

1 March 2018
[40–18]

Call for submissions – Proposal P1044

Plain English Allergen Labelling (PEAL)

FSANZ has assessed a proposal for requiring mandatory food allergen declarations to be made clearer and in plain English. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the proposal.

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 that 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 and quicker 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) 12 April 2018

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

| | |
|---|-----------|
| EXECUTIVE SUMMARY | 1 |
| 1 INTRODUCTION | 2 |
| 1.1 REASONS FOR PREPARING THIS PROPOSAL | 2 |
| 1.2 SCOPE | 3 |
| 1.3 PROCEDURE FOR ASSESSMENT | 3 |
| 1.4 RISK ASSESSMENT | 3 |
| 2 BACKGROUND | 4 |
| 2.1 THE CURRENT STANDARDS | 4 |
| 2.2 VOLUNTARY FOOD INDUSTRY GUIDELINES..... | 5 |
| 2.3 INTERNATIONAL AND OVERSEAS REGULATIONS..... | 5 |
| 3 ISSUES | 6 |
| 3.1 CLARIFYING TERMINOLOGY FOR FISH, CRUSTACEA AND MOLLUSC DECLARATIONS | 6 |
| 3.2 CLARIFYING TERMINOLOGY FOR TREE NUT DECLARATIONS | 10 |
| 3.3 TERMINOLOGY ISSUES FOR THE DECLARATION OF WHEAT AND CEREALS CONTAINING GLUTEN.. | 12 |
| 3.4 POTENTIAL APPROACHES FOR INTRODUCING PEAL | 15 |
| 3.5 PLACEMENT OF ALLERGEN DECLARATIONS ON FOOD LABELS..... | 19 |
| 4 MATTERS ADDRESSED IN ACCORDANCE WITH THE FSANZ ACT | 22 |
| 4.1 SECTION 59 – COSTS AND BENEFITS IDENTIFIED AT THE FIRST CALL FOR SUBMISSIONS | 22 |
| 4.2 SECTION 59 – ANY RELEVANT NEW ZEALAND STANDARDS | 22 |
| 4.3 SECTION 59 – OTHER RELEVANT MATTERS..... | 22 |
| 4.3.1 SECTION 18 – FSANZ’S OBJECTIVES IN DEVELOPING, REVIEWING AND VARYING STANDARDS .. | 23 |
| 5 RISK COMMUNICATION | 24 |
| 5.1 CONSULTATION | 24 |
| 5.2 WORLD TRADE ORGANIZATION (WTO)..... | 24 |
| 6 LIST OF QUESTIONS FOR SUBMITTERS | 25 |
| 7 REFERENCES | 27 |

Supporting documents

The [following documents](#)¹ informed the assessment of this proposal and are available on the FSANZ website:

- SD1 Safety Risk Assessment
- SD2 Consumer understanding, attitudes and behaviour in relation to food allergen labelling

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

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 the mandatory declaration of the presence of certain substances in food which can cause severe allergic and other reactions (referred to collectively in this paper as allergens). However, the Standard does not mandate how these declarations should be made or what terminology should be used.

FSANZ has previously identified a lack of clarity in the Code on how to declare certain allergens, which is resulting in the use of unclear terminology when these allergens are declared. These issues relate to:

- fish, crustacea and molluscs
- tree nuts
- cereals containing gluten.

From previous stakeholder consultations and a qualitative survey of New Zealand food labels, FSANZ has also identified other issues that may sometimes arise with allergen declarations.

The lack of clarity in the allergen declaration requirements in the Code mean food allergen sensitive consumers (or those who purchase foods for these consumers) may not always be able to use allergen declaration information to make informed food choices. This in turn creates risks for the health and safety of these consumers.

The purpose of this proposal is to consider variations to the Code that may be necessary to address the above risks to food allergen sensitive consumers. In particular, FSANZ is considering variations to the Code to provide clarity in allergen declaration requirements, and to require the use of plain English allergen labelling (PEAL) as a means of improving allergen information for consumers. PEAL is considered to be the use of clear and unambiguous terms in allergen declarations, primarily by reference to the specific source for the allergen.

For this proposal FSANZ has to date undertaken two assessment activities to explore issues associated with PEAL, consisting of:

- an assessment of safety issues relating to food allergy associated with fish, crustacea and molluscs; tree nuts; and cereals (see Supporting Document 1) including seeking advice from FSANZ's Food Allergy and Intolerance Scientific Advisory Group (FAISAG).
- a preliminary assessment of consumer understanding, attitudes and behaviour in relation to food allergen labelling (see Supporting Document 2).

FSANZ's preliminary view, based on the available evidence, is that:

- the status quo (Option 1) appears not to be an option that would address the risks to food allergen sensitive consumers mentioned above; and
- varying the Code (Option 2) appears warranted to clarify allergen declaration requirements for fish, crustacea, molluscs, tree nuts and cereals containing gluten, and to address other issues with the terminology used to declare allergens more generally.

The particular manner or form of any such variations to the Code has yet to be decided. Potential approaches for varying the Code are outlined throughout this report.

This proposal is being assessed under the Major Procedure requirements of the FSANZ Act, which require two rounds of public consultation. This is the first round of public consultation. Submitters are therefore invited to provide comment on the issues raised and potential approaches discussed. To facilitate submitter comment, a series of questions are located after each relevant section in the report, and are listed together at Section 6 of this report.

Information received in response to this consultation will inform any proposed draft variation of the Code, which would then be provided for comment at the next round of public consultation.

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 the mandatory declaration of the presence of certain substances in food which can cause severe allergic and other reactions (referred to collectively in this paper 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 that can lead to unclear allergen declarations. The first review *W3 – Review of the regulatory management of food allergens* (the W3 Review) (FSANZ, 2010) was completed in 2010, and identified potential issues specifically with the requirements to declare fish, crustacea and molluscs; tree nuts; and cereals containing gluten.

FSANZ conducted a further review *W1070 – Plain English Allergen Labelling* (W1070 review) in 2015 to explore how terminology was being used to declare allergens on Australian and New Zealand foods. This review included a qualitative survey of New Zealand food labels and targeted consultation (FSANZ, 2016). The review found issues with allergen declarations being either too vague (e.g. 'gluten containing cereals' rather than 'wheat'), inaccurate (e.g. 'fish' for foods containing molluscs), or too technical (e.g. 'sodium caseinate' without an indication it is from a dairy source). The W1070 Review concluded there is no consistency in how allergens are declared, due to variability in the terminology used across different foods (in the statement of ingredients and in the 'contains' statement) making identification of allergenic ingredients difficult. The W1070 Review also identified variability in the use of the 'contains' statement given it is voluntary, and difficulty in relating terminology used in the 'contains' statement to ingredient names.

The lack of clarity relating to allergen declarations under Code provisions means food allergen sensitive consumers (or those who purchase foods for these consumers) may not always be able to use allergen declaration information to make informed and safe food choices. This creates risks for the health and safety of these consumers, as well as making it harder for allergen sensitive consumers to find allergen information, and potentially a loss of confidence in allergen declarations in general.

Therefore, the purpose of this proposal is to consider variations to the Code that may be necessary to address the above risks to food allergen sensitive consumers. In particular, FSANZ is considering variations to the Code to provide clarity in allergen declaration requirements, and to require the use of plain English allergen labelling (PEAL) as a means of improving allergen information for consumers. PEAL is considered to be the use of clear and unambiguous terms in allergen declarations, primarily by reference to the specific source of the allergen.

1.2 Scope

Proposal P1044 will consider changes to the Code to address identified issues with the clarity of the existing allergen declaration requirements. It will also consider whether changes to the Code are required to ensure allergen declarations are made clearly and in plain English. The scope includes allergen declarations for both packaged food and food not required to bear a label, although FSANZ acknowledges there may be fewer issues associated with the latter (see Section 2.1.2 about food not required to bear a label).

The following matters are out of the scope:

- Consideration of new allergens requiring mandatory declaration in the Code.
- Formatting issues. For example, the emboldening of allergen declarations, which the Australia New Zealand Ministerial Forum on Food Regulation (the Forum) has considered in response to recommendation 47² of *Labelling Logic: Review of food labelling law and policy* (Blewett et al. 2011). In 2016, the Forum agreed no further action was required on this recommendation.
- Issues relating to the unintended presence of food allergens, specifically precautionary allergen labelling (PAL) e.g. '*May be present: allergen x, allergen y...*'.

1.3 Procedure for assessment

This proposal is being assessed under the Major Procedure requirements of the FSANZ Act, which require two rounds of public consultation. Any draft variation of the Code will be provided for comment at the next round of public consultation. Following this, the FSANZ Board will consider a final draft variation of the Code, and if approved, this will be provided to the Forum for their consideration.

1.4 Risk assessment

Two risk assessment activities have been undertaken by FSANZ at this stage of Proposal P1044 to explore the issues associated with introducing PEAL. These activities are:

- 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.
- a preliminary assessment of consumer understanding, attitudes and behaviour in relation to food allergen labelling.

The details of the risk assessment activities can be found in Supporting Documents 1 and 2. The findings of the risk assessment are also summarised throughout Section 3 this report as they apply to the various issues under consideration.

² Recommendation 47 from *Labelling Logic* states: *warning and advisory statements be emboldened and allergens emboldened both in the ingredients list and in a separate list.*

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>.

2 Background

2.1 The current 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 the specific foods and substances that 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). It should be noted that although a declaration of the food or substance is required, there is no requirement about the where declarations are to be made on the label of a packaged food.

The foods and substances requiring mandatory declaration are cereals containing gluten, crustacea, egg, fish, milk, peanuts, soybeans, sesame seeds, tree nuts, lupin (noting there are specific foods exempted as outlined below) and added sulphites in amounts of 10 mg/kg or more. Lupin was added to this list on 25 May 2017. Food businesses have until 26 May 2018 to meet mandatory allergen declaration requirements for any foods containing lupin.

Subsection 1.2.3—4(1) includes some exemptions to the declaration requirements, where FSANZ has assessed certain foods and ingredients as safe for allergies to wheat, soy, milk, tree nuts or fish (for example, in relation to milk, alcohol distilled from whey).

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

For food not required to bear a label (e.g. food for sale displayed in an assisted service display cabinet), Standard 1.2.1 requires the declaration of the presence of allergens to either be displayed in connection with the display of the food, or provided to the purchaser upon request (subsection 1.2.1—9(6)).

2.1.3 Standard 1.2.4 – statement of ingredients

Standard 1.2.4 – Information requirements – statement of ingredients sets out the requirements for how ingredients must be declared in a statement of ingredients. Ingredients must be declared by 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 Schedule 10.

Schedule 10 lists the generic names that can be used and includes conditions for the use of certain generic names. This provides clarification on the terminology to be used when certain generic names are used in the statement of ingredients.

The generic names and their conditions in Schedule 10, relevant to allergens, are:

- ‘cereals’ and ‘starch’, where the specific name of the cereal must be listed if the cereal is wheat, rye, barley, oats or spelt or a hybridised strain of one of these cereals
- ‘nuts’, where the specific name of the nut must be declared
- ‘fish’, where the specific name of a crustacea ingredient must be declared
- ‘fats’ or ‘oils’, where 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).

2.2 Voluntary food industry guidelines

The Australian Food and Grocery Council (AFGC) has developed a *Food Industry Guide to Allergen Management and Labelling* (AFGC Guide) (AFGC 2007) to assist the food industry in making allergen declarations. This guide has also been adopted by the New Zealand Food and Grocery Council. The AFGC Guide sets out a recommended approach to allergen labelling consisting of:

- declaring in bold, allergenic foods and substances and their derivatives in the statement of ingredients, and
- an 'allergen summary statement' (referred to hereafter in this report as a 'contains' statement). A 'contains' statement lists the allergens present in the food, and is separate to the statement of ingredients; e.g. 'Contains: allergen x, allergen y...').

The AFGC Guide provides recommended allergen labelling formats (which cover the use of bold text) for industry to adopt, legibility, terms to be used for declaring allergens, and indicates the 'contains' statement should appear directly below the statement of ingredients on a separate line. The AFGC Guide also contains guidance for the display of voluntary PAL statements (noting they are out of scope for this proposal).

With respect to the terms to be used in declarations, the AFGC Guide recommends:

- allergens must be declared using plain English terms consistent with the Code
- the gluten source (grain source) is qualified in the statement of ingredients at all times, and the 'contains' statement can either include the name of each of the source grains or use the phrase 'gluten containing cereals'. If only one gluten-derived ingredient is declared in the statement of ingredients, then the recommendation is for the summary statement to include the specific name of the source grain.
- if the product contains tree nuts, the specific name of the tree nut(s) should be declared in the statement of ingredients when added as a direct ingredient, whereas the 'contains' statement can use either the specific name of the tree nut or the general term 'tree nuts'. The AFGC Guide recommends against the use of the term 'nuts'.
- if the label size or other variables do not permit the use of the recommended labelling format, then qualifying allergenic substances (except for gluten) in the statement of ingredients is optional when a 'contains' statement is present. However, allergenic substances should always be qualified in the statement of ingredients when a 'contains' statement is not present (e.g. 'vegetable oil (soy)' or 'Soybean oil').

2.3 International and overseas regulations

FSANZ has considered international and overseas standards and regulations of Codex Alimentarius, the European Union, Canada and the United States of America for allergen labelling. These are:

- CODEX STAN 1-1985 General Standard for the Labelling of Prepackaged Foods (Codex, 1985)
- European Union Regulation 1169/2011 (Council of the European Union 2011) on the provision of food information to consumers
- Canadian Food and Drug Regulations (C.R.C., c. 870) (Department of Justice, 2013)
- United States Code Title 21 Food and Drugs, Chapter 9 – Federal Food, Drug and Cosmetic Act (Office of Law Revision Counsel, 2014a and 2014b), which incorporates the requirements in the Food Allergen Labelling and Consumer Protection Act 2004.

Subsequent sections and tables in this report describe how the Australian and New Zealand allergen labelling requirements compare with these international and overseas requirements.

3 Issues

3.1 Clarifying terminology for fish, crustacea and mollusc declarations

3.1.1 Identified issues

Standard 1.2.3 includes requirements to declare 'fish' and 'crustacea'. It does not include a separate requirement to declare molluscs. Additionally, the Code includes a definition for 'fish' at subsection 1.1.2—3(2) of *Standard 1.1.2 – Definitions used throughout the Code*:

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

However, this definition 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, molluscs would therefore need to be declared, but could be declared as 'fish'. While there is a separate declaration requirement for 'crustacea' in Standard 1.2.3, there is still the potential for the food industry to rely on the definition for 'fish' and use this term to declare crustacea.

The lack of clarity in finfish / crustacea / mollusc declarations prompted FSANZ to investigate this issue further in the W1070 Review (FSANZ 2016b). The qualitative survey of New Zealand labels undertaken for the W1070 Review found some labels declared individual finfish names in the statement of ingredients, and either referred to 'fish' in a 'contains' statement or did not include a 'contains' statement. For some foods, individual mollusc ingredients were listed in the statement of ingredients and the terms 'fish' or 'crustacea' were used in the 'contains' statement. In many cases, foods with crustacean or mollusc ingredients referred to the name of the crustacea (e.g. prawn, shrimp) or mollusc (e.g. clam, mussel). However, there was variability in the information presented in the 'contains' statement, if used.

While the qualitative survey did not find any labels referring to 'fish' without further clarification that the ingredient(s) were finfish or molluscs, FSANZ notes this could potentially occur. Consumers who are allergic to either finfish, molluscs and/or crustacea may find it difficult to make safe and informed food choices if 'fish' is declared on the label and no additional information is provided on the type of fish.

The W1070 Review recommended Standard 1.2.3 be clarified so that molluscs or products of molluscs in a food should be declared separately from 'fish'. It also recommended further clarity regarding what constitutes 'fish'/'finfish', 'crustacea' and 'molluscs' for allergen declaration purposes.

In addition to the above issues, FSANZ notes there are currently no requirements in the Code to declare the specific name of the finfish or mollusc. As discussed in Section 2.1.3, the conditions in Schedule 10 for using the generic ingredient name 'fish' require the specific name of the crustacea (if present) to be declared. The conditions in Schedule 10 only apply to ingredient labelling requirements and only if the generic ingredient name 'fish' is used.

3.1.2 International and overseas regulations

Table 1 (below) provides a comparison between the Australia/New Zealand and some international regulatory approaches for declaring fish, crustacea and molluscs.

Table 1: Comparison of terminology requirements for fish, crustacea and molluscs

| Regulation | Terminology requirements |
|--------------------------|--|
| Australia/New Zealand | General requirement to declare 'fish' and 'crustacea'. The definition of fish refers to a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish. |
| Codex | General requirement to declare fish and crustacea. |
| European Union | Requires a clear reference to the <u>name</u> 'fish', 'crustacea' or 'mollusc' (as listed in Annex II of the regulations) |
| United States of America | Requires food labels to declare the name of the species of fish and crustacean. Guidance material (Food and Drug Administration, 2006) indicates 'molluscan shellfish' (such as oysters, clams, mussels or scallops) are not considered major food allergens requiring declaration in the United States of America. |
| Canada | Requires the 'name' of the fish, crustaceans or shellfish (shellfish refers to molluscs) to be declared. |

3.1.3 Evidence about mollusc allergy

FSANZ's W3 Review identified that molluscs are allergenically distinct from fish, but was equivocal on whether they are allergenically distinct from crustaceans. Given this review finding, FSANZ has sought to characterise mollusc allergy, and identify the taxonomic classes of molluscs specifically implicated in this allergy. This assessment of mollusc allergy can be found in Supporting Document 1, and is summarised below.

The scientific and clinical literature confirms three classes of molluscs are relevant in the context of food allergy: gastropods (e.g. abalone), bivalves (e.g. oysters, scallop) and cephalopods (e.g. squid, octopus). Allergic reactions to all three classes have been reported. While other mollusc classes such as polyplacophora (chitons) and scaphopoda (tusk shells) are sometimes consumed in other countries, they are not commonly consumed in Australia and New Zealand and no reports of food allergy relating to these species were found. It is not clear if this is due to relatively low levels of consumption or a lack of allergenicity.

Seafood allergy is relatively common in Australia and New Zealand and is a major contributor to food-associated anaphylaxis. However, few data are available regarding the prevalence of allergy to specific types of seafood, including molluscs. One study of Australian seafood allergy patients reported the incidence of mollusc allergy in this group to be at five percent. The opinion of the FAISAG was although specific information on the prevalence of mollusc allergy is not available, mollusc allergy is of clinical significance in Australia and New Zealand. Whilst mollusc allergy is relatively uncommon in children, cases of anaphylaxis following consumption of molluscs such as calamari have been seen. The FAISAG also considered mollusc allergy may be more of an issue for children of ethnic minority groups for whom mollusc consumption is higher than among Caucasian children. Significant late-onset mollusc allergy is also seen in adults.

FSANZ has also reviewed the extent of cross-reactivity and co-allergy between crustacea and mollusc allergies as part of the assessment of mollusc allergy. There is a theoretical basis and some evidence of cross-reactivity or co-sensitisation between molluscs and crustaceans based on serological testing, self-reporting and clinically diagnosed allergy. However, overall the available data suggest the extent of clinically relevant cross-reactivity is likely to be relatively low.

FAISAG members noted the clinical advice provided to patients with crustacean allergy regarding consumption of molluscs is likely to vary between clinical practices. Advice on seafood allergy for patients, consumers and carers issued by the Australasian Society of Clinical Immunology and Allergy (ASCIA) states while those allergic to seafood from one group (e.g. crustaceans) can usually tolerate those from another (e.g. molluscs), this cannot be guaranteed without specific allergy testing (ASCIA, 2014a).

3.1.4 Potential approaches for clarifying how fish, molluscs and crustacea are to be declared

FSANZ has given consideration as set out below to potential approaches for clarifying the Code on how fish, molluscs and crustacea are to be declared.

1. Require 'molluscs' to be declared separately from 'fish'

FSANZ is of the view there is a case for a separate mollusc declaration requirement for molluscs (and their products) under section 1.2.3—4 of the Code. This position is based on the safety assessment finding that 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. Additionally, molluscs and crustacea are allergenically distinct from finfish. We also note FAISAG members were of the view mollusc allergy is clinically significant within Australia and New Zealand.

A separate mollusc declaration requirement aligns with European and Canadian regulations, in so far as Canada requires separate declaration for 'shellfish' (i.e. molluscs).

In addition to the potential approach described above, FSANZ acknowledges the collective term 'shellfish' is being used in the community. However, this term could refer to both crustacea and molluscs, which is inconsistent with the intent of declaring these allergens separately. As such, FSANZ is of the view that the term 'shellfish' should not be used for declaring crustacean or molluscs. However, any changes relating to the use of the term 'shellfish' have not been proposed at this stage, as they are subject to consideration of introducing PEAL into the Code (see Section 3.4).

2. Add further clarity to how 'fish', crustacea and molluscs have to be declared

FSANZ notes the definition of 'fish' in Standard 1.1.2, 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 on food labels. Potential approaches to clearly distinguish between these categories could include specifying in the Code that 'fish' means 'finfish', or to require 'finfish' to be declared instead of 'fish'. Either of these approaches, combined with declaration requirements to separately declare molluscs and crustacea, would facilitate informed choice for all seafood allergic consumers. Further, these approaches would assist in clarifying that the broad definition of 'fish' in Standard 1.1.2 would no longer apply to allergen declarations.

Another potential approach would be to continue with the requirement to declare 'fish' as it is currently listed in the Code. This approach aligns with EU regulations. However, it is possible consumers allergic to either molluscs or crustacea may not understand what is captured by 'fish' (if molluscs and crustacea were not present in the food) and the term 'fish' was not further qualified. Further, there may be some parts of the food industry who continue to rely on the general 'fish' definition in Standard 1.1.2, even if all three seafood categories were required to be declared separately as allergens in Standard 1.2.3.

FSANZ notes the approach to fish, crustacea or mollusc declaration requirements in the United States of America and Canada is to specify the name of the fish, crustacea or mollusc (i.e. the species) in declarations. However, FSANZ is not proposing to adopt these declaration requirements. because:

- The safety assessment has identified parvalbumins are major allergic proteins of concern across all finfish allergies and there is clinical cross-reactivity to multiple fish in individuals with fish allergy.
- Consumers who are allergic to finfish, crustacea and/or mollusc may not readily recognise certain less common species of foods from these categories.
- Such requirements could be onerous for the food industry and extend the statement of ingredients if multiple finfish, crustacea or mollusc species are present in a food.

Additionally, FSANZ is not proposing for any of the above approaches to include definitions of finfish, molluscs or crustacea for the purposes of allergen declarations in the Code. The ordinary dictionary definitions for these terms would apply.

3. Clarify Schedule 10 requirements for the generic ingredient name 'fish'

Section S10—2 of Schedule 10 sets out conditions for the use of the generic ingredient name 'fish', where the specific name of the crustacea must be declared if the generic name is being used for these ingredients. The reason for this requirement is that the generic name 'fish' was originally introduced during *Proposal P143 - Assessment of Provisions for the Statement of Ingredients* to reflect the inclusion of 'shellfish' in the definition for 'fish' (Standard 1.1.2). A crustacea allergen declaration requirement was introduced into the Code (during Proposal P161) after the generic name provisions had been finalised, and so a decision was made to clarify the use of the generic name 'fish' for crustacean ingredients rather than restrict the ingredients that could use the name.

However, this existing generic 'fish' name requirement is inconsistent with the potential approaches FSANZ has proposed above, and with the evidence showing fish, mollusc and crustacea are implicated in separate allergies. It is also inconsistent with FSANZ's view that specific species for finfish, crustacea and molluscs do not need to be declared.

FSANZ is interested in stakeholder views about how Schedule 10 could be clarified to prevent inconsistencies between ingredient labelling requirements and allergen declaration requirements. We will give further consideration to exactly how these ingredient naming requirements should be revised once a final approach to declaring fish, crustacea and molluscs has been determined.

Questions for submitters:

1. Do you agree there should be a separate declaration requirement in Standard 1.2.3 for molluscs?
2. How should finfish be declared on food labels? Should Standard 1.2.3 require a declaration of 'fish' or 'finfish'?

For questions 1 and 2, please provide your reasons for or against these proposed approaches, including comments on the costs to industry and trade considerations. If you do not support an approach(es), then please describe any alternatives that could be used.

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

3.2 Clarifying terminology for tree nut declarations

3.2.1 Identified issues

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. 'Tree nuts' are not defined in the Standard.

Stakeholder feedback to the W3 and W1070 Reviews highlighted that Standard 1.2.3 is unclear to some food manufacturers about which individual tree nuts are captured by the term 'tree nuts', and they are therefore uncertain about how and what to declare for 'tree nuts'. The reference to 'nuts' in Schedule 10 may also be adding to this uncertainty.

The W1070 Review also found the use of the collective term 'tree nuts' on food labels was problematic, because there is no means of identifying the specific tree nut source (e.g. almond or pine nut) without further information. Ordinarily this information would be available in the statement of ingredients, but the qualitative label survey of the W1070 Review found this was not always the case. The W1070 Review recommended the requirements in Standard 1.2.3 need to be clearer and the presence of individual tree nuts should be declared.

The targeted consultation for the W1070 Review also raised the issue of whether shea nuts and illipe nuts (types of tree nuts) are associated with allergic reactions, and if species of coconut other than *Cocos nucifera* (which is exempt from the tree nut declaration requirement) cause allergic reactions.

3.2.2 International and overseas regulation

The international, overseas and Australia/New Zealand regulatory approaches for declaring tree nuts are summarised in Table 2 below.

Table 2: Summary of terminology requirements for tree nut declarations

| Regulation | Terminology requirements |
|--------------------------------|--|
| Australia / New Zealand, Codex | General requirement to declare 'Tree nuts' and 'tree nut products', with no list of tree nuts requiring declaration, and no specific reference to the terminology to be used. |
| European Union | <p>The specific tree nuts requiring declaration are listed in Annex II of the EU regulations. A clear reference to the name of the tree nuts listed in Annex II (the specific source) must be indicated.</p> <p>Guidance provided by the European Commission states <i>where ingredients or processing aids derived from nuts listed in Annex II have been used, the ingredient has to be indicated with a clear reference to the specific name of the nut. For example: flavourings (almond)</i> (European Commission 2017).</p> <p>Annex II lists the following nuts: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts.</p> |
| United States of America | The specific type of tree nut must be declared, although no list is given of the tree nuts to declare except for three examples (almonds, pecans, walnuts). However, United States Food and Drug Administration guidance (Food and Drug Administration, 2006) contains a list of 19 tree nuts. This guidance lists almonds, pecans, walnuts, pine nut, hazelnut, cashew, Brazil nut, pistachio, macadamia, beech nut, butternut, chestnut, chinquapin, coconut, ginko nut, hickory nut, lichee nut, pili nut, and shea nut. |
| Canada | <p>Specifically lists nine tree nuts as food allergens to be declared. The source of these food allergens must be shown on the label, e.g. 'almonds'.</p> <p>The nine tree nuts requiring declaration are: almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts.</p> |

3.2.3 Evidence underpinning tree nut allergy

As part of the W3 Review, the FAISAG previously gave advice on which particular tree nuts are associated with allergies in Australia and New Zealand. These (nine) tree nuts are: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut.

For this proposal, FSANZ has further investigated whether there is any new information that would change this previous advice, and has sought updated advice from the FAISAG as detailed in Supporting Document 1. Clinically defined food allergy, clinical cases or positive responses to oral food challenges in Australia and/or New Zealand have been reported in the scientific literature for all nine of the tree nuts previously identified as being important allergens. No new information indicating a need to amend the list of tree nuts was identified. While a small number of cases of anaphylaxis have been seen following consumption of other tree nuts such as chestnuts, candle nuts and marking nuts, these are very rare.

FSANZ has also reviewed the scientific literature on cross reactivity of tree nut allergies. Clinical responses to more than one tree nut have been reported to occur in up to a third of allergic individuals, and the incidence of reactions to multiple nuts may be even higher. Some groups of strongly cross-reacting tree nuts have been identified, with the strongest reactions being found between: a) walnut and pecan; and b) cashew and pistachio. Clinical confirmation of a lack of cross-reactivity between specific tree nut types has not been reported. It has been suggested pine nuts may not cross-react with other tree nuts, however this has not been confirmed clinically to date.

FSANZ's safety assessment has concluded there is little evidence of allergenicity to less commonly consumed tree nuts such as nangai nuts, shea nuts and illipe nuts. However, this conclusion may change if there is greater consumption of these nuts in the future.

3.2.4 Proposed approach

Given the issues identified and the findings of the risk assessment, it is FSANZ's preliminary view there should be a clear requirement in Standard 1.2.3 to specifically declare each of the nine tree nuts implicated in food allergy. This 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 EU, the US and Canada.

Question for submitters:

Please provide the reasons for your views when responding to the following question.

4. Do you agree with FSANZ's preliminary view that the nine individual tree nuts associated with food allergy should be required to be specifically declared?
 - What would be the impacts of this requirement for industry (e.g. costs and trade considerations) and consumers?
 - Would this approach offer sufficient clarity in the Code with regard to which tree nuts / nuts should be declared?

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

3.3.1 Identified issues

The declaration requirements in Standard 1.2.3 do not distinguish between cereals associated allergies and cereals associated with gluten intolerance conditions (such as 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 introduction of Standard 1.2.3 into the Code occurred in 2000 through *Proposal P161 - Review of the declaration of specific labelling statements on packaged food*. The Full Assessment Report of Proposal P161 indicated the intent of the requirements of subparagraph 1.2.3—4(1)(b)(i) was to mandate the declaration of the source of cereal ingredients if they are wheat, rye, barley, oats or their hybridised strains. Proposal P161 stated:

The inclusion of cereals that contain gluten in the list of foods that may cause severe adverse reactions is seen to serve two purposes. It will require that wheat will always be declared. Wheat has been implicated as the cause of severe adverse reactions. It will also require wheat and other grains that contain gluten to be declared. Gluten free and low gluten foods are available in the market place specifically targeted at people with coeliac disease and dermatitis herpetiformis. However, general food stuffs may contain gluten containing cereals with no indication of the gluten content and no indication of the types of cereals used.

FSANZ notes the current wording of the 'cereals containing gluten' declaration requirement may not make the above intent clear, and that this may have led to potential confusion within the food industry on how to comply with this requirement, resulting in variable and unclear labelling practices.

The AFGC Guide suggests the term ‘gluten containing cereals’ can be used in the ‘contains’ statement if more than one ‘gluten derived ingredient’ (i.e. cereals containing gluten or products of these foods) is present in the product. However, the W1070 Review identified that some food manufacturers are using the term ‘gluten’ and that the terms ‘gluten’ and ‘cereals containing gluten’ are being used regularly in the ‘contains’ statement on foods, without any additional reference to the individual cereal. None of the above labelling practices are adequate for wheat allergic individuals, as they are not specific enough for identifying wheat in the food, although a declaration of gluten could be helpful to individuals with gluten intolerance conditions.

3.3.2 International and overseas regulations

Table 3 summarises the different international regulatory approaches for declaring cereals that contain gluten, and how they compare with the approach in Australia and New Zealand.

Table 3: Comparison of approaches for declaring cereals containing gluten

| Regulation | Terminology requirements |
|---------------------------------|---|
| Codex and Australia/New Zealand | Require a declaration of cereals containing gluten, namely wheat, rye, barley, oats, spelt or their hybridised strains. No further clarification on how the declaration is to be made is provided. |
| European Union | Requires a clear reference to the name of the substance or product (as listed in Annex II). Annex II lists cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains. Guidance provided by the European Commission (2017) states <i>In the case of cereals containing gluten listed in Annex II: where ingredients are produced from cereals containing gluten, they have to be declared under a name making a clear reference to the specific type of the cereal, i.e. wheat, rye, barley, oats. For example: barley malt vinegar, oats flakes.</i> |
| Canada | Requires the source of the food allergen (i.e. wheat and/or triticale) and the source of gluten (which is from barley, oats, rye, triticale, wheat or a hybridised strain) to be declared. |
| United States of America | Requires a declaration of ‘wheat’. Does not require the presence of other cereals containing gluten to be declared (e.g. rye, barley). |

3.3.3 Evidence underpinning cereal allergies

FSANZ’s scientific assessment undertaken during Proposal P161 confirmed that wheat is a food allergen of clinical significance for the Australian and New Zealand populations, and that it had been implicated as the cause of severe adverse reactions in Australia and New Zealand. Since Proposal P161, FSANZ has 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 2016a).

However, FSANZ has not previously assessed the evidence to establish whether rye, barley, oats and spelt are also IgE mediated allergens of clinical significance in Australia and New Zealand. Similarly, FSANZ has not specifically considered the allergenicity of wheat hybrids (such as triticale) for wheat allergic individuals. Therefore, as part of this proposal, FSANZ has reviewed the scientific literature to determine whether rye, barley, oats and wheat hybrids are IgE-mediated food allergens, and if so, whether these cereal allergies are clinically significant in Australia and New Zealand. The findings of this literature review are provided in Supporting Document 1.

In summary, the review found food allergies to rye, barley and oats can occur and are 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.

However, there is a lack of data regarding the prevalence of allergy to rye, barley and oats in Australia and New Zealand. FAISAG members advised that domestic cases of rye and barley allergy do occur, but these are uncommon. Oat allergy is very rare and problems are usually due to cross-contamination with other cereals. The FAISAG noted most patients with wheat allergy can eat rye and barley.

FAISAG members advised that clinical advice to patients with allergy to rye, barley or oats would generally be to avoid foods containing gluten, and because 'gluten containing cereals' are already identified on labels, the specific declaration of rye, barley and oats as allergens was not considered necessary. Advice to patients, consumers and carers on dietary avoidance for wheat allergy issued by ASCIA states that approximately 20 percent of individuals with wheat allergy may be allergic to other cereals such as barley, rye or oats. ASCIA recommends individuals with wheat allergy should ask their allergy specialist if they must avoid all gluten containing foods or just wheat (ASCIA 2014b).

FSANZ has been unable to identify evidence on the prevalence of allergies associated with wheat hybrid strains in Australia or New Zealand. However, the safety risk assessment has identified general scientific agreement that hybrid strains of wheat and other cereals such as triticale (a hybrid of wheat and rye) share antigenic potential with wheat. FAISAG members noted patients with wheat allergy are advised to avoid hybrids of this cereal.

3.3.4 Possible approaches for clarifying the declaration requirement for cereals containing gluten

FSANZ has confirmed that wheat remains an allergen of clinical significance, and that hybrid cereal strains are as potentially allergenic as their parent strains. Therefore, an approach requiring the separate declaration of wheat as well as wheat hybrid strains (e.g. triticale) is considered necessary to ensure the safety of sensitive individuals. This would mean that wheat and its hybrids should be declared irrespective of the presence of gluten in the food. FSANZ notes the requirement to separately declare wheat and wheat hybrids is consistent with the original intent of Proposal P161, which was for the presence of wheat to be declared as a means of addressing the only cereal allergy of clinical significance identified at that time (i.e. wheat allergy). FSANZ is of the view that wheat continues to be the only cereal of relevance for allergies, as the safety assessment has concluded that allergies to barley and rye are uncommon in Australia and New Zealand, and oat allergy is very rare. A separate wheat and wheat hybrid declaration requirement aligns with the United States and Canadian regulatory approaches, which have declaration requirements specifically for wheat and triticale as food allergens.

The second part of the original intent from Proposal P161 was that the cereal sources of gluten (i.e. wheat, barley, rye, oats and spelt) would be declared as a means of addressing the information needs of individuals with Coeliac disease and dermatitis herpetiformis. The words *cereals containing gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains* were intended by Proposal P161 to address this need. However, FSANZ recognises a lack of clarity with the current wording of the Code may not be achieving this original intent, and may have led to potential confusion on whether 'cereals containing gluten' or 'gluten' should be declared, or if the named individual cereals must always be declared.

FSANZ's preliminary view is that clarity is needed in Standard 1.2.3 so that declarations for consumers with a gluten intolerance condition are clearer. The original intent was that the individual cereal sources of gluten (e.g. wheat, rye, barley, oats and spelt and their hybridised strains) are declared. However, submissions to the W1070 Review commented

that the terms 'cereals containing gluten' or simply 'gluten' would also be helpful for gluten intolerant consumers if the source of the cereal could still be identified.

FSANZ is interested in submitter views on clarifying the intent in Standard 1.2.3 for declaring wheat and other cereals containing gluten, and in particular whether there are alternate approaches that could address the different information needs of wheat allergic and gluten intolerant consumers.

Questions for submitters:

Please provide the reasons for your views when responding to the following questions.

5. Do you support the approach of clarifying the original intent of Standard 1.2.3 by requiring wheat and its hybrids to always be declared irrespective of the gluten content in a food?
6. Would clarifying the intent of Standard 1.2.3, so that individual sources of gluten-containing cereals are declared provide adequate information about the presence of gluten in a food for gluten intolerant consumers?
7. Are there other approaches (if any) that could be used for declaring 'cereals containing gluten', which would provide information for both wheat allergic and gluten intolerant consumers?

3.4 Potential approaches for introducing PEAL

As noted in Section 1.1, FSANZ is considering the use of plain English allergen labelling (PEAL) as a means of improving allergen information for consumers. PEAL is considered to be the use of clear and unambiguous terms in allergen declarations, primarily by reference to the specific source of the allergen.

As part of initial consideration, FSANZ has investigated the use of PEAL in other countries, and reviewed our existing consumer research evidence.

3.4.1 Overseas approaches

Table 4 below summarises the different regulatory approaches for PEAL internationally and how they compare with the current approach in Australia and New Zealand.

Table 4: Summary of domestic and overseas approaches to PEAL

| Approach | Regulation | Terminology requirements |
|---|---------------------------------|--|
| 1. No PEAL | Codex and Australia/New Zealand | No explicit requirement to declare allergens using PEAL. |
| 2. General requirement for PEAL | European Union | General requirement for 'a clear reference to the name of the substance or product' as listed in Annex II of the European regulations. With a couple of exceptions (cereals, nuts), the regulations do not specify what exact name is to be used for each allergen declaration. |
| 3. A list of PEAL terms is prescribed for each allergen declaration | Canada | Requires allergens to be declared using terms reflecting the name of the source of the food allergen. For most food allergens the terms to be used are specifically listed in the regulations, e.g. 'peanut' or 'peanuts'; 'sesame', 'sesame seed' or 'sesame seeds', 'wheat', 'milk'. For fish, crustaceans and shellfish, the 'name' of the fish, crustacean or shellfish is to be declared. |
| | United States of America | Requires the 'name of the food source from which the allergen is derived' to be declared, along with a declaration of the name of the specific type of nut or species of fish or crustacean shellfish. Examples of these specific tree nuts and fish/crustacean shellfish species are provided. |

3.4.2 Consumer research findings

FSANZ's current evidence base on consumer understanding, attitudes and behaviour with respect to food allergen labelling is limited to findings from previous reviews and research it has conducted or commissioned. Following the first round of public comment, FSANZ intends to prepare a broader literature review to expand this evidence base. The full details of FSANZ's consumer research findings at this stage are in Supporting Document 2. A summary of these findings is provided below.

3.4.2.1 Consumers use of food labels to identify allergens

FSANZ currently has little evidence about how food allergen sensitive individuals use food labels to identify allergens. In one study of parents of children with medically diagnosed food allergies (Zurzolo et al. 2013), approximately 25 per cent of respondents checked the ingredients only, and approximately 74 per cent checked the statement of ingredients and precautionary allergen labelling (PAL). Another (low-quality) study (Henderson 2003) found consumers without identified allergies had differing views about where allergens are located on food labels. Consequently, FSANZ's current evidence base is insufficient for determining where on the label food allergen sensitive consumers look for allergen declaration information.

In addition, previous FSANZ consumer research (NFO Donovan Research 2004; TNS Social Research 2009) has found confidence and certainty in allergen labelling practices appears to have increased between 2003 and 2008–09 among food allergen sensitive consumers. However, one fifth of the 2008–09 respondents reported being often or always unsure about a food or particular ingredients when reading food labels because of concerns about allergens. In addition, reported uncertainty increased with the number of allergies present in the household.

FSANZ's consumer research also shows consumers' perceived ease of using food labels to identify allergens appears to have remained stable from the 2003 to 2008-09. Within the 2008-09 survey, the most commonly reported problems encountered by participants were that they found it hard to find the location of ingredients, or allergen declarations were hard to find/ non-existent.

FSANZ has no information at present about where food allergen sensitive individuals seek further information from when they experience uncertainty with food labels. Similarly, we do not have information on the food label advice provided by health care professionals when someone is diagnosed with a food allergy. FSANZ notes the 15 year-old findings of Henderson (2003), where 63 per cent of the respondents with diagnosed allergies were not shown how to read and understand a food label at the time of diagnosis.

3.4.2.2 *The 'contains' statement*

Feedback received from stakeholders in the W1070 Review indicate the 'contains' statement is an effective labelling tool for informing consumers about the presence of allergens in a food. However, some of the feedback to the W1070 Review also mentioned there was variability in the use of, and information provided in the 'contains' statement, which can lead to uncertainty and confusion over the presence of an allergen.

FSANZ has little direct evidence about consumers attitudes to and use of 'contains' statements. In addition, it is not known whether consumers are aware that 'contains' statements are voluntary and therefore not always present on the labels of foods that contain allergens.

3.4.2.3 *Consumer understanding of terminology across labelling elements*

FSANZ has previously identified the potential for consumers to misunderstand allergen declarations due to the use of inconsistent or unfamiliar terminology. When this practice occurs in conjunction with the 'contains' statement, it has the potential to cause confusion, as the information in the statement may differ from what is listed in the statement of ingredients. For example, the W1070 Review's qualitative label survey identified instances where the 'contains' statement declares 'milk', while the statement of ingredients on the same label used the ingredient name 'sodium caseinate'.

With respect to evidence on consumer behaviour itself, FSANZ's consumer research (TNS Social Research 2009) has identified instances where the primary grocery buyers for food allergen sensitive individuals were unable to correctly identify some ingredients likely to be allergens. This could potentially stem from the variability in how allergens are declared, and although one of FSANZ's label surveys has suggested this practice is infrequent (FSANZ, 2016), it may create doubt and confusion over whether the food contains the particular allergen or not.

Questions for submitters:

8. What evidence can you provide on how food allergen sensitive consumers use food labels to identify allergens?
 - Where on the label do they look to determine whether an allergen is present?
 - What types of terminology in allergen declarations are the most meaningful to consumers?
 - Do you have any evidence on the importance of the source allergen in a declaration (e.g. 'milk' versus 'sodium caseinate' in the statement of ingredients)?
9. What evidence can you provide about consumers' awareness that some allergen labelling formats are currently provided voluntarily (e.g. the 'contains' statement), and therefore may not always be present on all products?
10. Is there any evidence of consumers being confused when the terminology used for declaring allergens differs between the statement of ingredients and a 'contains' statement? How important to food allergen sensitive consumers is consistency in the terms used for declaring allergens across different labelling elements?
11. Where do food allergen sensitive consumers obtain information about how allergens are labelled? For example, GP, friend or family member, a support group, the Internet etc. What is the nature and quality of information provided from these sources?
12. **(Question for industry submitters)** How do you make mandatory allergen declarations on your product labels? For example, listing source allergens in brackets after the ingredient they relate to within the statement of ingredients or including a 'contains' statement. Why did you choose the method you use?

3.4.3 Potential approaches for introducing PEAL

Based on the use of PEAL overseas, there are two potential approaches which could be considered for introducing PEAL into the Code.

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

Specific allergen terms would not be prescribed in the Code. Instead the Code would contain a general requirement for a declaration to refer to the specific source of the allergen, without prescribing the specific terms to be used. This approach would allow some flexibility on the labelling that could be used, such as allowing variations of terms (e.g. 'soy' as well as 'soybean') and allow declarations using commonly recognised terms for specific allergen sources e.g. cheese for milk.

2. The Code requires the specific source of an allergen to be declared and prescribes the terms that must be used

Under this approach, the Code could include a list of terms to be used for the declaration of each food allergen. However, it would not preclude the additional use of other terms provided the prescribed ones are present (e.g. 'sodium caseinate (milk)' in the statement of ingredients). This approach would align with Canadian and US regulations, and has the advantage of standardising the terminology used for allergen declarations across the Australian and New Zealand food supply.

At this stage FSANZ is only canvassing stakeholder views on the potential approaches that could be used to introduce PEAL into the Code; a preferred approach has not been identified. Further consideration of potential approaches above will be provided following the first round of public consultation.

Question for submitters:

13. Which of the potential approaches outlined for applying PEAL to allergen declarations (if any) would you support? Please explain your reasons.
- a) The Code requires the specific source of an allergen to be declared but the terminology is not prescribed.
 - b) The Code prescribes the terms that must be used for each type of allergen declaration.

Please provide your reasons for or against these proposed approaches, including comments on which one would be the most effective, and any comments on the impacts to industry / trade considerations. If you do not support either approach, then please describe any alternatives that could be used for applying PEAL to allergen declarations.

3.5 Placement of allergen declarations on food labels

In addition to the two potential approaches described above for introducing PEAL into the Code, there are also practical issues associated with how PEAL would apply to different parts of a label. As outlined previously, the Code does not specify where on the food label mandatory allergen declarations must be made. This means that declarations could be made anywhere on the label, for example, in the statement of ingredients, in a 'contains' statement or in the name of the food.

Some submitters to the W1070 Review advocated for mandating a 'contains' statement so that the terminology used in this label element would align with what is declared in the statement of ingredients (FSANZ notes the specific allergen source is not always declared in the statement of ingredients; e.g. 'sodium caseinate', without reference to 'milk'). Some submitters mentioned mandating a 'contains' statement with standardised terminology, as this would inform consumers regardless of the terminology used in the statement of ingredients. Other submitters suggested if the 'contains' statement was not mandated, then further restrictions on the declaration terminology were needed (e.g. the specific allergen source should be declared in the statement of ingredients or the name of the food).

FSANZ has observed that allergen declarations are generally made in the statement of ingredients or in a 'contains statement'. In some instances, both labelling elements are used. During informal discussions with FSANZ, several food manufacturers mentioned they preferred using a 'contains' statement for declaring allergens as it is the simplest communication method for this information. Other food manufacturers preferred to declare allergens in the statement of ingredients, as this allows for the most meaningful detail about allergens in a food.

3.5.1 Overseas approaches

The US Code requires the allergen declaration to be made in the list of ingredients, or in a 'contains' statement printed immediately after or adjacent to the list of ingredients. The Canadian regulations are similar in that the source of the food allergen or gluten must be shown in the list of ingredients or in a 'contains' statement. The EU regulations require allergen declarations to be in the list of ingredients, or if there is no list of ingredients, the allergen(s) should be declared following the word 'contains'. FSANZ understands that in each of these regulations, the use of both the list of ingredients and the 'contains' statement on the same food label for making allergen declarations is prohibited.

3.5.2 Potential approaches for the placement of allergen declarations on food labels

It is unclear if only including a requirement to use clear and consistent terminology (PEAL) on food labels would meet allergic consumers' information needs if the placement of the allergen declaration still varies between food labels. Therefore, to aid consistency of information for allergen sensitive consumers, FSANZ is also considering whether to regulate where allergen declarations are made on food labels.

Potential approaches include:

- No requirement on where allergen declarations are made on food labels
- Require declarations in the statement of ingredients
- Require declarations in a separate 'contains' statement
- Require declarations in the statement of ingredients or a separate 'contains' statement.

Issues relating to these potential approaches are described below.

1. No requirement on where allergen declarations are made on food labels

This approach reflects the status quo where the Code is silent about placement of allergen information. The absence of a requirement for allergen information placement has led to variability in the terminology used between:

- different label elements on a single food label, and
- the same label element present on different food labels.

Variability in relation to both scenarios is likely to continue if food manufacturers retain the flexibility to choose where PEAL information is placed on the food label. However, it is unclear whether variability between different label elements on a single food label would be an issue for consumers if PEAL is present in at least one location on the label. Further, consumers may continue to find it hard to locate allergen declarations (as noted in section 3.4.2.1).

2. Require declarations in the statement of ingredients

For this approach, there would be no need to introduce a new labelling element because the statement of ingredients is already mandated and is commonly used to declare allergen information. A requirement to place allergen information in the statement of ingredients would override generic ingredient labelling requirements for:

- certain ingredients, where PEAL would require additional information about the specific allergen source (for example, identifying the food additive 'sodium caseinate is derived from milk), and
- certain generic names (for example, 'cereals' and 'nuts') and their conditions would become redundant.

Another issue for consideration would be whether the separate 'contains' statement should be prohibited or if the Code should remain silent about its voluntary use.

Prohibition of a separate 'contains' statement would require consumers to search the statement of ingredients to determine whether allergens are present. This could prove to be difficult for some consumers when the statement of ingredients is long and/or complex.

Alternatively, if the Code remained silent, the separate 'contains' statement could be used voluntarily. However, the absence of conditions set for its use could lead to continued variability in the terminology used for this label element.

3. Require declarations in a separate 'contains' statement

A new requirement for the mandatory use of a separate 'contains' statement could be introduced to declare allergen information. Some conditions would need to be set, for example the location of this statement in relation to the statement of ingredients. Use of a separate 'contains' statement would not preclude allergen information being declared elsewhere voluntarily, including in the statement of ingredients through generic ingredient labelling requirements.

The terminology used in the statement of ingredients may still vary between food labels. However, consumers may find it easier to refer to the separate 'contains' statement if the statement of ingredients is lengthy or contains terminology they do not understand.

4. Require declarations in either the statement of ingredients or a separate 'contains' statement

Under this approach, food manufacturers could choose which of the two label elements in which to declare allergen information. If the declaration was made in the statement of ingredients, then the separate 'contains' statement would be prohibited. This approach aligns with the United States and Canadian regulations, and to some extent with the EU regulations.

Depending on the label element, the issues noted for the second and third approaches would apply:

- possible variability in terminology used
- difficulty in reconciling PEAL information in a separate 'contains' statement with the some terms used for some allergen-containing ingredients in the statement of ingredients, and
- inconsistent placement of allergen information.

Stakeholder's views on potential approaches

Given the Code does not set conditions for a separate 'contains' statement, FSANZ believes it would be difficult to remove variability in the terminology used across different label elements for allergen declarations, without controlling where allergens are declared in addition to the (PEAL) terminology used across these labelling elements.

FSANZ is interested in stakeholder views about the need to introduce requirements for the placement of allergen declarations in combination with the use of PEAL. We are also interested in views on whether any variability in allergen declaration information will be an issue given it is proposed for PEAL to be used in at least one place on a food label.

Questions for submitters:

14. Should the location of the allergen declaration(s) be mandated on the label (e.g. in a separate 'contains' statement or in the statement of ingredients)? If so, where on the label should this information be located? (please give your reasons why)
15. If the location is not mandated, do you think the use of PEAL in at least one label element would provide sufficient information for consumers to make an informed choice?

4 Matters addressed in accordance with the FSANZ Act

4.1 Section 59 – Costs and benefits identified at the first call for submissions

Paragraph 59(2)(a) of the FSANZ Act requires FSANZ to have regard to whether the costs that would arise from a food regulatory measure developed or varied as a result of this proposal (e.g. the approaches discussed above) outweigh the direct and indirect benefits to the community, government or industry that would arise from the development or variation of the food regulatory measure.

Paragraph 59(2)(b) of the FSANZ Act also requires FSANZ to have regard to whether other measures (available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal.

4.1.1 Option 1: Status quo

In any consideration of changes to regulation, the status quo must be a part of FSANZ's assessment. For this proposal, the status quo is to retain the allergen declaration requirements in the Code in their current form. However, the status quo appears not to be an option that would address those risks to food allergen sensitive consumers that have been identified by FSANZ in the W3 and W1070 Reviews as outlined above.

4.1.2 Option 2: amend the Code

Under this option the Code would be amended to clarify and make consistent the terminology used for declaring allergens generally, with specific variations made to address issues relating to declaration requirements for fish, crustacea, molluscs, tree nuts and cereals containing gluten.

4.1.3 FSANZ's preliminary cost benefit analysis

FSANZ is not yet in a position to undertake a complete cost benefit analysis as the particular manner or form of any variation of the Code has yet to be decided.

A full range of options will be considered following the first round of public consultation. Information from submissions will be used to conduct an impact analysis and to prepare a consultation regulation impact statement that will be available for comment with the next round of public consultation.

4.2 Section 59 – 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. We note that Standard 1.2.3 applies in both Australia and New Zealand. FSANZ is not aware of any relevant New Zealand only standards for allergen labelling.

4.3 Section 59 – Other relevant matters

Paragraph 59(2)(d) requires FSANZ to have regard to any other relevant matters. FSANZ's objectives in developing, reviewing and varying standards, which are set out in subsection 18(1) of the FSANZ Act; and a list of matters FSANZ must have regard to in subsection 18(2), provide an indication about the scope of 'other relevant matters'.

4.3.1 Section 18 – FSANZ’s objectives in developing, reviewing and varying standards

4.3.1.1 Protection of public health and safety

FSANZ has assessed the scientific evidence relating to the safety aspects of allergies and intolerances for molluscs and crustacea, tree nuts, and cereals (including gluten content). Using these assessments, FSANZ has identified possible changes to the Code to clarify allergen declaration requirements, so that food allergen sensitive individuals (or those who purchase foods for them) will be able to make safer food choices.

Previous work by FSANZ during the W3 and W1070 Reviews has identified issues relating to lack of clarity and inconsistency with respect to terminology used in allergen declarations. At this stage of Proposal P1044, FSANZ has undertaken a preliminary consideration of introducing plain English terminology to further protect the health and safety of individuals with allergen sensitivities.

4.3.1.2 The provision of adequate information relating to food to enable consumers to make informed choices

At this stage, FSANZ has identified a range of potential methods that could be used to introduce PEAL requirements into the Code to make allergen declarations clearer for food allergen sensitive individuals (or those who purchase foods for them) to enable them to make informed choices. Further assessment and development of regulatory options will occur in the next stage of Proposal P1044.

4.3.1.3 The prevention of misleading or deceptive conduct

To date, FSANZ has not identified any issues relevant to this matter.

4.3.2 Subsection 18(2) considerations

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

FSANZ has undertaken two risk assessment activities at this stage of the proposal, which are provided in Supporting Documents 1 and 2. FSANZ will build upon the scientific evidence from these assessments in further stages of the proposal. Scientific evidence used in the W3 and W1070 Reviews has also been considered where applicable throughout this report.

- **the promotion of consistency between domestic and international food standards**

Codex allergen labelling requirements do not contain requirements for PEAL. However, other overseas regulations do include PEAL requirements, and we have had regard to these requirements at this First Call for Submissions.

- **the desirability of an efficient and internationally competitive food industry**

This proposal is considering approaches that are intended to clarify allergen labelling requirements, and are intended to be more consistent with overseas regulations where possible.

- **the promotion of fair trading in food**

By seeking to increase consistency of allergen declarations, this proposal will promote fair trade by providing industry with clarity and certainty on how to label their food products.

Consistent and standard practices for allergen declarations resulting in clear allergen labelling would also ensure greater health and safety for consumers in managing food allergies.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are no written policy guidelines from the Australia and New Zealand Ministerial Forum on Food Regulation that apply to this proposal.

5 Risk communication

5.1 Consultation

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 is also consulting with the [Allergen Collaboration](#) on this proposal.

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.

5.2 World Trade Organization (WTO)

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

This issue will be fully considered at the next stage of the assessment once regulatory options have been developed. If necessary, notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Application of Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO members to comment on any proposed amendments.

6 List of questions for submitters

FSANZ invites submitters to provide comment on the proposed approaches as outlined in this paper. To facilitate this feedback, FSANZ has proposed a series of questions for consideration. These questions are listed in the table below.

| Questions for submitters | |
|---|---|
| <i>Questions about fish, crustacea and mollusc declaration requirements</i> | |
| 1. | Do you agree there should be a separate declaration requirement in Standard 1.2.3 for molluscs? |
| 2. | How should finfish be declared on food labels? Should Standard 1.2.3 require a declaration of 'fish' or 'finfish'? |
| For questions 1 and 2, please provide your reasons for or against these proposed approaches, including comments on the costs to industry and trade considerations. If you do not support an approach(es), then please describe any alternatives that could be used. | |
| 3. | What amendments should be made to Section S10—2 of Schedule 10 (if any) to prevent inconsistencies between ingredient labelling requirements and allergen declaration requirements for finfish, crustacea and molluscs? Please provide reasons for your answer. |
| <i>Questions about tree nut declaration requirements</i> | |
| Please provide the reasons for your views when responding to the following question. | |
| 4. | Do you agree with FSANZ's preliminary view that the nine individual tree nuts associated with food allergy should be required to be specifically declared? <ul style="list-style-type: none">• What would be the impacts of this requirement for industry (e.g. costs and trade considerations) and consumers?• Would this approach offer sufficient clarity in the Code with regard to which tree nuts / nuts should be declared? |
| <i>Questions about declarations for wheat and cereals containing gluten</i> | |
| Please provide the reasons for your views when responding to the following questions. | |
| 5. | Do you support clarifying the intent of Standard 1.2.3 by requiring wheat and its hybrids to always be declared irrespective of the gluten content in a food? |
| 6. | Would clarifying the intent of Standard 1.2.3, so that individual sources of gluten-containing cereals are declared provide adequate information about the presence of gluten in a food for gluten intolerant consumers? |
| 7. | Are there other approaches (if any) that could be used for regulating how wheat, barley, rye, oats, spelt and their hybrids are declared to assist both allergen sensitive and gluten intolerant consumers? |

Questions for submitters

Consumer research questions

8. What evidence can you provide on how food allergen sensitive consumers use food labels to identify allergens?
 - Where on the label do they look to determine whether an allergen is present?
 - What types of terminology in allergen declarations are the most meaningful to consumers?
 - Do you have any evidence on the importance of the source allergen in a declaration (e.g. 'milk' versus 'sodium caseinate' in the statement of ingredients)?
9. What evidence can you provide about consumers' awareness that some allergen labelling formats are currently provided voluntarily (e.g. the 'contains' statement), and therefore may not always be present on all products?
10. Is there any evidence of consumers being confused when the terminology used for declaring allergens differs between the statement of ingredients and a 'contains' statement? How important to food allergen sensitive consumers is consistency in the terms used for declaring allergens across different labelling elements?
11. Where do food allergen sensitive consumers obtain information about how allergens are labelled? For example, GP, friend or family member, a support group, the Internet etc. What is the nature and quality of information provided from these sources?
12. **(Question for industry submitters)** How do you make mandatory allergen declarations on your product labels? For example, listing source allergens in brackets after the ingredient they relate to within the statement of ingredients or including a 'contains' statement. Why did you choose the method you use?

Questions about applying plain English to allergen declarations requirements

13. Which of the proposed approaches for applying PEAL to allergen declarations (if any) would you support? Please explain your reasons.
 - a) The Code requires the specific source of an allergen to be declared but the terminology is not prescribed.
 - b) The Code prescribes the terms that must be used for each type of allergen declaration.

Please provide your reasons for or against these proposed approaches, including comments on which one would be the most effective, and any comments on the impacts to industry / trade considerations. If you do not support either approach, then please describe any alternatives that could be used for applying PEAL to allergen declarations.

14. Should the location of the allergen declaration(s) be mandated on the label (e.g. in a separate 'contains' statement or in the statement of ingredients)? If so, where on the label should this information be located? (please give your reasons why)
15. If the location is not mandated, do you think the use of PEAL in at least one label element would provide sufficient information for consumers to make an informed choice?

7 References

1. AFGC (2007). Food Industry Guide to Allergen Management and Labelling. Australian Food and Grocery Council, Canberra, Australia. <http://www.afgc.org.au/download/655/>. Accessed 2 November 2015.
2. ASCIA (2014a). Information for patients, consumers and carers: Allergic and toxic reactions to seafood. Australian Society of Clinical Immunology and Allergy, Balgowlah, Australia. https://www.allergy.org.au/images/pcc/ASCIA_PCC_Allergic_Reactions_seafood_2014.pdf. Accessed 16 November 2017.
3. ASCIA (2014b). Information for patients, consumers and carers: Dietary avoidance – wheat allergy. Australian Society of Clinical Immunology and Allergy, Balgowlah, Australia. https://www.allergy.org.au/images/pcc/ASCIA_PCC_Dietary_avoidance_wheat_2014.pdf. Accessed 1 February 2018.
4. Blewett N, Goddard N, Pettigrew S, Reynolds C, Yeatman H (2011). Labelling logic: Review of food labelling law and policy (2011). Department of Health and Ageing, Canberra, Australia. [http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/48C0548D80E715BCCA257825001E5DC0/\\$File/Labelling%20Logic_2011.pdf](http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/48C0548D80E715BCCA257825001E5DC0/$File/Labelling%20Logic_2011.pdf). Accessed 4 March 2016.
5. Codex (1985). General Standard for the Labelling of Prepackaged Foods. Codex Alimentarius CODEX STAN 1-1985. Codex Alimentarius Commission, Rome. http://www.fao.org/fao-who-codexalimentarius/download/standards/32/CXS_001e.pdf Accessed 2 March 2016.
6. Council of the European Union (2011). Regulation (EU) No 1169/2011 - provision of food information to consumers. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011R1169>. Accessed 2 March 2016.
7. Department of Justice (2013). Food and Drug Regulations. Department of Justice Canada, Ottawa. http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html Accessed 2 March 2016.
8. European Commission (2017). COMMISSION NOTICE of 13.7.2017 relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II of Regulation (EU) No 1169/2011 on the provision of food information to consumers. https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_legislation_guidance_allegens-2017-4864_en.pdf. Accessed 17 November 2017.
9. Food and Drug Administration (2006). Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm059116.htm>. Accessed 28 September 2017.
10. Food and Drug Administration (2017). Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA). <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm>. Accessed 16 November 2017.
11. FSANZ (2010). Review of the Regulatory Management of Food Allergens. Food Standards Australia New Zealand, Canberra, Australia. www.foodstandards.gov.au/publications/Pages/Review-of-the-regulatory-management-of-food-allergens.aspx. Accessed 2 November 2015.
12. FSANZ (2016a). Proposal P161 – Allergen labelling exemptions: Approval report. Food Standards Australia New Zealand, Canberra, Australia. <http://www.foodstandards.gov.au/code/proposals/Pages/P1031Allergenlabellingexemptions.aspx>. Accessed 1 February 2018.
13. FSANZ (2016b). Final report – W1070 Plain English Allergen Labelling. Food Standards Australia New Zealand, Canberra, Australia. <http://www.foodstandards.gov.au/code/proposals/Pages/P1044PlainEnglishAllergenLabelling.aspx>. Accessed 6 October 2017.
14. Health Canada (2017). Seafood* (Fish, Crustaceans and Shellfish) - Priority food allergens. <https://www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/food->

- [safety/seafood-fish-crustaceans-shellfish-priority-food-allergens.html](#) . Accessed 28 September 2017.
15. Henderson, Johanna (2003). The impact of FSANZ labelling changes (unpublished). Thesis, kindly provided by HJ Heinz Co Australia Ltd.
 16. Legislative and Governance Forum on Food Regulation (2011). Response to the Recommendations of *Labelling Logic: Review of Food Labelling Law and Policy (2011)*. <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/Review-of-food-labelling>. Accessed 25 October 2017.
 17. NFO Donovan Research (2003): Quantitative research with consumers. Canberra (Food Standards Australia New Zealand, Evaluation Report Series No.4). Available online at https://www.foodstandards.gov.au/publications/documents/Part_1_with%20App_A.pdf. Accessed 8/8/2017.
 18. Office of Law Revision Counsel (2014b) United States Code Title 21 – Food and Drugs, Chapter 9 – Federal Food, Drug, and Cosmetic Act, Subchapter IV – Food, Sec.343 – Misbranded food. United States Government Publishing Office, Washington DC. <https://www.gpo.gov/fdsys/pkg/USCODE-2011-title21/html/USCODE-2011-title21-chap9-subchapIV-sec343.htm> Accessed 2 March 2016.
 19. Office of Law Revision Counsel (2014). United States Code Title 21 – Food and Drugs. United States Government Publishing Office, Washington DC, p. 87-88. <https://www.gpo.gov/fdsys/browse/collectionUScode.action?collectionCode=USCODE> Accessed 2 March 2016.
 20. TNS Social Research (2009): Consumer study on food allergen labelling: Follow-on survey 2008-09 (Food Standards Australia New Zealand, Evaluation Report Series No.20). Available online at <http://www.foodstandards.gov.au/publications/pages/evaluationreportseries/consumerstudyonfooda4610.aspx>., Accessed 8/8/2017.