attachments

- A. Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



Food Standards (Proposal P1044 – Plain English Allergen Labelling) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert name and position of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1044 – Plain English Allergen Labelling) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The Variation commences on the date of gazettal.

4 Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the food product complies with one of the following:
 - (a) the Code as in force without the variations made by this instrument; or
 - (b) the Code as amended by the variations made by this instrument.
- (3) A food product that was packaged and labelled before the end of the transition period may be sold during the post-transition period if the product complies with one of the following:
 - (a) the Code as in force without the variations made by this instrument; or
 - (b) the Code as amended by the variations made by this instrument.
- (4) For the purposes of this clause:
 - (a) **transition period** means the period commencing on the variation's date of commencement and ending 24 months after the date of commencement;
 - (b) **post-transition period** means the 12 month period commencing on the day after the transition period ends.

Schedule

Standard 1.1.1

[1] **Standard 1.1.1** is varied by omitting the words 'Mandatory advisory statements' from subsection 1.1.1—2(2), substituting 'Mandatory advisory statements and declarations'

Standard 1.1.2

[2] **Standard 1.1.2** is varied by inserting into subsection 1.1.2—2(3), in alphabetical order

required name, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3.

Standard 1.2.3

[3] **Standard 1.2.3** is varied by

[3.1] inserting after Note 2 to Standard 1.2.3

Division 1 Preliminary

[3.2] omitting section 1.2.3—1A, substituting

1.2.3—1A Definitions

Note In this Code (see section 1.1.2—2):

required name, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3.

size of type means the measurement from the base to the top of a letter or numeral.

[3.3] inserting after section 1.2.3—1A

Division 2 Mandatory statements

[3.4] inserting after section 1.2.3—3

Division 3 Mandatory declarations

[3.5] omitting section 1.2.3—4, substituting

1.2.3—4 Mandatory declarations of certain foods

- (1) For the labelling provisions, if a food to which this section applies is present in a food for sale in a manner listed in subsection (5), a declaration that the food is present is required.
Note The labelling provisions are set out in Standard 1.2.1.
- (2) A declaration required by subsection (1) must comply with this Division.
- (3) This section applies to:
 - (a) a food that is listed in Column 1 of the table to section S9—3; or
 - (b) a derivative of such a food.
- (4) Despite subsection (3), this section does not apply to a food that is listed in Column 2 of the table to section S9—3.
- (5) For the purposes of subsection (1), the food may be present as any of the following:
 - (a) an ingredient or as an ingredient of a *compound ingredient; or
 - (b) a substance *used as a food additive, or an ingredient or component of such a substance; or
 - (c) a substance *used as a processing aid, or an ingredient or component of such a substance.

1.2.3—5 Food name required for a mandatory declaration

The *required name of a food listed in Column 1 of the table to section S9—3 is:

- (a) when listed in a Statement of ingredients—the corresponding name or names in Column 3 of that table;
- (b) when listed in a summary statement required by paragraph 1.2.3—6(2)(b)—the corresponding name or names in Column 4 of that table;
- (c) for the purposes of subsections 1.2.3—6(5) and 1.2.3—8(2)—the corresponding name or names in Column 3 of that table.

1.2.3—6 Declarations on foods required to *bear a label

- (1) This section applies to a declaration that is:
 - (a) required by subsection 1.2.3—4(1); and
 - (b) made for the purposes of paragraph 1.2.1—8(1)(d), subsection 1.2.1—8(3), subparagraph 1.2.4—5(6)(b)(i), or paragraph 2.9.5—9(1)(d).
- (2) A declaration to which this section applies must be made by:
 - (a) listing in the Statement of ingredients of the food for sale—the *required name of the food to be declared; and
 - (b) including a summary statement on the label of the food for sale.
Note Statement of ingredients provisions are set out in Standard 1.2.4.
- (3) To avoid doubt, for the purposes of paragraph 1.2.3—6(2)(a), the *required name of the food to be declared must be listed separately in the Statement of ingredients for each ingredient that is or contains that food.

- (4) Subsection (2) does not apply to a food for sale to which subsection 1.2.4—2(2) or subsection 1.2.4—2(3) applies.

Note Subsections 1.2.4—2(2) and (3) provide that certain foods are not required to have a Statement of ingredients on their label.

- (5) If a declaration to which this section applies is made in relation to a food for sale to which subsection 1.2.4—2(2) or subsection 1.2.4—2(3) applies, the declaration must be made by stating on the label of the food for sale the *required name of the food to be declared.

1.2.3—7 Form of mandatory declarations on foods required to *bear a label

- (1) A *required name in a Statement of ingredients of a food for sale must be printed:
- (a) in a bold font that provides a distinct contrast with any other text in the Statement of ingredients which is not a required name; and
 - (b) in a *size of type that is not less than the size of type of the other text in the Statement of ingredients that is not a required name.
- (2) A summary statement must commence with the word 'Contains' and then list the *required name of each food to be declared.
- (3) A summary statement must:
- (a) appear on the label of the food for sale directly below the Statement of ingredients; and
 - (b) be distinctly separated from the Statement of ingredients.
- (4) A summary statement must be printed:
- (a) in the same typeface and *size of type as any *required name in the Statement of ingredients of the food for sale; and
 - (b) in a bold font that provides a distinct contrast with the background and the other text of the label of the food for sale.
- (5) In this section, a **summary statement** means a summary statement required by paragraph 1.2.3—6(2)(b).

1.2.3—8 Declarations for foods not required to bear a label or sold to a caterer

- (1) This section applies to a declaration that is:
- (a) required by subsection 1.2.3—4(1); and
 - (b) made for the purposes of paragraph 1.2.1—9(3)(d), paragraph 1.2.1—9(7)(b), or paragraph 1.2.1—15(c).
- (2) A declaration to which this section applies must be made by stating the *required name of the food.

Standard 1.2.4

[4] Standard 1.2.4 is amended by

[4.1] omitting the words 'A statement of ingredients' from section 1.2.4—4, substituting 'Subject to Division 3 of Standard 1.2.3, a statement of ingredients'

[4.2] inserting after section 1.2.4—4

Note Division 3 of Standard 1.2.3 provides for mandatory declarations of certain foods, including by declarations in a statement of ingredients.

Standard 2.9.5

[5] Standard 2.9.5 is amended by omitting paragraph 2.9.5—10(2)(a), substituting

- (a) items 1, 4, 6 or 9 of the table to section S9—2; or

Schedule 9

[6] Schedule 9 is varied by

[6.1] omitting the heading of the Schedule, substituting

Schedule 9 **Mandatory advisory statements and declarations**

[6.2] omitting Note 1 of the Schedule, substituting

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Standard 1.2.3 is a standard for the information requirements relating to warning statements, advisory statements, and declarations. Standard 2.9.5 contains similar information requirements for food for special medical purposes. This Standard lists mandatory advisory statements for subsection 1.2.3—2(1) and paragraph 2.9.5—10(2)(a); and mandatory declarations for subsection 1.2.3—4(1).

[6.3] omitting ‘Mandatory advisory statements’ in section S9—1, substituting ‘Mandatory advisory statements and declarations’

[6.4] inserting after section S9—2

S9—3 **Mandatory declarations**

- (1) For Division 3 of Standard 1.2.3, a reference to the table in section S9—3 is to the table to subsection (3).
- (2) For the purposes of the table to subsection (3):
 - (a) the definition of **fish** in subsection 1.1.2—3(2) does not apply; and
 - (b) **fish** excludes crustacea and molluscs.
- (3) The table to this subsection is:

Mandatory declarations

<i>Item</i>	<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>	<i>Column 4</i>
	<i>Food</i>	<i>Exemption</i>	<i>Required name for declarations other than declarations in a summary statement</i>	<i>Required name for declarations in a summary statement</i>
1	added sulphites in concentrations of 10 mg/kg or more		sulphites	sulphites
2	Any of the following cereals (including hybridised strains thereof) if they contain *gluten:	the cereal or its hybridised strain that is present in beer or spirits		
	barley		barley	gluten
	oats		oats	gluten
	rye		rye	gluten
	spelt		spelt	gluten
3	wheat (including its hybridised strain) irrespective of whether it contains gluten	(a) the wheat or its hybridised strain that is present in beer or spirits; (b) glucose syrups made from wheat starch and that:	wheat	(a) wheat; and (b) if gluten is present - gluten.

Item	Column 1	Column 2	Column 3	Column 4
	<i>Food</i>	<i>Exemption</i>	<i>Required name for declarations other than declarations in a summary statement</i>	<i>Required name for declarations in a summary statement</i>
		(i) have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable; and (ii) have a gluten protein content that does not exceed 20 mg/kg; (c) alcohol distilled from wheat.		
4	Any of the following tree nuts:			
	almond		almond	tree nut
	brazil nut		brazil nut	tree nut
	cashew		cashew	tree nut
	hazelnut		hazelnut	tree nut
	macadamia		macadamia	tree nut
	pecan		pecan	tree nut
	pine nut		pine nut	tree nut
	pistachio		pistachio	tree nut
	walnut		walnut	tree nut
5	crustacea		crustacean	crustacean
6	egg		egg	egg
7	fish	isinglass derived from fish swim bladders and used as a clarifying agent in beer or wine	fish	fish
8	lupin		lupin	lupin
9	milk	alcohol distilled from whey	milk	milk
10	mollusc		mollusc	mollusc
11	peanut		peanut	peanut
12	sesame seed		sesame	sesame
13	soybean	(a) soybean oil that has been degummed, neutralised, bleached and deodorised; (b) soybean derivatives that are tocopherol or phytosterol.	soy, soya or soybean	soy

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1044 to make allergen information clearer and more consistent for consumers through the use of plain English allergen labelling. The Authority considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and has prepared a draft variation.

2. Purpose

The Authority has prepared variations to Standard 1.2.3 and Schedule 9 of the Code (the primary amendments) to improve the protection of the public health and safety of food-allergic consumers, by introducing requirements that make allergen information clearer and more consistent.

The Authority has also prepared amendments to Standards 1.1.1, 1.1.2, 1.2.4, and 2.9.5; and Schedule 10, which are consequential and related to the primary amendments.

Standard 1.2.3 of the Code requires mandatory declaration of the presence of certain substances in food which can cause severe allergic and other reactions. However, the Standard currently does not mandate how these declarations should be made or the terminology to use when making allergen declarations.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1044 includes two rounds of public comment following an assessment, targeted communication with key stakeholders, and the preparation of a draft Standard and associated assessment summaries.

A Regulation Impact Statement was not required because the proposed variations are likely to have a minor impact on business and individuals (see OBPR reference 25283).

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] varies Standard 1.1.1 by replacing the existing heading of Schedule 9 in subsection 1.1.1—2(2) with a new heading: ‘Mandatory advisory statements and declarations’ (see also **item [6.1]** below).

Item [2] varies Standard 1.1.2 by adding a definition for ‘required name’ in subsection 1.1.2—2(3).

‘Required name’ refers to the name of the food that must be used when making declarations in accordance with new Division 3 of Standard 1.2.3 (see **sub-item [3.5]**—section 1.2.3—5 below).

Item [3] varies Standard 1.2.3. As explained below, this item divides Standard 1.2.3 into the following Divisions:

- Division 1 containing section 1.2.3—1 and revised section 1.2.3—1A;
- Division 2 containing existing sections 1.2.3—2 and 1.2.3—3; and
- Division 3 containing a revised section 1.2.3—4 and new sections 1.2.3—5 to 1.2.3—8.

Sub-item [3.1] inserts a new heading: ‘Division 1 Preliminary’ after Note 2 to the Standard.

Sub-item [3.2] replaces existing section 1.2.3—1A with a revised section 1.2.3—1A.

Existing section 1.2.3—1A is redundant. It provided for transitional arrangements relating to the *Food Standards (Proposal P1026 – Lupin as an Allergen) Variation* which are no longer in force or required because the relevant transitional period has expired.

Revised section 1.2.3—1A includes a Note to the section setting out the following terms used in Division 3 of the Standard, which are defined in subsection 1.1.2—2(3) of the Code: ‘required name’ and ‘size of type’.

Sub-item [3.3] inserts a new heading: ‘Division 2 Mandatory statements’ after section 1.2.3—1A.

Sub-item [3.4] inserts a new heading: ‘Division 3 Mandatory declarations’ after section 1.2.3—3.

Sub-item [3.5] replaces the existing section 1.2.3—4 with a revised section 1.2.3—4 and new sections 1.2.3—5 to 1.2.3—8.

Revised section 1.2.3—4

Section 1.2.3—4 is the primary provision relating to mandatory declarations in relation to certain food and requires the declarations to be made in accordance with Division 3 of Standard 1.2.3.

Subsection 1.2.3—4(1) provides that, if a food to which section 1.2.3—4 applies is present in a food for sale, a declaration that that food is present must be made.

Subsection 1.2.3—4(2) provides that the declaration required by subsection (1) must be made in accordance with Division 3.

Subsection 1.2.3—4(3) provides that section 1.2.3—4 applies to a food that is listed in Column 1 of the table to S9—3 or to a derivative of such a food. These are referred to below as ‘relevant foods’.

Subsection 1.2.3—4(4) provides that section 1.2.3—4 does not apply to a food that is listed in Column 2 of the table to section S9—3 or to a derivative of such a food. This means that, if any of these foods or derivatives are present in a food for sale, a declaration that the food or derivative is present is not required by Division 3.

Subsection 1.2.3—4(5) clarifies that a relevant food may be present in a food for sale in any of the following ways:

- an ingredient or as an ingredient of a compound ingredient; or
- a substance used as a food additive, or an ingredient or component of such a substance; or
- a substance used as a processing aid, or an ingredient or component of such a substance.

The following terms used in subsection 1.2.3—4(5) are defined in Standard 1.1.2:

- ‘compound ingredient’;
- ‘used as a food additive’; and
- ‘used as a processing aid’.

New section 1.2.3—5

Division 3 imposes a requirement to declare the ‘required name’ of a relevant food (see below).

Section 1.2.3—5 sets out what is the required name for the purposes of that requirement.

Section 1.2.3—5 provides that the required name is:

- for declarations in a statement of ingredients—the corresponding required name(s) in Column 3 of the table to section S9—3 (paragraph 1.2.3—5(a));
- for declarations in a summary statement—the corresponding required name(s) in Column 4 of the table to section S9—3 (paragraph 1.2.3—5(b)) (further details about requirements relating to summary statements are provided in the explanations for sections 1.2.3—6 and 1.2.3—7 below);
- in specific other circumstances, for example, food sold to a caterer—the corresponding required name(s) in Column 3 of the table to section S9—3 (paragraph 1.2.3—5(c)).

New section 1.2.3—6

Subsection 1.2.3—6(1) provides that section 1.2.3—6 applies to declarations that are required by subsection 1.2.3—4(1) and made for the purposes of any of the following provisions in the Code:

- paragraph 1.2.1—8(1)(d) (related to foods required to bear a label);
- subsection 1.2.1—8(3) (related to portion packs of food);
- subparagraph 1.2.4—5(6)(b)(i) (related to compound ingredients); or
- paragraph 2.9.5—9(1)(d) (related to foods for special medical purposes).

Subsection 1.2.3—6(2) sets out how the above declarations must be made. That is, these declarations must be made by: listing the required name in the Statement of ingredients of the food for sale; and including a summary statement on the label of the food for sale.

A Note to subsection 1.2.3—6(2) explains that provisions related to statements of ingredients are set out in Standard 1.2.4.

Subsection 1.2.3—6(3) clarifies that, in the Statement of ingredients, the required name of the food to be declared must be listed separately for each ingredient that is or contains that food.

Subsections 1.2.3—6(4) and (5) set out how declarations must be made on foods for sale that do not have a Statement of ingredients due to the operation of subsection 1.2.4—2(2) or (3) of the Code. Subsection 1.2.3—6(4) exempts these foods for sale from the requirements imposed by subsection 1.2.3—6(2). Subsection 1.2.3—6(5) provides that, for these foods for sale, a declaration to which subsection 1.2.3—6(1) applies must instead be made by stating on the label of the food for sale the required name of the food to be declared.

New section 1.2.3—7

Section 1.2.3—7 sets out how a declaration made in accordance with subsection 1.2.3—6(2) must appear on a food for sale.

Subsection 1.2.3—7(1) sets out how a required name must be printed in a Statement of ingredients. The required name must be printed: in a bold font that provides a distinct contrast with any other text in the Statement of ingredients which is not a required name; and in a size of type that is not less than the size of type of the other text in the Statement of ingredients that is not a required name.

'Size of type' is defined in subsection 1.1.2—2(3) of the Code.

Subsection 1.2.3—7(2) sets out what a summary statement on the label of a food for sale must contain or state. The summary statement must commence with the word 'Contains' and then list the required name of each food to be declared.

Subsection 1.2.3—7(3) sets out where a summary statement must appear on the label of a food for sale. It must appear on the label directly below the Statement of ingredients for the food and be distinctly separated from the Statement of ingredients.

Subsection 1.2.3—7(4) sets out the format for a summary statement on the label of a food for sale. The summary statement must be printed in the same typeface and size of type as the text of the required name or names in the Statement of ingredients for that food for sale; and in a bold font that provides a distinct contrast with the background and the other text of the label of the food for sale.

Subsection 1.2.3—7(5) provides that a reference to a 'summary statement' in section 1.2.3—7 is to a summary statement required by paragraph 1.2.3—6(2)(b) (see above).

New section 1.2.3—8

Section 1.2.3—8 sets out declaration requirements relating to food not required to bear a label and foods sold to a caterer.

Subsection 1.2.3—8(1) provides that section 1.2.3—8 applies to declarations that are required by section 1.2.3—4(1) and made for the purposes of any of the following provisions in the Code:

- paragraph 1.2.1—9(3)(d) (related to information about a food not required to bear a label and sold from a vending machine, which must accompany or be displayed with the food);
- paragraph 1.2.1—9(7)(b) (related to information about a food for sale not required to bear a label, which may either be displayed with the food, or be made available to the purchaser on request) ; or
- paragraph 1.2.1—15(c) (related to information required to be on labelling for food sold to a caterer).

Subsection 1.2.3—8(2) provides that such declarations must be made by stating the required name of the food. No other additional requirements apply to these foods.

Item [4] varies Standard 1.2.4.

Sub-item [4.1] adds 'Subject to Division 3 of Standard 1.2.3' (with associated grammatical amendments), at the start of section 1.2.4—4.

Section 1.2.4—4 requires ingredients to be listed in a statement of ingredients by their common, descriptive or generic names. The effect of this amendment is to make these existing requirements subject to the new declaration requirements in Division 3 of Standard 1.2.3.

Sub-item [4.2] adds a Note after section 1.2.4—4 informing readers that Division 3 of Standard 1.2.3 provides for mandatory declarations of certain foods, including by declarations in a statement of ingredients.

Item [5] makes a consequential amendment to paragraph 2.9.5—10(2)(a) of the Code as a result of amendments to Schedule 9 by replacing 'the table in Schedule 9' with 'the table to section S9—3'. Paragraph 2.9.5—10(2)(a) operates specifically for the purposes of labelling requirements in relation to food for special medical purposes, which are set out in paragraph 2.9.5—9(2)(d). Paragraph 2.9.5—10(2)(a) only refers to 'the table in Schedule 9', which is the table to section S9—2 (Mandatory advisory statements). However, **sub-item [6.4]** of the variation (see below) inserts a second table into Schedule 9 for the purposes of new Division 3 of Standard 1.2.3 (Mandatory declarations). The amendment in **sub-item [6.4]** made the amendment in **item [5]** necessary to avoid any confusion.

Item [6] varies Schedule 9.

Sub-items [6.1] to [6.3] amend Schedule 9 as a consequence of amendments in **sub-item [6.4]**.

Sub-item [6.1] replaces the heading of Schedule 9 with 'Mandatory advisory statements and declarations'. This new heading reflects that, as a consequence of amendments in **sub-item [6.4]** of the variation (see below), the Schedule deals with both mandatory advisory statements and mandatory declarations.

Sub-item [6.2] amends Note 1 of the Schedule by including, in the Note, a reference to mandatory declarations for subsection 1.2.3—4(1). This clarifies that Schedule 9 lists mandatory advisory statements for the purposes of subsection 1.2.3—2(1) and paragraph 2.9.5—10(2)(a); as well as mandatory declarations for subsection 1.2.3—4(1).

Sub-item [6.3] amends section S9—1 as a result of the change of the heading of Schedule 9 in **sub-item [6.1]** (see above), by updating the name of the Schedule to include ‘Mandatory advisory statements and declarations’.

Sub-item [6.4] adds new section S9—3 to Schedule 9, which contains the following provisions related to the mandatory declarations requirements in Division 3 of Standard 1.2.3.

Subsection S9—3(1) states that a reference to ‘the table in section S9—3’ in Division 3 is a reference to the table to subsection S9—3(3).

Subsection S9—3(2) states that the definition of ‘fish’ in subsection 1.1.2—3(2) of the Code does not apply for the purposes of the table to subsection S9—3(3) (paragraph (a)) and that ‘fish’ in this table does not include crustacea and molluscs (paragraph (b)). This amendment is required because of the separate and distinct references to (and different declaration requirements) for ‘fish’, ‘crustacea’ and ‘molluscs’ in the table to subsection S9—3(3).

Subsection S9—3(3) sets out the table to this subsection, which has the following four columns.

Column 1: lists the food that must be declared under section 1.2.3—4 (see **sub-item [3.5]**—subsection 1.2.3—4(3) above).

Column 2: lists what food is exempted from the declaration requirements in section 1.2.3—4 (see **sub-item [3.5]**—subsection 1.2.3—4(4) above) .

Column 3: lists the ‘required name’ for the corresponding food in Column 1, for declarations other than declarations made in a summary statement. This includes declarations made in a statement of ingredients; and declarations made in relation to:

- food for sale that is not required to have a statement of ingredients on its label,
- food that is not required to bear a label, and
- food that is sold to caterers (see **sub-item [3.5]**—paragraphs 1.2.3—5(a) and (c) above).

Column 4: lists the ‘required name’ for the corresponding food in Column 1, for declarations made in a summary statement (see **sub-item [3.5]**—paragraph 1.2.3—5(b) above).

Item [7] varies Schedule 10 by amending the table to section S10—2.

The table to section S10—2 lists generic names of ingredients and any conditions for their use for the purposes of section 1.2.4—4 of the Code. Section 1.2.4—4 provides for ingredients to be identified in a Statement of ingredients by a generic name listed in table to section S10—2 (among other things).

Amendments to this table are related to the amendment made to section 1.2.4—4, which makes existing requirements in section 1.2.4—4 (ingredients to be listed their common, descriptive or generic names in a statement of ingredients) subject to the declaration requirements in Division 3 of Standard 1.2.3 (see **sub-item [4.1]** above).

Sub-item [7.1] omits the condition of use for ‘cereals’ from the table to section S10—2.

This amendment reflects the new declaration requirements in relation to a food for sale that contains an ingredient that is one of the following cereals—wheat, rye, barley, oats or spelt; or a hybridised strain of one of those cereals. That is, the required name of the cereal must be declared in the Statement of ingredients in accordance with Division 3 of Standard 1.2.3. The amendment removes the requirement under section 1.2.4—4 to also declare the *specific* name of the cereal in the Statement of ingredients.

Sub-item [7.2] amends the condition of use for ‘fats or oils’ in the table to section S10—2 to remove the conditions relating to:

- oil sourced from lupin, peanut, or sesame; and
- oil sourced from soybeans where the oil has not been degummed, neutralised, bleached and deodorised.

This amendment reflects the new declaration requirements in relation to a food for sale that contains an ingredient that is an oil and the source of the oil is lupin, peanut, sesame or soybeans (subject to any exceptions). That is, the required name of the source must be declared in the Statement of ingredients in accordance with Division 3 of Standard 1.2.3. The amendment removes the requirement under section 1.2.4—4 to also declare the *specific* name of the source in the Statement of ingredients.

Sub-item [7.3] omits the condition of use for ‘fish’ from the table to section S10—2.

This amendment reflects the new declaration requirements in relation to a food for sale that contain any ‘crustacea’ as an ingredient. That is, the required name for crustacean must be declared in the Statement of ingredients in accordance with Division 3 of Standard 1.2.3. The amendment removes the requirement under section 1.2.4—4 to also declare the *specific* name of the crustacea in the Statement of ingredients.

Sub-item [7.4] omits the whole entry for ‘nuts’ in the table to section S10—2.

This amendment reflects the new declaration requirements in relation to a food for sale that contains a nut as an ingredient. That is, the relevant required name must be declared in the Statement of ingredients in accordance with Division 3 of Standard 1.2.3. The amendment removes the requirement under section 1.2.4—4 to also declare the *specific* name of the nut in the Statement of ingredients

Sub-item [7.5] omits paragraph (a) of the conditions of use for ‘starch’ in the table to section S10—2. Paragraph (a) of the conditions of use relates to the source of the starch being one of the following cereals: wheat, rye, barley, oats or spelt; or a hybridised strain of those cereals.

This amendment reflects the new mandatory declaration requirements in relation to a food for sale that contains starch sourced from any of those cereals or a hybridised strain of those cereals. That is, the required name of the cereal must be declared in the Statement of ingredients in accordance with Division 3 of Standard 1.2.3. The amendment removes the requirement under section 1.2.4—4 to also declare the *specific* name of the cereal in the Statement of ingredients.

The only condition of use for ‘starch’ in the table to section S10—2 is that ‘starch’ may be used for any unmodified starch or any starch which has been modified by either physical means or enzymes.

Consequently, the numbering has also been omitted to reflect that there is only one condition of use for ‘starch’ in the table to section S10—2.

Transitional arrangements

The above variations will commence or take effect on the date of gazettal. See clause 3 of the instrument of variation (the instrument).

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the above variations. See subclause 4(1) of the instrument.

Clause 4 provides two transitional arrangements:

First, there is a general transitional arrangement where during a two year transition period commencing on the date of gazettal, a food product may be sold if the food product complies with either the Code as in force without the amendments made by the instrument; or the Code as amended by the instrument.

Second, there is a specific transitional arrangement where a food product that was packaged and labelled before the end of the general transition period may be sold for a specified period of time after the general transition period if the product complies with either the Code as in force without the amendments made by the instrument; or the Code as amended by the instrument.

The intent of these transitional arrangements is to assist in minimising the costs of complying with the new mandatory declaration requirements for industry while not unduly delaying exposure to the new declarations.