

15 December 2020
[145-20]

Approval report – Proposal P1044

Plain English Allergen Labelling

FSANZ has assessed a proposal to require mandatory food allergen declarations to be clearer, more consistent and in plain English, and has prepared a draft variation.

On 27 November 2019, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received 44 submissions.

After having regard to the submissions received and the relevant matters as set out in this report, FSANZ approved the draft variation on 1 December 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 December 2020.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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

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. These foods and substances can cause severe allergic and other reactions of public health significance in Australia and New Zealand (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 work by FSANZ had identified issues which can lead to unclear and inconsistent allergen declarations. This can create difficulties for food allergic consumers (and their caregivers) 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 a potentially fatal reaction known as anaphylaxis. The lack of explicit requirements on how to declare allergens also creates compliance uncertainty for industry, and for regulators in enforcing the Code.

Therefore, this proposal has considered changes to the Code to make allergen information clearer and more consistent for food allergic consumers through requirements for the presentation of allergen information and the use of plain English allergen labelling (PEAL).

As part of the assessment of the proposal, FSANZ has undertaken a literature review of consumer awareness, understanding, attitudes and behaviour relating to allergen labelling (Supporting Document 1) and a safety assessment (Supporting Document 2).

FSANZ has established a principle-based framework to guide its risk management. The framework reflects the findings of:

- the consumer behaviour literature review which found consistency and clarity in allergen information are important for consumers
- the safety assessment in addressing the risk to public health and safety in the context of Australia and New Zealand.

For this proposal, 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 them 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 3) FSANZ’s assessment is that on balance, Option 3 provides the greatest net benefit and is therefore the preferred option.

FSANZ is therefore amending the Code to require the following:

- the use of mandatory specified terms of the allergen source (required name) when declaring allergens
- 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 their hybrids and gluten if present.

- for food required to bear a label, allergens are to be declared:
 - in the statement of ingredients for each ingredient that is, or contains, an allergen and also in a separate but co-located summary statement beginning with the word ‘contains’
 - using bold type that provides a distinct contrast with any other text to make declarations easier to identify from surrounding information
 - in a size of type no less than that used for other text
 - with the use of the required name ‘gluten’ in the summary statement if the allergen is wheat, barley, rye, oats or their hybrids.

FSANZ has also considered how these requirements will apply to foods not required to bear a label or display a statement of ingredients, foods sold to caterers and special purpose foods.

From the date of gazettal of the variation to the Code, there is a 3 year transition period followed by a 2 year stock-in-trade period for implementation of PEAL. The transition period will allow any relevant food to be sold as long as the food complies with either the existing allergen declaration requirements in the Code, or the amendments arising from this proposal.

The subsequent stock-in-trade period will allow a food packaged and labelled before the end of the transition period to continue to be sold for up to 2 years after the end of the transition period. This five-year implementation timeframe aims to strike a balance between the industry operating in the current challenging COVID19 business environment, and the need to implement the PEAL changes in a timely and definitive way for food allergic consumers to have confidence when making safe food choices.

The draft variation in the Second Call for Submissions was amended after further consideration using assessment criteria and evidence, including submissions received and views expressed by stakeholders during consultation. FSANZ decided to approve the amended draft variation, which is at Attachment A. The related explanatory statement is at Attachment B.

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. These foods and substances can cause severe allergic and other reactions of public health significance in Australia and New Zealand (for simplicity, these substances will be collectively referred to as ‘allergens’ in this report). However, the Code 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 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 used to declare allergens (FSANZ 2016). The W1070 Review concluded there is no consistency in how allergens are declared, due to variability in the terminology used, 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 known as anaphylaxis. Other consequences include the exclusion of foods due to uncertainty about the presence of an allergen, greater effort and time to search for allergen information, and a lack of confidence in allergen labelling.

The lack of explicit requirements on how to declare allergens also creates compliance uncertainty for industry, 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, this proposal has considered changes to the Code to make allergen information clearer and more consistent for food allergic consumers through requirements for the presentation of allergen information and the use of plain English allergen labelling (PEAL).

1.2 Procedure for this Proposal

This proposal was assessed under a Major Procedure of the *Food Standards Australia New Zealand Act 1991* (Cth) (the FSANZ Act) involving two rounds of public consultation.

1.3 Scope

Proposal P1044 has considered draft variations to the Code for 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, upon considering submitter comments and the findings of the consumer behaviour literature review (see section 3.2.1 and Supporting Document 1), FSANZ included consideration of the presentation of allergen declarations at the Second Call for Submissions.

Excluded from the scope of Proposal P1044 was assessment of new allergens requiring declaration, and exemptions from existing requirements to declare allergens. Issues relating to the unintended presence of food allergens such as the use of precautionary allergen labelling (PAL) statements, e.g. 'May be present: allergen x, allergen y...'. have also not been included in the scope of the proposal.

1.4 Decision

The draft variation as proposed in the Second Call for Submissions was amended after further consideration using assessment criteria and evidence, including submissions received and views expressed by stakeholders following release of the second Call for Submissions. The amended draft variation was approved and takes effect on gazettal. The approved draft variation is at Attachment A, and the related 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.

2 Background

2.1 Relevant Code requirements

Standard 1.2.1 – Requirements to have labels or otherwise provide information

Where a food for sale must bear a label, section 1.2.1—6 of Standard 1.2.1 requires the declaration of the presence of allergens to 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
- 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 declarations must be 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 other food sales (e.g. from an ingredient supplier to a food manufacturer), information must 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.

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 food allergic individuals (e.g. alcohol distilled from whey).

Standard 1.2.4 – Information requirements – statement of ingredients

Standard 1.2.4 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 their use. Some of these conditions provide the terminology to be used when certain generic names are used for ingredients that potentially contain allergens. These 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 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

Internationally there are different approaches adopted for the declaration of allergens. This includes the foods and substances that must be declared as well as differences in the presentation and terminology used.

For this proposal, FSANZ has considered the following international and overseas standards and regulations relevant to the declaration of allergens.

- CODEX STAN 1-1985 *General Standard for the Labelling of Prepackaged Foods* (the Codex Standard) (Codex 1985)¹
- European Union Regulation 1169/2011 on the provision of food information to consumers (Council of the European Union, 2011)
- 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, which incorporates the requirements in the Food Allergen Labelling and Consumer Protection Act 2004 (US FALCPA) (Office of Law Revision Counsel, 2014).

3 Summary of findings

3.1 Issues raised by stakeholders

Consistent with a major procedure, FSANZ held 2 rounds of public comment on this proposal. A First Call for Submissions was made in March 2018 followed by a Second Call for Submissions between November 2019 and February 2020. The relevant documents and submissions received to both rounds of public comment are published on the FSANZ website at [P1044 – Plain English Allergen Labelling](#).

At First Call for Submissions, FSANZ sought comments on a safety assessment and preliminary assessment of consumer understanding, attitudes and behaviour relating to allergen labelling, and canvassed issues on how PEAL requirements could be introduced into the Code.

Submitters in general supported changing the Code to introduce PEAL. Comments received:

- highlighted the importance of consistency in how allergens are declared (presentation, terminology and placement on a label) for consumers to identify the presence of allergens and make safe food choices.
- supported mandatory plain English terms to be used for each allergen declaration, which need to be a reference to the source allergen.
- supported a consistent location for allergen declarations on labels (i.e. statement of ingredients and/or summary statement) as well as the bolding of allergen declarations.
- supported the separate declarations of wheat (separate from cereals containing gluten), molluscs (separate from fish) and individual tree nuts.

For the Second Call for Submissions, FSANZ undertook a literature review of consumer understanding, attitudes and behaviour relating to allergen labelling, revised its safety assessment, and made an assessment of the costs and benefits.

Based on the assessment findings and submitters comments, FSANZ's preferred regulatory option stated in the Second Call for Submissions was to require allergens to be declared in the statement of ingredients using mandatory specified terms in bold font, as well as in a separate bolded summary statement.

In response to the Second Call for Submissions, 44 submissions were received, consisting of 27 from food industry, five health professional organisations and individuals, five allergy support groups, four government, and three from consumer groups and private individuals.

¹ The allergen labelling provisions in the Codex *General Standard for the Labelling of Prepackaged Foods* are currently under review. See [REP19/FL](#)

In general, submitters supported the preferred regulatory option as a means of achieving consistency in allergen information to assist consumers in identifying allergens and making safe food choices. However, industry submitters also sought to balance this with flexibility in the required changes to assist implementation across the broad range of products impacted.

Table 1 below summarises the issues raised by submitters in response to the Second Call for Submissions and provides FSANZ's response.

Table 1: Summary of submitter issues raised and FSANZ response

Note: Column 2 of Table 1 indicates the stakeholder groups which raised the issue. However, the issues raised are not necessarily the representative view of all submitters in a stakeholder group.

Issue	Raised by	FSANZ response
PRESENTATION OF DECLARATIONS (REQUIRED NAME, LOCATION, FORMAT)		
<p><i>Placement of summary statement</i></p> <p>Do not support the summary statement being directly below and distinctly separated from the statement of ingredients, for the following reasons:</p> <ul style="list-style-type: none"> • it is highly prescriptive • limited label space for small packs and other packaging formats • ‘distinctly separated’ is subjective and open to interpretation. <p>Suggest it is ‘in close proximity to and in the same view’ or co-located with the statement of ingredients for greater flexibility.</p>	<p>Industry</p>	<p>Based on available evidence and the views of submitters, FSANZ has reconsidered the approach to require the summary statement to appear directly below the statement of ingredients. To provide flexibility the summary statement is to be co-located within the same field of view as the statement of ingredients and will be able to be placed above, below or to the side of the statement of ingredients.</p> <p>However the requirement for the summary statement to be distinctly separate from the statement of ingredients is retained. This approach is supported by consumer evidence. The practice of the two elements appearing on the same line impairs consumers’ ability to identify allergen information (see Section 3.3.2.1).</p>
<p><i>Use of summary statement</i></p> <p>Support the summary statement being voluntary because:</p> <ul style="list-style-type: none"> • it is of less value to consumers when a short statement of ingredients is present • allows for flexibility. 	<p>Industry</p>	<p>Consumer evidence indicates that: consumers can find and understand summary statements more quickly and easily; repeating allergen information across different locations on the label benefits consumer identification and comprehension; and consumers may assume the absence of a summary statement means there is an absence of allergens in the food (Supporting Document 1). Based on this evidence and to provide consistency, FSANZ has decided to require the declaration of allergens in both the statement of ingredients and a separate summary statement for foods required to bear a label (subject to certain exceptions) (see Section 3.3.2.1)</p>

Issue	Raised by	FSANZ response
<p>Summary statement on foods with no statement of ingredients</p> <p>A summary statement should be mandated for packaged foods not required to display a statement of ingredients, as this is the requirement in the E.U. for such foods.</p>	Government	As noted in Section 3.3.4.2, certain foods are not required to have a statement of ingredients (e.g. standardised alcoholic beverages). Existing requirements to declare allergens apply, however the PEAL changes will mean required names will be used for these foods. FSANZ is not proposing to mandate the summary statement for these foods as the evidence indicates the use of required names will make declarations clearer, and to provide flexibility for industry when declaring allergens for these foods.
<p>Summary statement prefix</p> <p>Request for allowing different prefixes, for example:</p> <ul style="list-style-type: none"> • 'Contains Allergens' • 'Allergen Statement' • 'Allergy Advice' 	Industry; Consumer organisation	Prescribing the format of the summary statement including the prefix achieves consistency, which the consumer evidence indicates is important for consumers. Available evidence suggests the term 'contains' is already commonly used voluntarily on products, and is consistent with existing industry guidance (see Section 3.3.2.2.2).
<p>Minimum font size for summary statement</p> <p>Summary statements should have a minimum font size of 3mm to protect allergenic consumers in the same way as warning statements.</p>	Health professional	FSANZ considers a mandated summary statement with prescribed format and location requirements, when used in association with existing generic legibility requirements, will assist consumers to identify the presence of allergens in a food (see Section 3.3.2.2.2).
<p>Declaring the same allergen multiple times in the statement of ingredients</p> <p>Do not support as this increases the length of the statement of ingredients and is overly repetitive. Consider there is no additional benefit or risk to the allergic consumer. Other alternatives proposed:</p> <ul style="list-style-type: none"> • any subsequent listing after the first listing of an allergen is voluntary • require only highest risk ingredient(s) to declare each allergen • refer to the required names once, unless when technical terms are used (e.g. 'sodium caseinate (milk)). 	Industry	Based on available evidence and the views of submitters, FSANZ has decided to require allergen declarations in the statement of ingredients to be provided separately for each ingredient that is, or contains, an allergen (see Section 3.3.2.2.1). FSANZ also notes this approach aligns with current industry guidance.

Issue	Raised by	FSANZ response
<p><i>The use of bold font</i></p> <p>Recommend FSANZ adopts a principle-based requirement that stipulates prominence of allergen declarations instead of prescribing bold font, because:</p> <ul style="list-style-type: none"> • the legibility of bold font for small type sizes may be compromised • bolding is unnecessary because current industry practice is to bold allergens voluntarily • it would allow flexibility in how allergens were declared (e.g. boxing, italics, colour or bolding) • manufacturers may wish to use bold font for one label element only (either the summary statement or the statement of ingredients) • there are technological difficulties with digitally printed labels and ink jet printed or stamped text. 	<p>Industry</p>	<p>FSANZ considers prescribing bold font to be an important presentation element for consumers to identify the presence of allergens in a food product. Adopting a principle-based approach would likely result in different types of emphasis for allergen declarations and less consistency in allergen declarations for allergic consumers (see Sections 3.3.2.2.1 and 3.3.2.2.2).</p> <p>FSANZ understands foods with ink jet or digitally printed labels are commonly labelled in-store, for example in supermarkets. Foods not required to bear a label (e.g. food made and packaged on the premises from which it is sold) are exempt from format and location requirements (see Section 3.3.4.2).</p>
<p><i>Bolding of non-allergen information</i></p> <p>Request clarity on whether bolding of non-allergen related information is permitted. For example, other ingredient names of interest to consumers (quinine, caffeine); advisory statements (such as 'CONTAINS PHENYLALANINE'); and bolded headings ('Ingredient list').</p>	<p>Industry</p>	<p>The requirement for bold font only applies to allergen declarations, specifically to provide a distinct contrast with the other text in the statement of ingredients, and in the case of the summary statement the background and the other text on the label. FSANZ notes as long as the requirement to provide a distinct contrast for allergen declarations is met it does not prevent other information from being bolded.</p>
<p><i>Contrast distinctly with the label background</i></p> <p>Request clarity on the intent of the requirement <i>contrast distinctly with the background of the label</i>. It is unclear if it applies to prominence, legibility and prominence together, or is a separate requirement. Consider the requirement should apply to contrast with the colour of the product in the transparent packaging, not just the background of the label.</p>	<p>Consumer organisation</p>	<p>The requirement for bold font (described above) is an extension of existing general legibility requirements which require <i>any word, statement, expression or design must be prominent so as to contrast distinctly with the background of the label</i> (paragraph 1.2.4—24(1)(b)).</p> <p>Suppliers will need to meet this requirement taking into consideration the nature of packaging, including transparent packaging when making allergen declarations.</p>

Issue	Raised by	FSANZ response
<p><i>Individual portion packs and small packages</i></p> <p>Request clarity on declaration requirements for the inner packages of individual portion packs when the outer layer displays all mandatory allergen declarations. The draft variation indicates a statement of ingredients and a summary statement is required, which is not supported.</p> <p>Request small packages are exempted from summary statements due to space constraints and legibility issues.</p>	Industry	The draft variation has been clarified to reflect the intent that format (bolding) and location requirements (a statement of ingredients or summary statement) will not apply to individual portion packs. The draft variation already excludes small packages from format and location requirements (see Section 3.3.4.2).
<p><i>Food not required to bear a label</i></p> <p>Considers allergen declaration requirements for required name, format and location should not extend to in-store ticketing for unpackaged foods (e.g. deli and seafood), marketing collateral or ecommerce platforms, because this would require further investment, and third party vendor engagement.</p> <p>Request FSANZ considers mandating the format of allergen declarations on foods exempt from a statement of ingredients or not required to bear a label, because the health risk is the same irrespective of the size of the package or the method of delivery of the food to consumers.</p>	Industry; Government	<p>Consistent with existing requirements, allergen declarations for food not required to bear a label are to be displayed in connection with a food or provided to the purchaser on request. As discussed in Section 3.3.4.2, format and location requirements for allergen declarations in the statement of ingredients and summary statement will not apply to food not required to bear a label.</p> <p>However, these foods will be required to declare allergens using the required name in Column 4 of the table to section S9—3, for consistency with allergen declarations in the summary statement of a packaged food.</p>
<p><i>Formatting the statement of ingredients</i></p> <p>Consider consumers would benefit if ingredient labels were positioned in a defined box with a black border, like the format commonly used for nutrition information panels.</p>	Allergy support group; Consumer organisation	The scope of Proposal P1044 includes terminology, formatting and location requirements for allergen declarations. The application of formatting to other information in the statement of ingredients is beyond the scope of P1044.

Issue	Raised by	FSANZ response
TERMINOLOGY		
<p>Plural terms</p> <p>Request FSANZ considers plural versions for some of the required names. There are inconsistencies in the table to Schedule 9 with some terms listed as plural (e.g. oats) and some as singular (e.g. soybean). In some instances, a singular version of a required name could be misleading and potentially present a safety risk to food allergic consumers (e.g. 'tree nut' in the summary statement).</p>	<p>Industry; Allergy support group; Government</p>	<p>It is unnecessary for the draft variation to refer to plural versions of required names in section S9—3 because they have the same meaning as singular versions. However, the draft variation now contains a provision to make this clear (refer to Attachment A).</p>
<p>Permit additional text</p> <p>Request clarity on whether additional text can be used with the required names. Examples provided:</p> <ul style="list-style-type: none"> • 'Cream (from milk)' compared to 'cream (milk)' • Extensions to required names such as 'sesame seeds' • Additional information on the source of allergens, such as 'Contains cow's milk'. 	<p>Industry</p>	<p>In the statement of ingredients the requirement to use required names does not prevent the use of additional text.</p> <p>However, the draft variation has been revised so required names are the only text permitted in the summary statement. This is because the intent is to provide consumers with a short statement for clear and easier identification of allergens (refer to Attachment A).</p>
<p>Required names embedded within ingredient names</p> <p>Request clarity on whether a longer ingredient name containing a required name would satisfy allergen declaration requirements in the statement of ingredients. For example, 'oatmeal or buttermilk'.</p>	<p>Industry; Consumer organisation; Health professional; Government</p>	<p>The intent of the draft variation (refer to Attachment A) is for the required name to be separately declared and not appear as part of a longer ingredient name. FSANZ considers this will assist consumers to readily identify the presence of allergens in a food product (see Section 3.3.2.2.1).</p>

Issue	Raised by	FSANZ response
<p><i>Tree nuts, cereal names, 'gluten containing cereals' and soy synonyms in the summary statement</i></p> <p>Prescribing 'tree nut', 'gluten' and 'soy' as required names in the summary statement is overly prescriptive, imposes costs on industry to change labels and would take information away from consumers. Regarding 'tree nut', there is a potential conflict with voluntary precautionary allergen labelling (PAL) statements (e.g. 'May be present: tree nuts').</p> <p>Suggest there is some flexibility in permitting:</p> <ul style="list-style-type: none"> • specific tree nut names with or without the 'tree nut' required name. 'Tree nut' could be retained when the individual nut cannot be identified and for harmonisation purposes • specific cereal names with or without the 'gluten' required name (excepting wheat, which must always be declared) • the term 'gluten containing cereals', because it is widely used and understood and reflects the combined presence of wheat and gluten • soy synonyms 'soya' or 'soybean'. 	<p>Industry</p>	<p>FSANZ has considered submitter comments and revised the approach for declaring tree nuts in the summary statement. For each specific tree nut, the required name will now be the name of the specific tree nut, instead of 'tree nut' (see Section 3.3.3.3).</p> <p>However, 'gluten' will remain as the required name in the summary statement when wheat, barley, rye or oats (or their hybrids) are present and contain gluten, because it reflects the substance of concern for individuals with Coeliac Disease and Dermatitis Herpetiformis. Except for 'wheat', specific cereal names will not be permitted in the summary statement (see Section 3.3.3.4).</p> <p>For clarity and consistency, 'soy' will be the required name for declarations of soy in the summary statement (see Section 3.3.3.1).</p>
<p><i>Required names for specific cereals in the summary statement</i></p> <p>Request required names for specific cereals are mandated in the summary statement. Concerned that consumers with an allergy to barley, rye or oats expect these cereals to be declared in the summary statement. If only 'gluten' is declared, the assumption could be made that the cereal, or a derivative, is not present.</p>	<p>Allergy support groups</p>	<p>The safety assessment found that allergies to barley and rye are uncommon in Australia and New Zealand, and oat allergy is rare (Supporting Document 2). Therefore, wheat is the only cereal of public health significance for allergy.</p> <p>FSANZ considers the presence of the required name 'gluten' in the summary statement will provide a prompt for those consumers allergic to rye, barley or oats to seek information on the presence of these cereals from the declarations made in the statement of ingredients.</p>

Issue	Raised by	FSANZ response
<p>Use of soy synonyms</p> <p>Synonyms for soy should be prohibited so there is consistency between the summary statement and the statement of ingredients. Noted that 'soya' can have a different meaning in the Hindi language.</p>	<p>Government</p>	<p>FSANZ notes current labelling practice of manufacturers to use soy synonyms in the statement of ingredients. The use of the required name 'soy' in the summary statement will assist consumers to identify the presence of soy (see Section 3.3.3.1) and reduce the likelihood of any confusion.</p>
<p>'Dairy' as a required name instead of 'milk'</p> <p>Request FSANZ considers the term 'dairy' instead of, or as a voluntary option to, 'milk', because:</p> <ul style="list-style-type: none"> • it is less ambiguous and more likely to clearly convey the range of milk-derived food sources as well as the animal source • the use of dairy terms on plant based products could create confusion with regards to presence (or not) of allergens • it is uncertain whether 'milk' still clearly represents mammalian milk given the use of 'milk' as a name in plant-based 'milk' products. • of the international food law principles outlined in Codex STAN 206-1999 that protects (and restricts) the use of dairy terms for dairy products • milk-allergic consumers are more likely to report they have a 'dairy' allergy, which accords with evidence that U.S. consumers prefer the term 'dairy' (although 'milk' is mandated in the U.S.). 	<p>Industry; Government; Private submitter</p>	<p>FSANZ has no evidence to indicate Australian and New Zealand consumers do not understand the term 'milk' when searching for allergen information about the presence of milk in food. Use of terms such as 'dairy', or the name for a milk product (e.g. 'butter'), should not be used for 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' will be required with the name). Existing declaration requirements in the Code refer to 'milk and milk products' and 'milk' is defined in part to mean <i>the mammary secretion of milking animals</i>.</p> <p>The use of bold type and the required name 'milk' appearing in a summary statement will distinguish mammalian 'milk' as an allergen from plant-based milk products.</p> <p>This approach is consistent with the Codex Standard and allergen declaration requirements in overseas regulations.</p>
<p>Permit terms used overseas</p> <p>Suggest terms used overseas are permitted for use in the draft variation.</p>	<p>Industry</p>	<p>The required names are mandated in the statement of ingredients and summary statement for clarity and consistency (see Section 3.3.3.1). FSANZ considers the use of different terms would create consumer confusion.</p>

Issue	Raised by	FSANZ response
<p>Generic ingredient names</p> <p>Request FSANZ:</p> <ul style="list-style-type: none"> • considers amending the Table to Schedule 10 for 'cheese' to 'cheese (milk)' • clarifies if 'milk protein' and 'milk solids' satisfy declaration requirements for the required name 'milk' • clarifies whether the generic name 'cereals' is intended to capture products derived from cereals (e.g. flours) or only the grains. 	<p>Industry; Allergy support group</p>	<p>FSANZ has clarified intent for how allergens are to be declared with ingredient names, including the use of a required name as a separate word (e.g. 'milk solids') and where an ingredient name does not include the required name (e.g. 'cheese (milk)')(see Section 3.3.2.2.1).</p> <p>Suppliers must consider whether the generic name 'cereals' reflect the true nature of the ingredient. However, the specific cereal listed in the table to section S9—3 must be declared using a required name in the statement of ingredients for ingredients that are cereal grains or their derivatives.</p>
DECLARATIONS SPECIFIC TO CERTAIN FOODS AND INGREDIENTS		
<p>Required names for food sold to caterers</p> <p>Do not support required names being provided on the label of food sold to caterers if supporting documentation uses the required names. Foods for catering purposes are not presented to consumers and therefore fall outside the scope of the purpose of P1044 which relates specifically to consumers.</p>	<p>Industry</p>	<p>The Code allows allergen declaration information to be provided with the food if the food sold to caterers does not have to bear a label. This requirement will remain (see Section 3.3.4.2). This information must be provided to enable a purchaser of food, in this case caterers, to comply with any compositional, labelling or declaration requirements (sections 1.2.1—13 and 1.2.1—17).</p>
<p>'Gluten' declarations for food not required to bear a label</p> <p>Do not support individual cereals being declared instead of 'gluten' for these foods as poses a risk for Coeliac disease consumers and those purchasing foods for such consumers.</p>	<p>Health professional; Government</p>	<p>FSANZ has changed its approach and will require 'gluten' instead of 'barley', 'rye' and 'oats' to be declared for food not required to bear a label. 'Wheat' must still be declared when it is present in food, irrespective of whether gluten is present (see Section 3.3.3.4).</p>

Issue	Raised by	FSANZ response
<p><i>'Gluten' declaration and 'gluten-free' claims</i></p> <p>Request clarity on the interaction between 'gluten' declarations in the summary statement and 'gluten-free' claims. The proposed standard appears to rely on industry testing ingredients and/or food products to determine whether gluten is present.</p> <p>Consider a 'gluten free' claim should not be made when 'gluten' is declared in a summary statement.</p> <p>Request clarity about the level of detection for gluten to be eligible for the declaration exemption.</p>	<p>Industry; Government</p>	<p>The presence of gluten in wheat, rye, barley and oats will trigger the requirement to declare the required name 'gluten' in the summary statement (see Section 3.3.3.4.3).</p> <p>The conditions for making a 'gluten-free' claim (in particular, the condition that the food contains no detectable gluten) have not changed. A 'gluten free' claim cannot be made if gluten is present in a food.</p>
<p><i>Exemption for 'gluten' declaration if wheat does not contain gluten</i></p> <p>Do not support the declaration for 'gluten' in the summary statement to be contingent on "if gluten is present":</p> <ul style="list-style-type: none"> • when the summary statement does not reconcile with the statement of ingredients, this is a source of confusion for consumers • consumers would not be aware the absence of 'gluten' means the wheat ingredients are required to be 'gluten-free' • food industry must determine whether gluten is present in the wheat ingredient. 	<p>Allergy support groups</p>	<p>FSANZ considers it would be misleading to require 'gluten' to be declared in the summary statement if the food does not contain gluten. The presence of wheat will require a 'wheat' declaration in the summary statement and the statement of ingredients, irrespective of whether or not gluten is present.</p>
<p><i>Exemption for allergen declaration requirements when barley, rye and oats do not contain gluten</i></p> <p>Do not support the exemption from allergen declaration requirements in the statement of ingredients when barley, rye and oats do not contain gluten because they contain other proteins implicated in cereal allergies.</p>	<p>Allergy support groups; Health professional</p>	<p>As previously noted, the safety assessment found that allergies to barley and rye are uncommon in Australia and New Zealand, and oat allergy is rare (Supporting Document 2). Therefore, wheat is the only cereal of public health significance for allergies.</p>

Issue	Raised by	FSANZ response
<p>Spelt is a form of wheat</p> <p>Recommend FSANZ considers how spelt is declared, noting:</p> <ul style="list-style-type: none"> that spelt is a type of wheat, and should be declared as 'wheat' rather than as a separate declaration using a different required name, or consider specifying other wheat varieties (e.g. freekeh, kamut and einkorn) as required names. 	Allergy support groups	Several species of wheat (genus <i>Triticum</i>) are cultivated, one of which is spelt (<i>Triticum spelta</i>). The most commonly grown and used wheat species are <i>Triticum aestivum</i> and <i>Triticum durum</i> , whereas spelt is not common in Australia and New Zealand. For clarity, FSANZ has now removed spelt as a required name. Food containing any wheat species, or hybrid strains will be required to declare 'wheat' (refer to Section 3.3.3.4.1).
<p>Clarity required for declaring hybridised cereals</p> <p>Request clarity on whether all prescribed cereal names must be declared when a hybrid cereal is present (e.g. rye and wheat would need to be declared in the statement of ingredients for triticale).</p>	Allergy support group; Industry	As discussed in Section 3.3.3.4.1, the required names 'wheat', 'barley', 'rye' and 'oats' must be declared when a hybrid of these cereals is present. FSANZ's safety assessment concluded that hybrid strains of wheat and other cereals should be avoided by wheat-allergic individuals (Supporting Document 2).
<p>Retain coconut exemption</p> <p>Request the exemption for coconut from tree nuts be reinstated for clarity.</p>	Industry	Only those foods listed in the table to section S9—3 must be declared, which does not include coconut. The current exemption for coconut is therefore redundant (see Section 3.3.3.3).
<p>Coconut as an allergen</p> <p>Request FSANZ considers undertaking an assessment of coconut as an allergen. Evidence was provided from the Victorian Anaphylaxis Notification System that 12 people reported a medically diagnosed allergy to coconut (1.4% of food allergic cases).</p>	Government	<p>At Second Call for Submissions, FSANZ undertook a risk assessment of the available evidence of coconut as a potential allergen of public health concern. An assessment of published literature found no reported cases of coconut allergy in Australian and New Zealand populations. The risk assessment concluded that allergy to coconut is rare and the risk of coconut allergies in individuals allergic to tree nuts is very low (see Section 3.2.4 of Supporting Document 2). The Food Allergy and Intolerance Scientific Advisory Group (FAISAG) agreed with this conclusion. The Australasian Society of Clinical Immunology and Allergy also considers allergy reactions following coconut consumption are relatively rare.</p> <p>If sufficient evidence emerges indicating that coconut has become a food allergen of public health significance to the Australian and New Zealand populations, FSANZ would need to undertake a separate assessment. An assessment of coconut as a potential food allergen is therefore out of scope.</p>

Issue	Raised by	FSANZ response
<p><i>Declaration of individual species for fish, crustacea and molluscs</i></p> <p>Request FSANZ consider:</p> <ul style="list-style-type: none"> • mandating individual species names in association with the required names in the statement of ingredients: <ul style="list-style-type: none"> – for 'fish', to assist consumers in identifying specific fish for non-allergic reasons (e.g. those containing high mercury levels) – for 'mollusc' and 'crustacean', to assist consumers in detecting the relevant allergen by either the common name or class of allergen and to align with US and Canadian requirements • Permitting the voluntary use of individual species names in association with the required names in the statement of ingredients and summary statement. 	<p>Allergy support groups; Government; Industry; Health professionals</p>	<p>The requirement to declare the required names 'molluscs' and 'crustacean' will remain given they represent the allergens of concern. That is, a crustacean-allergic individual would be allergic to all crustaceans.</p> <p>The use of a single term for each allergen ensures consistency in declarations across food product labels. In contrast, mandating individual species would be onerous for suppliers, and likely make statement of ingredients longer and less clear for consumers. However, FSANZ notes the voluntary listing of a species name alongside the required name in the statement of ingredient would be permitted but not in the summary statement. As previously discussed the summary statement is intended is to provide consumers with a short statement for clear and easy identification of allergens (see above response on <i>Permit Additional Text</i>).</p>
<p><i>Declaration of soy synonyms for new ingredients</i></p> <p>Request FSANZ clarifies how the required names 'soy' or 'soya' or 'soybean' would apply to new substances being proposed for introduction into the Australia New Zealand food supply such as soy leghemoglobin? If so, how will they be referenced if not sourced from soybeans?</p>	<p>Government</p>	<p>The existing allergen declaration requirements apply to new foods or substances in the food supply. In the case where a new food or substance contains soy the required name for 'soy' must be declared in the summary statement, with either 'soy', 'soya' or 'soybean' as the required name in the statement of ingredients (see Section 3.3.3.1).</p>
<p><i>Sulphites not listed in the summary statement if present at less than 10 ppm</i></p> <p>Concern that added sulphites present at less than 10 ppm would not trigger a sulphite declaration in the summary statement and this would be confusing to consumers.</p>	<p>Industry</p>	<p>Consistent with the scope of P1044, FSANZ has considered the application of PEAL changes (i.e. terminology, format or location) only to existing allergen declaration requirements, including for sulphites (i.e. declaration when present in concentrations of 10 mg/kg or more). FSANZ notes generic ingredient naming requirements will apply to sulphite ingredients.</p>

Issue	Raised by	FSANZ response
<p><i>Declaration of processing aids that contain allergens</i></p> <p>Request clarity on the declaration of processing aids when they contain allergens, noting:</p> <ul style="list-style-type: none"> the required name for the allergen would appear in the summary statement with no corresponding declaration in the statement of ingredients consumers may be confused if the processing aid itself was not declared it may pose a safety risk to consumers if only 'tree nut' and 'gluten' appear in the statement of ingredients. <p>Suggest:</p> <ul style="list-style-type: none"> using the required name for the allergen in the statement of ingredients in the summary statement declaring the processing aid in both locations. 	<p>Industry; Government</p>	<p>FSANZ has revised the approach to require processing aids containing allergens to be listed in the statement of ingredients with the words 'processing aid' in conjunction with the required name of the allergen concerned. The allergen would also be declared in the summary statement (see Section 3.3.4.3.2).</p>
<p><i>Foods for special medical purpose (FSMPs) and Infant Formula for Special Dietary Use (IFPSDU)</i></p> <p>Do not support the application of proposed allergen declaration requirements to FSMP or IFPSDU, because:</p> <ul style="list-style-type: none"> these products are manufactured globally, often in small volumes, and specific labels for the Australasian market are not possible (e.g. the EU prohibits summary statements) label space is restricted due to large amounts of mandatory information these products are used under medical supervision, which provides additional protection for vulnerable consumers. 	<p>Industry; Government</p>	<p>FSANZ has revised the approach so that requirements for format, location and required names will not apply to FSMPs and IFPSDU (see Section 3.3.4.3.1).</p>

Issue	Raised by	FSANZ response
REGULATORY OPTIONS		
<p><i>Option 3 is more costly than Option 2</i></p> <p>Noted Option 3 will result in more costs than Option 2 because:</p> <ul style="list-style-type: none"> • most products already comply with Option 2 and their labels would have to change • the added requirement for a summary statement, which is inconsistent with EU requirements • of prescriptive requirements for formatting and location requirements • label redesigns to accommodate the new requirements, particularly for smaller pack sizes • artwork design costs and additional printing plate charges. 	<p>Allergy support group; Industry; Health professionals</p>	<p>Refer to Section 3.5.1.1 Consideration of Costs and Benefits.</p>
IMPLEMENTATION ISSUES		
<p><i>Transition period</i></p> <p>Request FSANZ considers:</p> <ul style="list-style-type: none"> • a one-year transition period, because Proposal P1044 has taken some years to develop. • a longer period (suggestions ranging between three to five years) because: <ul style="list-style-type: none"> – it would reduce costs and minimise wastage – it would align with the standard cycle of labelling updates, particularly for small businesses – domestic food suppliers need time to implement changes to packaging and time to text and implement new labels/printers – food importers have complex supply chains 	<p>Allergy support group; Industry</p>	<p>Based on feedback from the August 2020 targeted consultation, FSANZ has decided to provide a three year transition period along with a two-year stock-in-trade period. This five-year implementation timeframe strikes a balance between the industry operating in the current challenging business environment, and the need to implement the PEAL changes in a timely and definitive way for food allergic consumers to have confidence when making safe food choices (see Section 4.1).</p>

Issue	Raised by	FSANZ response
<p>Stock-in-trade</p> <p>Request FSANZ considers:</p> <ul style="list-style-type: none"> • removing the stock-in-trade provision because food industry has been aware of the proposed changes and many businesses have already implemented these changes voluntarily. • a longer period (between 18 to 36 months, or as an enduring stock-in-trade) because: <ul style="list-style-type: none"> – the large number of products requiring labelling changes – longer shelf life foods require label changes in the first year of the transition period, but would not be permitted to stay on shelves for their entire shelf life – products declaring allergens under the existing regime would need to be recalled – of the complexity associated with foods produced on a seasonal basis – costs and complexity of labelling changes arising from other regulatory changes. 	<p>Government Industry</p>	<p>See above response and Section 4.1.</p>
<p>Enforcement issues</p> <p>Concern there is a high level of prescription and seek clarification on the level of non-compliance that would result in a recall.</p> <p>Suggest:</p> <ul style="list-style-type: none"> • Enforcement agencies assist in the promotion of educational resources for industry • the appropriate enforcement agency approaches the manufacturer/importer to agree on a plan to bring products into compliance. • a label template should be developed that businesses can be referred to that sets out what information needs to be included on a label. 	<p>Industry; Health professional</p>	<p>FSANZ is unable to respond to issues relating to enforcement policy and procedures. Matters relating to enforcement reside with Australian state and territory enforcement agencies and the New Zealand Ministry for Primary Industries.</p>

Issue	Raised by	FSANZ response
<p>Identifier of compliance with new requirements</p> <p>Suggest an identifier code be located on food labels to alert consumers and regulators when new allergen declaration requirements have been applied. This measure would be useful for compliance purposes.</p>	<p>Allergy support group</p>	<p>FSANZ considers the combination of a required name(s), format (bold type) and location (summary statement and statement of ingredients) will indicate food products that have applied the new allergen declaration requirements. It would be impractical and costly to require an identifier code for food products already declaring allergens in accordance with the new requirements.</p>
<p>Labelling discrepancies between the summary statement and the statement of ingredients</p> <p>Note labelling discrepancies may occur between the summary statement and the required names in the statement of ingredients, which may lead to more food recalls for undeclared allergens.</p>	<p>Allergy support group</p>	<p>Noted. The new requirements will need to be communicated to food industry, to promote compliance and minimise food recalls.</p>
<p>Need for a new barcode</p> <p>Note the GS1 Standard requires a new barcode to be generated where there is any change in allergen declaration information. This could raise some very impactful consequences with manufacturers and retailers.</p>	<p>Industry</p>	<p>The changes in Proposal P1044 are in relation to how allergen declarations are made rather than a change of composition or functionality of the products. FSANZ understands from the GS1 support documents that this is unlikely to trigger new barcode numbering.</p>
<p>Communication and Education</p> <p>Request FSANZ updates its website to refer to the required names, and develops:</p> <ul style="list-style-type: none"> • a plain English labelling guide • a consumer education campaign • education courses for food manufacturers. <p>Note educational resources and guidance documents need to be:</p> <ul style="list-style-type: none"> • developed for consumers, allergy support groups and health professionals • updated for industry. 	<p>Allergy support group; Health professional; Industry; Government</p>	<p>FSANZ will develop communication messages and consider opportunities to work with key stakeholders to alert industry (particularly small to medium enterprises), consumers and health professionals to the new labelling requirements within the transition period (refer to Section 4.2).</p>

Issue	Raised by	FSANZ response
<p><i>Lack of harmonisation with overseas regulations</i></p> <p>Concern there is a lack of harmonisation between the proposed allergen declaration requirements and overseas allergen regulations for the following reasons:</p> <ul style="list-style-type: none"> • differences (particularly with the European Union (E.U.), such as its prohibition of a summary statement) mean imported product labels would not comply and there will be associated costs and likely environmental impacts if over-stickering is required and/or costs would be incurred for separate labelling of products exported to the E.U. • trade implications. <p>Suggest allergens recognised in overseas jurisdictions (but not in Australia or New Zealand) are permitted to be declared in bold type and included in the summary statement (e.g. the E.U. requires celery and mustard to be declared).</p>	<p>Industry</p>	<p>FSANZ notes there is generally a lack of harmonisation between overseas regulations for allergen labelling. For example, the list of foods and substances of concern, formatting and location requirements.</p> <p>As noted above, additional text in the summary statement that is not a required name will not be permitted. Formatting requirements in the statement of ingredients (bold type) will apply to the existing allergen declaration requirements. However, foods and substances of public health concern in other countries may still be listed as ingredients in the food. These may be emphasised differently to required names, which must be printed in bold font that provides a distinct contrast with any other text in the statement of ingredients that is not a required name.</p>
DRAFTING ISSUES		
<p><i>Definitions for 'fish', 'crustacea' and 'molluscs'</i></p> <p>Request FSANZ includes clear definitions for fish, crustacea and molluscs because:</p> <ul style="list-style-type: none"> • it is information the industry uses to avoid errors • there is a need to align definitions for food and therapeutic/medicines, and • they could be included in education material. <p>If the 'fish' definition in Standard 1.1.2 cannot be altered to suit allergen declarations, a separate definition of 'fish' s needed for allergen declarations.</p>	<p>Allergy support groups; Health professional; Government; Industry</p>	<p>The ordinary meaning of 'fish' will apply for the purposes of new mandatory declaration requirements. It is common practice to rely on ordinary meanings of terms by using, for example, dictionary definitions.</p> <p>The definition of 'fish' in subsection 1.1.2—3(2) will not apply to the mandatory declaration for 'fish' because it is specifically intended for compositional and identification purposes relating to Standard 2.2.3 – Fish and fish products (see Section 3.3.3.2).</p>

Issue	Raised by	FSANZ response
<p>Definition of 'fish' applied to generic name 'fish'</p> <p>Request Schedule 10 be aligned with Schedule 9 in regard to the definition of 'fish', because the meaning of 'fish' in Schedule 10 would revert to the meaning in Subsection 1.1.2—3(2).</p>	Allergy support group	The definition of 'fish' in subsection 1.1.2—3(2) will no longer apply to the generic name 'fish' in the table to section S10—2 (see Attachment A).
<p>Clarify only marine molluscs require declaration</p> <p>Recommend FSANZ specify the declaration for 'molluscs' applies to marine molluscs only. The dictionary definition of 'molluscs' would capture terrestrial molluscs (e.g. garden snails), which would extend existing requirements.</p>	Industry	At Second Call for Submissions, the intention was to capture marine molluscs only. Therefore, the draft variation has been revised to make clear that mollusc declarations apply to marine molluscs only (see Section 3.3.3.2).
<p>Clarify unlisted tree nuts are exempt from declaration requirements</p> <p>Suggest Schedule 9 includes a note to the effect that tree nuts not listed in the Schedule are not subject to the allergen declaration requirements under Standard 1.2.3.</p>	Industry; Allergy support group	FSANZ considers a note would be redundant because only those tree nuts listed in the table to section S9—3 are required names that must be declared in accordance with allergen declarations requirements.
<p>Required name</p> <p>Seek clarification whether a required name is also a 'specific word'. Subsection 1.1.1—8(1) states that <i>if a provision of this Code requires a warning statement or specific words to be used, the warning statement or words must be expressed in the words set out in this Code without modification.</i></p> <p>Question if lower case is prescribed for required names.</p>	Industry	<p>In the draft variation (Attachment A), the required names listed in the table to section S9—3 will be specific words for the purposes of subsection 1.1.1—8(1). As such, the required name must be expressed using the relevant word or words as set out in the table to subsection S9—3(3) without modification, noting that proposed section 1.2.3—8 will permit a required name to be declared or stated in either the singular or plural form as required.</p> <p>Subsection 1.1.1—8(1) does not prescribe the format (e.g. size, font, colour or capitalisation) in which specific words must be expressed or stated.</p>

Issue	Raised by	FSANZ response
<p><i>Cross reference to allergen declarations</i></p> <p>Note Standard 1.2.1 does not include cross references to allergen declaration requirements for foods not required to bear a label or sold to a caterer.</p>	Government	<p>Standard 1.2.1 includes the following cross references to allergen declaration requirements for foods not required to bear a label or sold to caterers:</p> <ul style="list-style-type: none"> • food not required to bear a label are referred to in paragraph 1.2.1—9(3)(d) and in paragraph 1.2.1—9(7)(b), • food sold to caterers are referred to in paragraph 1.2.1—15(c).
<p><i>'Derivatives of'</i></p> <p>Request clarity on how 'products of' or 'derivatives of' exempted allergens will be treated. The heading for column 1 in the table should be changed from 'food' to 'food and derivatives thereof' (or similar wording).</p>	Industry	<p>The draft variation has been revised to improve clarity (see Attachment A) as follows:</p> <ul style="list-style-type: none"> • Column 1 of the table to section S9—3 lists the relevant food, not the derivatives of the food. • Subsection 1.2.3—4(3) makes it clear that mandatory declaration requirements in section 1.2.3—4 apply to: <ul style="list-style-type: none"> (a) a food that is listed in Column 1 of the table to section S9—3; or (b) a derivative of food that is listed in Column 1 of that table. <p>Subsection 1.2.3—4(4), which exempts certain food from the mandatory declaration requirements in section 1.2.3—4, has been amended so to also refer to derivatives of those foods.</p>
<p><i>Flavouring exemptions</i></p> <p>Concern that ingredients of flavouring substances are not required to be declared in a statement of ingredients if they are listed allergens (subsection 1.2.4—3(2)(a)). Suggest adding a provision to clarify allergens must always be declared.</p>	Allergy support group	<p>FSANZ considers there is no need to provide an exemption for Division 3 mandatory declarations in subsection 1.2.4—3(2) for the following reasons.</p> <ul style="list-style-type: none"> • Standard 1.2.3 creates a stand-alone and self-contained regime for mandatory declarations. How it operates does not depend on provisions in Standard 1.2.4, e.g. subsection 1.2.4—3(2). • Subsection 1.2.4—3(2) itself only provides specific exemptions to the ingredient declaration requirement listed in subsection 1.2.4—3(1). It does not provide an exemption to the requirements imposed by Division 3 of Standard 1.2.3.
<p><i>Structure of Schedule 9</i></p> <p>Suggest 'peanut' is positioned in closer proximity to the tree nut grouping in Schedule 9. 'Fish', 'crustaceans' and 'molluscs' could also be co-located.</p>	Industry	<p>The approach in the Code is to have either alphabetical or category lists, but not combinations of the two. In this respect the table at section S9—3 is ordered consistently with the rest of the Code, and has not been altered.</p>

Issue	Raised by	FSANZ response
<p>Listing of Brazil nut in Schedule 9</p> <p>Suggest 'Brazil nut' has an upper case 'B'.</p>	Industry	The draft variation has been revised to refer to the capitalised form (see Attachment A).
<p>Requirements are difficult to read</p> <p>Concern that the proposed draft variations are convoluted and difficult to follow, with many cross references. The Code also needs to be written in plain English.</p>	Industry; Government	<p>This is outside the scope of Proposal P1044.</p> <p>FSANZ notes that the draft variation is prepared based on the Code as it is. The draft variation reflects and is consistent with the approach, format and text used in the rest of the Code. That approach, format and text was endorsed by New Zealand and all Australian Governments following Proposal P1025 in which the Code was revised, rewritten and restructured, after extensive public consultation.</p> <p>The draft variation is consistent with Commonwealth legislation. Cross referencing of provisions is usual practice in drafting Commonwealth legislation and avoids the legislation being longer/bigger than necessary. However, FSANZ has revised the drafting to reduce the amount of cross-referencing.</p>
<p>Meaning of animal fats or oils</p> <p>Request FSANZ clarifies what is meant by 'animal fats or oils' in the table to section S10—2(a)(ii):</p> <ul style="list-style-type: none"> • 'animal fats and animal oils' or • 'animal fats and (animal and vegetable oils)' 	Government	Proposal P1044 is not changing the generic ingredient names that are already included in Schedule 10, but only the allergen declaration conditions associated with those names. Changing the ingredient names themselves is not related to declaring allergens and so it outside the scope of this proposal. The draft variation reflects the generic ingredient names in paragraph S10—2(a)(iv) of the Schedule.
OTHER ISSUES		
<p>Precautionary allergen labelling (PAL)</p> <p>Consider regulation for PAL should be prioritised for the following reasons:</p> <ul style="list-style-type: none"> • the variety of PAL statements cause great confusion and unnecessary dietary restriction, and conversely risk taking among consumers with food allergies 	Industry; Allergy support groups; Health professional; Government; Private submitter	Noted. PAL is excluded from the scope of Proposal P1044 (see Section 1.3).

Issue	Raised by	FSANZ response
<ul style="list-style-type: none"> it is important proposed changes to mandatory allergen declarations allow for current voluntary PAL recommendations to align with them PAL statements should be standardised, to ensure maximum benefit for consumers and provide certainty for manufacturers. 		
<p><i>Declaring new allergens</i></p> <p>Recommend FSANZ reviews which food allergens should require mandatory declaration on labels, following completion of this Proposal.</p>	Government	FSANZ notes this request, but will consider it outside of Proposal P1044, as the introduction of declaration requirements for new allergens is outside the scope of Proposal P1044 (see Section 1.3).
<p><i>Exemption for alcoholic beverages</i></p> <p>Do not support the existing exemption from allergy labelling with respect to barley, oats, rye, spelt and wheat for beer and spirits.</p>	Allergy support groups	Noted. Changes to existing allergen declaration exemptions are out of scope of Proposal P1044 (see Section 1.3).
<p><i>Harmonise declarations between foods and therapeutic goods/medicines</i></p> <p>Suggest allergen declarations for foods, therapeutic goods and medicines are harmonised because:</p> <ul style="list-style-type: none"> consistent terminology is needed for some allergens (such as crustaceans) reduces red-tape and confusion for the industry sector it would reduce confusion and misunderstandings by consumers. 	Industry	Noted. FSANZ has liaised with the Australian Therapeutic Goods Administration (TGA) on the proposed changes to the Code.

3.2 Evidence summary

3.2.1 Consumer behaviour literature review

FSANZ prepared a literature review on consumers' awareness, attitudes, understanding and behaviours related to allergen labelling. Some minor amendments (typographical errors, incorrect author attributions) have been made since its release as Supporting Document 2 to the Second Call for Submissions.

The literature review highlighted a number of key themes:

Consistency: The studies reviewed reported consumer preference for allergen information to be presented in a clear, consistent manner. This was considered to enable efficient identification and comprehension of the information required for informed and safe food choices. Consistency in the nature and style of allergen declarations can also assist where assumptions about the absence of information or particular style of formatting are taken to indicate the absence of the allergen.

Location: To reduce the time required to locate allergen information and determine if a product was suitable, consumers reported a desire for a brief allergen summary statement in addition to the statement of ingredients. Difficulty in locating allergen information was a consistent theme reported by food allergic individuals in the studies reviewed.

Terminology: Use of complex or technical terminology (e.g. 'casein' for milk or 'ovalbumin' for egg) was a key concern reported by consumers in the studies reviewed. Difficulty with terminology 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. The use of vague or ambiguous terms such as 'nut', without reference to the specific nut may cause food allergic consumers to unnecessarily exclude certain foods from their diet. Consumers expressed a preference for the adoption of plain English language to be consistently used when listing mandatory allergens.

Formatting: Many 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. 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. Devices to do this included preference for emboldening of text and use of different colour text. Some studies reported consumer preference for using graphical symbols and borders to make allergen summary statements distinguishable from surrounding text.

Cereals containing gluten: The review examined consumer preferences for terminology concerning cereals containing gluten. Studies included 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 preference for specificity extends to gluten containing cereals. Specifying the allergen source conveys to consumers that the allergen content of the food product has been overtly considered by the manufacturer. Some individuals that were experienced food label readers identified whether gluten is present based solely on examination of the statement of ingredients.

3.2.2 Safety 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)².

Details of the safety assessment, which has been updated following the First Call for Submissions, can be found in Supporting Document 2. A summary of the findings of this assessment is provided below.

Three mollusc classes (bivalves, gastropods and cephalopods) have been implicated in cases of food allergy. Although there are few published data specifically regarding the prevalence of mollusc allergy in Australia and New Zealand, 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 types of 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 are little data on the prevalence of allergy to barley, rye and oats 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 adverse reactions are usually due to cross-contamination with other cereals.

3.3 Risk management

3.3.1 Principles

Based on the assessment findings using best available evidence, FSANZ established a principle based framework to guide the risk management approach (see Table 2 below). The first principle reflects the findings of the safety assessment and FSANZ's primary objective of addressing the risk to public health and safety in the context of Australia and New Zealand.

² 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>.

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 2: 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.

Drawing on these principles, FSANZ has considered the presentation (e.g. location, format) and terminology of allergen information to make allergen declarations clearer and more consistent to assist food allergic consumers in making safe food choices.

3.3.2 Presentation

3.3.2.1 Location

Decision

FSANZ’s decision is for foods required to bear a label to declare allergens in:

- the statement of ingredients; and
- a co-located and distinctly separate summary statement.

Rationale for decision

As noted in section 2.1.2, the Code does not specify where allergen declarations must be made on the label of packaged foods. FSANZ has observed that allergen declarations are generally made in the statement of ingredients or in a summary statement. In some instances both labelling elements are used.

The available consumer evidence indicates consumers’ identification and comprehension of food allergen information is enhanced when it is repeated across different locations of the same label and when those locations are consistent. Mandating the location also achieves consistency across different product labels (Supporting Document 1). The W1070 Review and the First Call for Submissions both identified the lack of consistency in the location of allergen declarations as a contributor to the variability of allergen information. In response, most submitters supported mandating the location of allergen declarations on food labels, but some noted that consumers use the two label elements in different ways, with the summary statement used for simple, fast allergen searches, and the statement of ingredients for more detailed ingredient and allergen searches.

At Second Call for Submissions, we noted the Food Industry Guide recommends the use of a summary statement, and that many products manufactured in Australia and New Zealand include this voluntary label element. FSANZ has previously observed inconsistencies in the terminology used between the summary statement and the statement of ingredients (FSANZ 2016a). Therefore, in the absence of regulations on the use of a summary statement, differences in terminology and presentation for allergen declarations will likely continue.

Internationally, the Codex Standard specifies allergens to be declared in the list of ingredients. Some overseas national food regulations also 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 a summary statement or the statement of ingredients. The European Union requires allergen declarations in the statement of ingredients and explicitly prohibits the use of a summary statement, except when a statement of ingredients is not provided (due to exemptions).

FSANZ considers it is appropriate to mandate allergen declarations in the statement of ingredients, given the listed foods and substances are intentionally added to food as ingredients or food additives, or are present through the use of processing aids. Furthermore, the 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.

Consumer evidence shows that food allergic individuals and those who shop for them prefer to see a summary statement in addition to the statement of ingredients. A separate summary statement reduces the search times for identifying allergens and is easier to identify and read compared to when allergens are only declared in the statement of ingredients, which may be long and detailed (Supporting Document 1).

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

This approach is also consistent with the education and advice given to food allergic consumers by health professionals and allergy support groups to inspect the statement of ingredients (and summary statement, if one is provided) to determine if allergens are present in the packaged food.

In the Second Call for Submissions, FSANZ proposed a requirement for the summary statement to be located directly below and distinctly separated from the statement of ingredients. At the time we noted most food labels with a summary statement place it below the statement of ingredients (NSWFA 2018), an approach which is also recommended in the Food Industry Guide. This approach also aligns with approaches used overseas.

Allergy support groups and health professionals supported this requirement. However, industry submitters identified issues with limited label space and other packaging format constraints and suggested a less prescriptive approach of co-location for the two label elements.

Consumer evidence indicates the label elements should be in close proximity, and that positioning the summary statement either just above or adjacent to a statement of ingredients is preferred. Positioning the summary statement immediately following or below the statement of ingredients was not favoured, given consumers often only noticed it after reading through the statement of ingredients. Consumers frequently missed seeing summary statements that were located at the end of a long statement of ingredients. The consumer

behaviour literature review identified a preference by food allergic consumers for some method of differentiating (e.g. boxing) the summary statement from other labelling information (e.g. statement of ingredients) to assist allergen identification (see Section 3.2.1).

Having further considered the evidence and to provide flexibility for industry, FSANZ has decided the summary statement is to be co-located with the statement of ingredients rather than placed directly below. The summary statement will be required to appear in the same field of view as the statement of ingredients and appear either directly to the side, directly above, or directly below it for consumers to be able to quickly locate the information. This approach will accommodate label space and packaging formats as identified by industry.

Based on the importance of differentiation between the two label elements, the requirement for the summary statement to be distinctly separate from the statement of ingredients will remain. This, in addition to bolding of the summary statement (see Section 3.3.2.2.2 below), will provide sufficient emphasis for consumers when the summary statement is positioned below the statement of ingredients.

3.3.2.2 Format

3.3.2.2.1 Declarations in statement of ingredients

Decision

FSANZ's decision is to require allergen declarations in the statement of ingredients to be:

- printed in bold font that provides a distinct contrast with any other text.
- printed in a size of type no less than that used for other text.
- provided as a separate word for each ingredient that is, or contains, an allergen.

Rationale for the decision

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.

The findings from the available consumer evidence show food allergic consumers have difficulty in identifying allergens within a statement of ingredients if the relevant allergen-containing ingredient names are not distinguished from the surrounding text. Further, the evidence indicates consistency in formatting across food products can reduce the time consumers take to identify allergens, particularly if inspecting a new product (Supporting Document 1). Consumer preference was for allergen declarations to be more prominent; bold font, larger size of type, different colour text and the grouping of similar information as these all assist food allergic consumers or those purchasing for them to identify allergens. The evidence indicates consumers may assume bolding is mandatory for allergen declarations and its absence may be confused with absence of allergens (Supporting Document 1).

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 a summary statement to be displayed with the same size of

type as used in the statement of ingredients (see next section). FSANZ notes bold font is also commonly used for declaring allergens in the statement of ingredients and is recommended by the Food Industry Guide, which also recommends a minimum size of type of 1.5 mm.

Based on the evidence and submitter comments, FSANZ has decided to require allergen declarations to be printed in bold font that provides a distinct contrast with any other text in the statement of ingredients. This requirement will ensure allergens can be identified, especially in long statements of ingredients.

The size of type for allergen declarations will be required to be no less than that used for other ingredient names, although suppliers may choose a larger size of type for allergen declarations that is larger than other non-allergenic ingredients. FSANZ considers the existing general legibility requirements in the Code are sufficient to ensure allergen declarations are presented in a size which can generally be read by consumers.

When used together, the bold font and size of type requirements will ensure allergen declarations in the statement of ingredients are prominent and easily identifiable for consumers. The approach will also achieve consistency in format between the statement of ingredients and the summary statement on the same product label and across different product labels.

FSANZ considers it unnecessary to prescribe other labelling devices to emphasise allergens (e.g. use of font colour, parentheses or graphical symbols), although it does not preclude their voluntary use in addition to the format requirements.

At Second Call for Submissions, a number of industry submitters sought clarity on whether separate declarations were to be made each time an allergen was present in an ingredient, and whether declarations could be made when embedded in an ingredient name (e.g. buttermilk). During targeted consultation, some industry stakeholders supported an approach where each allergen is declared once and embedded ingredients names would be permitted. Other industry stakeholders noted embedded required names could lead to inconsistencies in the statement of ingredients. Consumer and public health stakeholders supported separate declarations each time an allergen was present in an ingredient. These submitters also opposed embedded required names, stating consumers would be confused as to what is an allergen containing ingredient, and whether an allergen is being declared.

The consumer evidence found that consumers reported frustration at how ingredients of concern are often buried in extensive statements of ingredients. The studies also indicate that clear and unambiguous terms for allergen declarations aid identification (Section 3.2.1).

Based on available evidence and stakeholder views, FSANZ has decided to require allergen declarations in the statement of ingredients to be provided separately for each ingredient that is, or contains, an allergen. FSANZ considers an allergen name embedded within an ingredient name (e.g. milk in 'buttermilk') is not sufficient to draw consumer attention, even if the allergen name is in bold font. However, ingredient names that incorporate the allergen name as a separate word (e.g. 'milk solids') are appropriate, because the allergen name will be separated from other words and is therefore more readily identifiable.

A requirement to declare the same allergen separately in all cases will prevent consumers from being confused that an ingredient should be declared as an allergen when it is not. FSANZ notes this approach aligns with current recommendations in the Food Industry Guide.

3.3.2.2.2 Declaration in the summary statement

Decision

FSANZ's decision is to require the summary statement to:

- be printed in a bold font that provides a distinct contrast with any other text in the statement of ingredients that is not a required name.
- be printed in the same type face and size of type as the declarations in the statement of ingredients.
- commence with the word 'Contains' and only include the allergens required to be declared.

Rationale for the decision

As noted above in Section 3.3.2.2.1, the Code does not currently mandate specific format requirements for allergen declarations, and that generic legibility requirements apply.

Consumer evidence indicates consistency in the presentation of the summary statement is important for consumers. As with allergens declared in the statement of ingredients, consumers expressed a desire for the summary statement to be in bold font. Some consumers suggested the summary statement should be placed within a box (or some other eye catching shape)(see Supporting Document 1).

To ensure consistency and clarity for consumers, FSANZ has decided to require the summary statement to 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. The requirement will emphasise the summary statement from the statement of ingredients and other text, for consumers to locate it using a quick label search. Use of bold font will also provide consistency with allergen declarations made in the statement of ingredients.

The size of type and typeface will be required to be the same as that used for declarations in the statement of ingredients. This requirement will avoid the potential for the summary statement to be displayed using a smaller size of type, which would cause it to lose prominence compared to the statement of ingredients. Having the summary statement displayed prominently is important for the clear identification of allergen information.

This approach was generally supported by submitters and aligns with the Food Industry Guide recommendations for the entire summary statement to be presented in bold font and using the same text size as in the ingredient list, or a minimum print size of 1.5 mm.

At Second Call for Submissions, FSANZ noted there is variation in the prefix used for a summary statement, and that the Food Industry Guide recommends a 'contains' prefix. Further, a food label survey by the NSW Food Authority (NSWFA 2018) reported the majority of labels (84%) with a 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 summary statement was identified in the consumer behaviour literature review as important for food allergic consumers. However, the studies reviewed did not examine whether certain prefixes were more readily understood or preferred by consumers (see Supporting Document 1). Therefore, the summary statement will be required to begin with the prefix 'Contains', which reflects the most common approach currently used by industry. To ensure the summary statement is presented consistently across product labels and allows consumers to make a

quick label search for allergen information, the allergens to be declared (using required names) will be the only terms permitted in the summary statement.

3.3.3 Terminology

3.3.3.1 Required names

Decision

FSANZ's decision is to require allergens to be declared using mandatory specified terms of the allergen source (required names) when present in a food for sale.

Synonyms will only be permitted for soy, where 'soya' and 'soybean' can be used for soy declarations in the statement of ingredients.

Rationale for the decision

The Code currently does not mandate the terminology to use when making allergen declarations. A previous review (FSANZ 2016a) found there was no consistency in how allergens are declared, due to the variability in terminology used.

FSANZ's consumer behaviour literature review examined the consumer attitudes towards the terminology currently used and their preferences for how it could be improved to aid identification of allergens (Supporting Document 1). The review found consumers were confused by complex or technical terminology (e.g. 'casein' for milk or 'ovalbumin' for egg), and its use was a significant barrier to consumers correctly identifying whether a product was safe for consumption. In some cases, food allergic individuals would unnecessarily restrict certain foods or engage in risk-taking behaviour. The evidence indicates that children, those shopping for food allergic consumers, or food allergic consumers recently diagnosed or from culturally and linguistically diverse (CALD) backgrounds find complex or technical terminology to be particularly challenging when searching for allergen information.

Consumers expressed a preference for plain English language to be consistently used for allergen declarations (Section 3.2.1). Studies found the use of the same, simple and specific terms across different products and across different locations on the label of the same product enhances allergen identification and results in appropriate precautionary action (i.e. avoiding the purchase and consumption of unsafe food)(Supporting Document 1).

At First Call for Submissions, FSANZ proposed two approaches for applying plain English allergen labelling. Both approaches required the specific source of an allergen to be declared, however the first approach proposed not to prescribe terminology whereas the second approach would prescribe the terms that must be used.

The majority of submitters supported the second approach noting this 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 to use for individuals with limited allergy knowledge (e.g. carers) and those with English as their second language.

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 US FALCPA and Canadian Food and Drug Regulations provide lists of the specific terms to be used for declaring allergens (and some of these terms differ between the two countries).

Following assessment, FSANZ has decided allergens are to be declared using required names (refer to Section 3.3.3.5 for the list of required names). 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 consistency, as no variations in the terms will be permitted (with the exception of soy synonyms in the statement of ingredients). A single term that reflects the source of the allergen will also be clearer and therefore easier for consumers to comprehend.

However, in the case of soy, FSANZ has decided to permit, use of 'soya' and 'soybean' as suitable synonyms 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 'soy'. Some industry submitters requested flexibility to also use soy synonyms in the summary statement. However, FSANZ considers the required name 'soy' should always be declared in the summary statement, as this is the simplest and most accurate summary term for this allergen. Its use in the summary statement will also provide greater consistency between different product labels, and assist consumers to identify the presence of soy.

Submitters to the Second Call for Submissions were supportive of the use of required names to provide consistency for consumers, although clarity was sought on additional text and ingredient names with embedded required names (see Section 3.3.2.2.1 above).

3.3.3.2 Fish, crustacea and molluscs

Decision

FSANZ's decision is to require fish, crustacea and molluscs to be separately declared when present in a food for sale, using 'fish', 'crustacean' and 'mollusc' as required names.

Rationale for the decision

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'³ in Standard 1.1.2 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'. 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. Adding further to this, section S22—2 of *Schedule 22 Foods and Food classes* 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.

FSANZ has assessed the allergenicity of molluscs and whether molluscs could be considered as an allergen distinct from 'fish' and 'crustacea'. The safety assessment concluded mollusc allergy is of clinical significance in Australia and New Zealand and that

³ **Fish** means a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish, but not including amphibians or reptiles (subsection 1.1.2—3(2) of Standard 1.1.2 – Definitions used throughout the Code).

cross-reactivity between molluscs and crustacea is likely to be relatively low, meaning individuals who are allergic only to one of these foods can usually tolerate the other (Supporting Document 2).

Based on the findings of the safety assessment, and the need to clearly distinguish molluscs in the Code as a food allergen, FSANZ at First Call for Submissions proposed to require the separate declaration for molluscs. Submitters were supportive of this approach to provide clarity.

Therefore, the terms 'fish', 'crustacean' and 'mollusc' will be required names for the declaration of these allergens. These terms reflect the allergens of concern (e.g. a crustacean-allergic individual would be allergic to all crustaceans) and will ensure mollusc-allergic consumers have access to information that is specific to their allergy. Use of a single term for each allergen will provide consistency in the terminology used. Generic ingredient naming requirements for the common or descriptive name to be used will continue to apply, meaning the ingredient names can refer to individual species for crustaceans and molluscs. The approach reflects best practice labelling recommendations in the Food Industry Guide for fish and crustacea (noting the requirement for 'mollusc' is new).

FSANZ intends that the ordinary dictionary definitions for fish, crustacean and molluscs will apply to the declaration requirement. The existing definition of 'fish' in Standard 1.1.2 will not apply to allergen declaration requirements because it refers to 'shellfish' and is intended for compositional and identification purposes relating to *Standard 2.2.3 – Fish and fish products*. At Second Call for Submissions, a range of submitters requested FSANZ include definitions for fish, crustacean and molluscs in the Code to provide clarity and to align definitions for food and therapeutics/medicines. However, FSANZ's approach has not changed, given the ordinary meaning of a word is used in the absence of a definition.

Some industry submitters noted the mollusc dictionary definition captures land molluscs and therefore has a broader meaning than what was originally intended in the Code (i.e. molluscs as aquatic invertebrates). FSANZ has clarified the declaration requirement for molluscs will apply only to marine molluscs.

3.3.3.3 Tree nuts

Decision

FSANZ's decision is to require specific tree nuts to be declared separately in the statement of ingredients and summary statement using the required names 'almond', 'Brazil nut', 'cashew', 'hazelnut', 'macadamia', 'pecan', 'pine nut', 'pistachio' and 'walnut'.

Rationale for the decision

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' is not defined for the purposes of making allergen declarations, and so the Code is unclear about which individual tree nuts are captured by the term. This has created uncertainty for food industry about what tree nuts should be declared and whether to use the 'tree nuts' term or the individual tree nut names when making an allergen declaration about tree nuts.

The following existing Code requirements have also added to this uncertainty:

- the generic ingredient name 'nuts' in Section S10—2 with the condition that the specific name of nut to be declared
- the list of 16 individual tree nuts under the heading of 'tree nuts' in section S22—2 for the purpose of categorising foods for assigning agricultural pesticide permissions.

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 tree nuts are: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut. FSANZ's safety 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 these tree nuts.

At Second Call for Submissions, FSANZ proposed the required names for the specific tree nuts in the statement of ingredients and the required name 'tree nut' in the summary statement. The intent was to provide consumers with a shorter summary statement to quickly identify the presence (or not) of tree nuts. Consumers could then undertake a more detailed search of the statement of ingredients for information about the specific tree nuts. A shorter summary statement was also seen to assist the food industry in managing label space.

Although most submitters supported the use of the term 'tree nut' in the summary statement, some industry submitters requested flexibility to use specific tree nut required names in the summary statement, to avoid potential conflict between the required name 'tree nut' and voluntary PAL statements about specific nuts. These submitters also considered the required name 'tree nut' would be less clear for consumers. An allergy support group submitter considered allergens in the summary statement need to be identical to those in the statement of ingredients, although the term 'tree nut' required name could be used as well.

The consumer evidence indicated a consumer preference for specific nut terms over the term 'tree nuts'. The presence of generic terms on food labels can cause food allergic consumers to unnecessarily exclude certain foods from their diet. Consumers were also more likely to take precautionary action when a specific nut was labelled, and labelling specific nuts suggested to consumers that the manufacturer had a greater level of knowledge about the allergen risk. Generally, there was a preference for consistency in the terminology of allergen declarations, which indicates there is a benefit for specific nut names to be declared in both the summary statement and the statement of ingredients (see Supporting Document 1). Following assessment of the consumer evidence and consideration of submitter comments, FSANZ has revised its approach to remove the required name 'tree nut' for the summary statement. The individual nut names 'almond', 'Brazil nut', 'cashew', 'hazelnut', 'macadamia', 'pecan', 'pine nut', 'pistachio' and 'walnut' will be required names in the statement of ingredients and in the summary statement.

FSANZ considers this approach will promote consistency between both label elements as well as consistency across different food products for tree nut declarations, and considers the individual tree nut names reflect the allergen risk. Individuals allergic to certain tree nuts will be able to safely choose from a broader range of foods. The requirement will provide certainty to the food industry about which specific tree nuts are implicated in food allergy and how they must be declared. It will also enable voluntary PAL statements about different tree nuts to be made. FSANZ notes the approach is similar to the Food Industry Guide, which recommends the specific name of each tree nut is declared in the statement of ingredients and as an option for the summary statement.

The decision to declare specific tree nuts as required names also clarifies the declaration requirement for 'tree nuts' (and their products) does not apply to coconut from the fruit of the palm *Cocos nucifera*.

3.3.3.4 Cereals

3.3.3.4.1 Wheat

Decision

FSANZ's decision is to require 'wheat' as the required name in the statement of ingredients and the summary statement when any wheat species or wheat hybrids are present.

Rationale for the decision

Standard 1.2.3 currently requires cereals containing gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains (or products of these foods) to be declared when present in a food for sale. The original intent was for the individual cereals to be declared, however the Standard does not make a distinction between cereals associated with allergies and cereals associated with gluten-related disorders (i.e. Coeliac disease and Dermatitis herpetiformis). FSANZ is aware this requirement could be interpreted as a requirement to declare using the words 'cereals containing gluten', and that there are products labelled with this declaration on the market (FSANZ 2016).

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. Several species of wheat (genus *Triticum*) are cultivated, the most common of which are *Triticum aestivum* and *Triticum durum*. Allergic reactions to wheat can be caused by one or more wheat proteins, which include gliadins and glutenins (which form the gluten fraction), albumins, and globulins (FSANZ 2010).

FSANZ's safety assessment has 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 (see Supporting Document 2).

Based on the findings of the safety assessment, FSANZ proposed at First Call for Submissions to require the separate declaration of wheat and wheat hybrid strains from the declaration requirement for cereals containing gluten (i.e. from barley, rye, oats), irrespective of the presence of gluten in the food. Submitters mentioned a separate wheat declaration will allow wheat-allergic consumers to obtain labelling information applicable to their condition, as 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.

At Second Call for Submissions, FSANZ proposed 'wheat' as a required name for its separate declaration in the statement of ingredients and summary statement, if wheat or wheat hybrids are present. This approach will apply when any wheat species or wheat hybrids are present (unless there is an existing exemption from declaring wheat, e.g. alcohol distilled from wheat). In the case of Triticale (as an example of a wheat and rye hybrid), the

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

presence of both wheat and rye would need to be declared in the statement of ingredients, and wheat and gluten in the summary statement (see section 3.3.3.4.2 below regarding rye).

FSANZ also proposed that declaration requirements for cereals containing gluten would apply to spelt, and that 'spelt' would be a required name. However, allergy support group submitters commented that spelt is a type of wheat and, in the context of allergen declarations, the required name 'wheat' should be declared when spelt is used as an ingredient. FSANZ notes spelt is one of several species of wheat from the genus *Triticum*.

Following assessment and consideration of submitter comments, FSANZ has reconsidered the approach for spelt and has removed 'spelt' from the list of required names. In accordance with generic ingredient naming requirements, spelt may still be listed as the ingredient in the statement of ingredients, however a 'wheat' declaration will also be required.

3.3.3.4.2 *Barley, rye and oats*

Decision

FSANZ's decision is to require 'rye', 'barley' and 'oats' as required names in the statement of ingredients when these cereals (or their hybrids) and gluten are present.

Rationale for the decision

As noted above, Standard 1.2.3 currently requires cereals containing gluten, including rye, barley, oats and their hybridised strains to be declared when present in a food for sale, but does not make a distinction between cereals associated with allergies and cereals associated with gluten-related health conditions (i.e. Coeliac disease and Dermatitis herpetiformis).

The safety assessment noted little data are available on the prevalence of allergy to barley, rye and oats in Australia and New Zealand. Also FAISAG advised that cases of rye and barley allergy do occur but are not common and cases of oat allergy are very rare (Supporting Document 2). Therefore, gluten is the substance of concern for these cereals.

The available consumer evidence indicated gluten-sensitive consumers (individuals with Coeliac disease and non-Coeliac gluten sensitivity) or those purchasing for them appear to rely on the term 'gluten' somewhere on the label. In addition to 'gluten', these consumers prefer the source of the cereal be identified in the statement of ingredients because it conveys the 'allergen' content of the food product has been assessed and considered by the manufacturer. However, the studies did not examine whether these consumers required the specific cereal name (e.g. barley) to be declared on the label to identify the presence of gluten (Supporting Document 1).

Following assessment and consideration of submitter comments, FSANZ has decided to require 'barley', 'rye', and 'oats' as required names in the statement of ingredients when these cereals (or their hybrids) and gluten are present in a food for sale.

As gluten is the substance of concern for individuals with Coeliac disease and Dermatitis herpetiformis, allergen declaration requirements (e.g. required names and bold type) will not apply to these cereals if they are present in food but do not contain gluten (e.g. due to processing or breeding techniques to remove gluten proteins). Generic ingredient naming requirements for a common or descriptive name to be used will still apply to barley, rye and oat ingredients listed in the statement of ingredients.

3.3.3.4.3 *Gluten declaration in the summary statement*

Decision

FSANZ's decision is to require 'gluten' as the required name in the summary statement when gluten from wheat, barley, rye, oats or their hybrids are present.

Rationale for the decision

As noted in section 3.3.3.4.1, the original intent of the existing requirements for cereals containing gluten was for the individual cereals to be declared. There is no requirement for gluten to be declared. However, given the Code does not currently specify the terminology or location of allergen declarations, there are labels displaying 'gluten' in a summary statement.

At First Call for Submissions, FSANZ canvassed views about alternative methods for declaring the presence of gluten in food. Submitters were asked if declaring individual sources of gluten-containing cereals would provide adequate information about the presence of gluten, or if there were other approaches. There was strong submitter support 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 a summary statement combined with a declaration of the specific cereal name in the statement of ingredients. Allergy support group submitters noted concerns that a 'gluten' declaration was not specific for consumers with allergies to barley, rye and oats.

FSANZ's consumer behaviour literature review indicated consumers prefer the term 'gluten' to the cereal names (Supporting Document 1) and that gluten-intolerant consumers, individuals with Coeliac disease or Dermatitis herpetiformis, and those purchasing for them rely on the inclusion of the word 'gluten' somewhere on the label. Some individuals that were experienced food label readers (e.g. individuals with Coeliac disease) would use specific cereal names in assessing the suitability of products (Section 3.2.1). There is also evidence to suggest that, when the term 'gluten' is not used in a summary statement or in association with the ingredient declaration, people following a gluten free diet find it difficult to assess whether or not certain ingredients are gluten-free (Supporting Document 1).

Based on submitter views, the consumer evidence and the evidence that gluten is the substance of concern for individuals with Coeliac disease and Dermatitis herpetiformis (see previous section), FSANZ has decided to require 'gluten' as the required name in the summary statement when gluten from wheat, barley, rye, oats or their hybrids are present. With the exception of 'wheat' (which is to be declared when present in food irrespective of gluten), the specific cereal names will not be permitted in the summary statement.

Highlighting gluten in the summary statement will assist both gluten intolerant and wheat-allergic consumers to make fast searches. The absence of the required name 'gluten' in the summary statement will indicate to consumers the food does not contain gluten. FSANZ considers this approach will make it clearer for consumers when voluntary 'gluten-free' claims are present on the label.

3.3.3.5 List of required names

As discussed above, FSANZ has decided to prescribe required names in for mandatory allergen declarations as detailed in Table 2.

Table 2: Required names for making mandatory declarations

Allergen declaration		For declarations in a Statement of ingredients	For all other declarations
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	
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	soy
Peanut		peanut	peanut
Almond		almond	almond
Brazil nut		Brazil nut	Brazil nut
Cashew		cashew	cashew
Hazelnut		hazelnut	hazelnut
Macadamia		macadamia	macadamia
Pecan		pecan	pecan
Pine nut		pine nut	pine nut
Pistachio		pistachio	pistachio
Walnut		walnut	walnut

3.3.4 Allergen declaration requirements for specific standards

3.3.4.1 Ingredient names

Decision

FSANZ's decision is to clarify how allergen declaration requirements apply to ingredient names by:

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

Rationale for the decision

Standard 1.2.4 requires ingredients to be listed by a common, descriptive or generic name in the statement of ingredients (when on food required to bear a label). Additionally, the table to section S10—2 sets out conditions for the use of certain generic names when declaring an allergen source (see Section 2 of this report).

To ensure these existing requirements are subject to the new allergen declaration requirements, FSANZ has decided to include a provision in Standard 1.2.4 to make clear the requirements in Division 3 of Standard 1.2.3 apply and to remove existing provisions in the table to section S10—2 for certain generic ingredient names as follows:

- Conditions for use of ‘cereals’, ‘fats and oils’, ‘fish’ and ‘starch’ that relate to allergen declarations have been removed to ensure the required names are used with these generic names.
- The generic name ‘nuts’ and its condition for use have been removed because the name is inconsistent with the required names for specific tree nuts and peanut (a legume).

This means the terminology and format requirements for allergen declarations will apply to generic ingredient names. As discussed in Section 3.3.2.2.1 above, an ingredient name that includes the required name as a separate word would meet the requirement for a mandatory allergen declaration, noting the required name would be in bold type (e.g. ‘**milk** solids’). If the ingredient name does not include the required name, the latter must be provided in association with the ingredient name (e.g. ‘cheese (**milk**)’).

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

Decision

FSANZ’s decision is to apply the required names to allergen declarations made for food:

- not required to bear a label
- exempt from displaying a statement of ingredients (including small packages)
- in individual portion packs
- sold to caterers

Rationale for the decision

The Code currently allows allergen declarations to be provided through different means for certain foods for sale. These include:

- food exempt from bearing a label (e.g. food displayed in an assisted service display cabinet) (subsection 1.2.1—6(1)). These foods must 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)).
- standardised alcoholic beverages and food for sale in small packages (subsection 1.2.4—2(3) of Standard 1.2.4) are not required to have a statement of ingredients although allergen declarations are required for these foods.
- food sold in individual portion packs is only required to bear a label with allergen declarations (subsections 1.2.1—6(3) and 1.2.1—8(3)).

- food sold to caterers that is required to bear a label must include allergen declarations on the label (paragraph 1.2.1—15(c)). However, where food sold to caterers do not have to bear a label, the allergen declarations must be provided to the caterer with the food (section 1.2.1—13).

FSANZ proposed at Second Call for Submissions that required names should always be used when allergen declarations are communicated, so there is a level of consistency in the provision of allergen information across the food supply. In particular, the required names for individual tree nuts and cereals (wheat, rye, barley and oats) would be declared. It also noted that the presentation and format requirements for allergen declarations in the statement of ingredients and allergen summary statement (e.g. bold text) would not apply to these foods for sale.

Submitters supported the approach, although there were divergent views about the requirement to declare the required name for barley, rye and oats for these foods (noting wheat will always be declared). Some allergy support group and health professional submitters supported these required names to inform individuals with allergies to these cereals. Whereas, some health professional and government submitters preferred the required name 'gluten' be used because consumers were familiar with this term and declaring the specific cereals could pose a risk for individuals with gluten-related disorders.

After considering submitters' views and other available evidence, FSANZ has reconsidered the approach for required names and decided to prescribe 'gluten' as the required name for food for sale as listed above. This approach reflects the safety assessment finding that gluten is the substance of concern for individuals with Coeliac disease and Dermatitis Herpetiformis (not the specific cereals; see Section 3.3.3.4.2). FSANZ also considers consumers are more likely to ask if gluten is present instead of the specific cereal and retailers and caterers are more likely to declare gluten when they provide allergen information in connection with the display of the food or provide the information to the consumer on request.

FSANZ considers consumers should have access to allergen information that is as consistent as possible across the food supply. By only mandating the use of required names for foods that do not have to bear a label or display a statement of ingredients, the approach provides this consistency while accommodating the different sale arrangements for these foods. It is also consistent with the declaration requirements for the summary statement on packaged food. Furthermore, suppliers can choose to voluntarily use format (e.g. bolding) or location (e.g. a summary statement) when making declarations.

3.3.4.3 Declarations for specific foods and ingredients

3.3.4.3.1 Special purpose foods

Decision

FSANZ's decision is to not apply requirements related to the use of required names, formatting or location, to declarations of allergens made for food for special medical purposes (FSMP) and infant formula products for special dietary use (IFPSDU). However, these foods will still be required to declare the presence of the allergen(s) concerned.

Rationale for the decision

Special purpose foods regulated in Part 2.9 of the Code are subject to allergen declaration requirements in Standard 1.2.3.

At Second Call for Submissions, FSANZ did not explicitly consider the application of the proposed PEAL allergen declaration requirements to Part 2.9 *Special purpose foods*. This meant that proposed requirements for formatting, location and required names would apply including to FSMP (Standard 2.9.5) and to IFPSDU (Division 4, Standard 2.9.1).

Industry submitters did not support this approach, noting FSMP and IFPSDU are highly specialised, low volume products manufactured globally and imported into Australia and New Zealand for vulnerable individuals in the population. These submitters raised issues about requiring additional labelling requirements for the Australasian market (e.g. the summary statement which the EU prohibits), when label space was limited because labels are shared with other countries and these products must be used under medical supervision.

In light of submitter views, FSANZ has reconsidered the approach to FSMPs and IFPSDU. The existing requirement for these products to declare the listed allergens will continue, but required names, format and location requirements will not apply to FSMP and IFPSDU. This is to ensure the supply of specialised FSMP and IFPSDU can continue uninterrupted, and recognises that these products are used under medical supervision and cannot be directly accessed by consumers.

PEAL requirements will however apply to other special purpose foods regulated in Part 2.9 of the Code, namely infant formula products excluding IFPSDU (Standard 2.9.1), food for infants (Standard 2.9.2), formulated meal replacements and formulated supplementary foods (Standard 2.9.3), and formulated supplementary sports foods (Standard 2.9.4).

3.3.4.3.2 *Processing aids*

Decision

FSANZ's decision is to require the term 'processing aid' (or its plural) to be listed in the statement of ingredients in association with the allergen it contains or is derived from.

Rationale for the decision

At Second Call for Submissions, FSANZ proposed the allergen declaration requirements would apply to food that may be present as a substance used as a processing aid, or an ingredient or component of such a substance. This requirement reflected the status quo, where the food allergen must be declared but not the processing aid.

Several industry submitters and a government submitter raised issues relating to inconsistencies between the summary statement and the statement of ingredients when the processing aid is not declared. There was concern the absence of an allergen declaration in the statement of ingredients may confuse consumers and a declaration for 'tree nut' only in the summary statement may pose a safety risk. Several industry submitters suggested the required name for the allergen is declared in both locations. However no submitters referred to identifying the processing aid itself.

FSANZ's consumer behaviour literature review did not identify studies that specifically explored consumers' responses to allergen declarations about processing aids. However, some literature reported that consumers did find non-specific terms like 'flavours', 'spices' 'vegetable oil' and 'e numbers' to cause problems when trying to identify suitable products. The general preference for consistency may suggest that allergens declared in a summary statement, but not included (or included with a different term) in the statement of ingredients may cause problems for some consumers (see Supporting Document 1).

In targeted consultation following the Second Call for Submissions, FSANZ canvassed stakeholder views about an approach that required processing aid names to be declared along with the relevant allergen declaration. Industry stakeholders expressed concern that a requirement for specific processing aid names would lengthen the statement of ingredients and create issues for certain labels where space is restricted.

FSANZ has considered the issues raised by submitters and the available consumer evidence, and will require processing aids to be listed in the statement of ingredients in association with the allergen they contain or are derived from. Manufacturers will be required to use the term 'processing aid' (or its plural) in association with the required name(s) of the allergens, for example 'processing aids (wheat, egg)' or 'processing aid containing wheat'.

FSANZ considers this approach is consistent with declaration requirements for ingredients and food additives, and will provide consistency for consumers between the summary statement and the statement of ingredients. The prescribed term 'processing aid' will allow for a shorter statement of ingredients and will distinguish processing aids from food additives.

3.4 Risk communication

3.4.1 Public consultation process

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and implemented a communication strategy for this proposal. Subscribers and interested parties were notified about the public consultation periods via FSANZ Notification Circulars, media release and through FSANZ's website, social media tools and Food Standards News.

A First Call for Submissions was released for public comment from 1 March to 10 May 2018 with 42 submissions received in response. FSANZ received 44 submissions in response to a Second Call for Submissions between 29 November 2019 and 27 February 2020.

FSANZ considered all feedback received from the consultations as part of its assessment. FSANZ appreciates the time taken by individuals and organisations to make submissions on this proposal. All comments are valued and contribute to the rigour of our assessment.

3.4.2 Targeted stakeholder consultations

In August 2020, FSANZ conducted targeted consultations with key consumer, public health (including allergy educators) and industry stakeholders. FSANZ also engaged with Australian jurisdictions and the New Zealand government at that time.

The purpose of this consultation was to seek key stakeholder views on a number of issues raised at Second Call for Submissions, to inform changes to the draft variation prior to approval by the FSANZ Board. Issues discussed included presentation of allergen declarations (location, format and required names), requirements specific to certain foods and ingredients, and the transitional arrangements. FSANZ also considered all views expressed by the stakeholders during these consultations.

3.4.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed draft variations are inconsistent with any existing or imminent international standards and the proposed variation may have a significant effect on trade.

FSANZ made a notification to the WTO in accordance with the WTO Agreement on the Technical Barriers to Trade for this proposal. The notification was published on 19 December 2019 from both the Australian government (Notification G/TBT/N/AUS/115) and New Zealand government (Notification G/TBT/N/NZL/95). The closing date for the notification was 27 February 2020. No comments were received.

3.5 FSANZ Act assessment requirements

3.5.1 Section 59 of the FSANZ Act – Assessing a proposal

3.5.1.1 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 draft variation developed for this proposal would outweigh the direct and indirect benefits to the community, government and industry that arise from the variation.

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 consideration to the costs and benefits associated with Proposal P1044, which is provided as a separate document to this report (Supporting Document 3).

Proposal P1044 has reviewed the Code's allergen declarations requirements and has identified adjustments to improve the clarity and consistency of declarations. Presently a lack of clarity is caused by some labels using terms that are vague, inaccurate, or too technical. Inconsistency issues also exist on some labels as a result of differing terminology, formatting, whether an allergy summary statement is used, and location of allergy declarations on the food packaging.

FSANZ considered two options to address the clarity and consistency issues, along with the status quo. The options were:

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.

Allergies represent a group of chronic disorders in which morbidity rather than mortality is predominant. Food allergies range from mild symptoms to life threatening allergic reactions (anaphylaxis) and nutritional compromise, particularly if the individual has multiple food allergies (National Allergy Strategy, 2015). A diagnosis of food allergy has a significant effect on quality of life in children and their parents (Access Economics Pty Limited, 2007). In children with severe food allergy, management in the community is complex and has the potential to cause significant anxiety within affected families regarding care in schools, risk of death and the need or otherwise for injectable adrenaline (Hu, Kerridge, & Kemp, 2005). For affected adults, allergic disorders lead to impaired quality of life, absenteeism from work, reduced productivity and can be a substantial financial burden (Access Economics Pty Limited, 2007).

Australian hospital admissions due to food related anaphylaxis have increased rapidly in recent times. Anaphylaxis due to food allergy in children aged zero to four years increased five-fold over the last decade (Australasian Society of Clinical Immunology and Allergy, 2019) and overall anaphylaxis hospital admissions increased from 8,098 in 2014-15 to 11,856 in 2018-19 (Australian Commission on Safety and Quality in Health Care, 2019). Although mild, moderate and severe allergic reactions (anaphylaxis), to foods are common in Australia and New Zealand, deaths from anaphylaxis due to food allergy are rare. Most deaths can be prevented by careful allergen avoidance measures, and immediate administration of an adrenaline (epinephrine) autoinjector. There were 324 anaphylaxis fatalities recorded by the Australian Bureau of Statistics between 1997-2013 (Mullins, Wainstein, Barnes, Liew, & Campbell, 2016).

An Australasian Society of Clinical Immunology and Allergy (ASCIA)-Access Economics Report (2007) estimates the financial cost of all allergies in Australia⁵ to be around \$10.21 billion per annum⁶. This includes productivity, carer, funeral, deadweight loss⁷, and aids and home modification costs. Additionally, the net value of the lost wellbeing (disability and premature death) was a further \$28.28 billion or 156,144 Disability Adjusted Life Years (DALYs). This gives a total cost to the Australian society of approximately \$38.49 billion per annum or an average of \$9,427 per annum per person with allergies.

ASCIA's Food Allergy fact sheet (2019) states that food allergy occurs in around 10% of infants, 4-8% of children, and about 2% of adults in Australia and New Zealand. Using June 2019 population statistics (Australian Bureau of Statistics, 2019), this suggests that between 656,045 and 856,178 Australians experience food allergies in a given year. In the absence of more specific data, with the average per annum cost of all allergies per person at \$9,427, we estimate the societal cost of food allergies to be between \$6 and 8.1 billion per annum.

Societal allergy costs are more associated with ongoing management of exposure to allergens (or attempting to avoid exposure) rather than premature mortality and given that this proposal is optimising current allergen declaration requirements, the benefits are most likely to be obtained from reducing avoidance and search costs.

P1044's aim is to make it easier for consumers to determine the presence (or absence) of allergens by requiring clearer and more consistent allergen declarations. This may reduce:

- The number of foods avoided due to consumers not being able to conclude if an allergen is absent (reduced avoidance costs).
- The time and effort required to study packaging or other information collection activities undertaken to reliably determine the safety of the product (reduced search costs).
- Inadvertent consumption of allergens, causing illness or death (reduced healthcare and lost welfare costs).

There are assumed to be not more than 30,000 retail food products or 'Stock Keeping Units' (SKUs) in the Australian market (including fresh produce). Half of these are expected to contain allergens. All products containing allergens are expected to need updates to reflect the requirements. The majority of the updates are assumed to be minor reflecting the updates to required names and bolding. Minor label updates cost between \$1,788 and \$4,688. However, some products may require more substantial updates given the increased length of the statement of ingredients. Non-minor label updates cost between \$5,528 and \$12,088.

⁵ We could not find any reports on the economic or financial cost of allergies in New Zealand

⁶ Please note these costs includes allergic rhinitis, asthma, chronic sinusitis and other allergies and has been indexed to 2019 calendar year using [ABS Cat. No. 6401.0, Consumer Price Index](#).

⁷ Loss of economic efficiency from transfer payments, such as government welfare and income support payments (Access Economics Pty Limited, 2007)

There is also expected to be an additional 5,000 packaging items (e.g. inner packets) that would also need to have allergen declarations updated. These are all expected to be minor label updates.

Option 3 is expected to cost slightly more than Option 2 due to the mandatory allergen summary statement being more likely to require a major label redesign (it is estimated that 60% of products with allergen declarations currently use an allergen summary statement) and being more likely to have components that are different to overseas allergen declaration requirements.

Option 2 is assumed to cost between \$37 million and \$96 million (\$2,467 to \$6,400 per SKU) in Australia plus the cost of managing the transition and implementation. Option 3 is assumed to cost between \$41 million and \$105 million (\$2,733 to \$7,000 per SKU) in Australia plus the cost of managing the transition and implementation, as well as managing differing international allergen declaration requirements where products are traded and not already using market specific labels.

The five year implementation period (see Section 4 below) will enable the majority of businesses to incorporate the label updates within their normal label update cycle. FSANZ estimates that this may reduce the label costs by 70% (i.e. down to \$31.5 million or \$2,100 per SKU).

There are significant differences with how allergen declarations are required to be made in overseas markets. Internationally traded products that do not already have market specific labels may incur ongoing costs to manage the different labelling requirements. FSANZ was not able to obtain evidence of how many products would be required, because of this proposal, to use different labels for the different markets. FSANZ notes that many products are currently labelled specifically for the Australia New Zealand market.

A once-off \$105 million cost to industry incurred in the first year, a societal food allergy cost of \$6 billion per annum, and a 7% discount rate, means the change would need to result in a reduction of at least 0.25% of the annual societal cost of food allergies over a 10 year period to provide a benefit.

If we include the reduction to label costs assumed from being able to combine the mandated updates within the normal label update cycle, a once-off \$31.44 million cost to industry incurred in the first year, a societal food allergy cost of \$6 billion per annum and a 7% discount rate, means the change would need to result in a reduction of at least 0.075% of the annual societal cost of food allergies over a 10 year period to provide a benefit.

FSANZ was unable to obtain any regulatory analysis data estimates for New Zealand, although we have assumed they are similar to Australian data due to similarities in the food supply systems and prevalence of food allergies.

Option 3 is likely to provide more benefit to consumers than Option 2 as it addresses both the clarity and the consistency issues identified. It gives greater surety of where to look for allergen declarations. This will make it easier for consumers in identifying the presence of food allergens, which may lead to reduced healthcare costs and increased wellbeing, as compared to Options 1 and 2. This was generally supported in submissions.

FSANZ's conclusion from analysis of available literature and consultations is that Option 3 (required names, 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 food products.

3.5.1.2 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 the last 13 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 the food regulatory measure developed as a result of this proposal.

3.5.1.3 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 the relevant standards for allergen labelling apply in both Australia and New Zealand, and there are no relevant New Zealand standards that apply.

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

Other relevant matters are considered below.

3.5.2 Section 18 of the FSANZ Act – FSANZ Objectives

3.5.2.1 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 to make safer food choices.

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

Together with existing labelling requirements in the Code, FSANZ considers that the amendments in the draft variation will provide food allergic consumers (or those who purchase foods for them) with adequate information relating to the allergens present in food, enabling them to make informed food choices.

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

FSANZ has not identified any issues relevant to this objective.

3.5.2.4 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 changes to allergen declaration requirements as set out in FSANZ's consumer behaviour literature review (Supporting Document 1) and safety assessment (Supporting Document 2). 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 Codex Standard does not include provisions for mandatory specified terms or presentation of allergen declarations. However, the standard is currently under review with the scope including aspects that have been considered under Proposal P1044.

Amendments in the draft variation to mandate the format and use of specific terminology of allergen declarations are similar to approaches used by other countries. Where possible, FSANZ has sought to align with relevant overseas allergen labelling regulations. However, internationally there is no consistency in allergen labelling regulations (see Section 2.3 of this report).

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 was made to the WTO to enable its members to comment on the draft variation to the Code (see [Section 3.4.3](#) of this report).

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.

4 Implementation

4.1 Transitional arrangements

FSANZ has decided on a three year transition period for the introduction of the PEAL requirements.

Additionally, food packaged and labelled before the end of the transition period may be sold for a period of two years (stock-in-trade period).

At Second Call for Submissions, FSANZ proposed the draft variation would take effect on the date of gazettal, with a two year transition period followed by a 12-month stock-in-trade period. The proposed transition period was to allow any relevant food to be sold as long as the food complied with either the existing allergen declaration requirements in the Code, or the amendments arising from Proposal P1044. The subsequent stock-in-trade period was to allow a food packaged and labelled before the end of the transition period to continue to be sold for up to 12 months after the end of the transition period.

Jurisdictions and consumer/public health submitters in general supported the proposed transition period and/or stock-in-trade. Although most industry submitters supported a two-year transition period, they expressed concern over the proposed 12-month stock-in-trade. This was based on the large number of products and SKUs affected by the labelling change; the complexity of making changes for foods produced in large volumes on a seasonal basis; and the need to accommodate longer shelf products and avoid recalls of products for non-

compliance at the end of the 12 month period. Industry submitters also noted other wide-impact labelling changes they are facing within the next 1-3 years (e.g. Health Star Rating) creating complexity and cost.

Overall, Industry submitters indicated that the proposed changes to allergen labelling would result in significant costs, due to the broad range of products impacted by the proposed changes to allergen labelling and the large number of SKUs that will need label changes. The costs estimates provided by submitters broadly aligns with FSANZ's assessment of costs as outlined in Supporting Document 3.

Since the Second Call for Submission consultation in February 2020, FSANZ notes the coronavirus pandemic has made the current and immediate future business environment more challenging. FSANZ is aware the coronavirus pandemic has added complexities to food business operations, primarily from supply chain disruptions such as difficulties in packaging supplies, sourcing ingredients, and delays to the transportation and distribution of finished products. These complexities can increase the costs for food businesses.

During targeted consultations in August 2020, industry stakeholders indicated that the business challenges resulting from coronavirus pandemic environment mean additional time is needed to implement PEAL requirements. Whereas consumer and public health stakeholders expressed concern that providing a longer transition period will continue to create confusion for consumers and that the PEAL changes have already taken a long time to be developed.

Given the above considerations, FSANZ has decided to provide a **3-year transition** period along with a **2-year stock-in-trade** period. This 5-year implementation timeframe aims to strike a balance between the industry operating in the current challenging COVID19 business environment, and the need to implement the PEAL changes in a timely and definitive way. A longer transition period assists the food industry by providing opportunity to coordinate PEAL with other labelling changes and to manage the large number of products that will need to be updated for PEAL. The two-year stock-in-trade provision will accommodate longer shelf life products being able to maintain their normal label update cycle and still be sold within the implementation timeframe. This will assist businesses to mitigate label update costs and avoid food wastage.

FSANZ also considered requests from food industry stakeholders for an enduring stock-in-trade period (i.e. no end date to the stock-in-trade period). Given the risk to food allergic consumers depends on their confidence that one labelling regime has ended and another has been fully introduced, FSANZ has decided on a stock-in-trade period that provides a definitive end date to aid food allergic consumers. We also note it is only slower turnover and longer-shelf life products that will benefit the most from an enduring stock-in-trade period.

4.2 Communication

Following gazettal, FSANZ intends to prepare communication materials in consultation with jurisdictions and other key stakeholders to raise awareness of the introduction of the new allergen labelling requirements.

FSANZ recognises communication with 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 supporting food allergic consumers to make safe allergen-based food choices. We are aware a number of Australian and New Zealand government agencies and not-for-profit organisations have existing activities that may support the introduction of PEAL. For example, this includes education programs for food-allergic individuals, and for the food manufacturing and food service industries. FSANZ will also consider opportunities to work

with food allergy and intolerance support groups, health professionals, and food industry representative organisations in the development of relevant communication materials to further assist implementation.

We also note the Victorian government has implemented a notification register for hospital anaphylaxis admissions. Data from this and other relevant notification systems may also inform and support communication activities and the implementation of PEAL more broadly.

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Attachments

- A. Approved draft variations to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variations to the *Australia New Zealand Food Standards Code* provided at Second Call for Submissions

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 36 months after the date of commencement;
 - (b) **post-transition period** means the 24 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 related to this requirement are set out in Standard 1.2.1, subparagraph 1.2.4—5(6)(b)(i), and paragraph 2.9.5—9(1)(d).

- (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) a food that is listed in Column 2 of the table to section S9—3; or
 - (b) a derivative of such a food.
- (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 one of the corresponding names in Column 3 of that table;
- (b) in all other cases—the corresponding name or names in Column 4 of that table.

1.2.3—6 What a mandatory declaration must state

- (1) A declaration other than a declaration to which subsection (2) or (4) applies must be made by stating the *required name of the food to be declared.
 - (2) A declaration made for the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i) must be made by:
 - (a) listing in the statement of ingredients of the food for sale:
 - (i) the *required name of the food to be declared; and
 - (ii) if the food to be declared is a substance *used as a processing aid or an ingredient or component of such a substance, the words 'processing aid' in conjunction with that required name; and
Examples: processing aids (**wheat, egg**); processing aid containing **wheat**.
 - (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) 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.

- (4) A declaration made in relation to any of the following foods for sale must be made by stating the name of the food to which subsection 1.2.3—4(1) applies and that is present in the food for sale:

- (a) a food for special medical purposes; or
- (b) an infant formula product that is:
 - (i) specifically formulated for premature or low birthweight infants;
 - (ii) specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions;
 - (iii) represented as lactose free formula or low lactose formula; or
 - (iv) based on a *protein substitute.

Note 1 Paragraph 2.9.5—9(1)(d) applies to food for special medical purposes and provides that a label that is required for such food must make (among other things) any mandatory declarations required by section 1.2.3—4.

Note 2 Division 4 of Standard 2.9.1 applies to infant formula products for special dietary use and sets out compositional and labelling requirements for such food.

- (5) For the purposes of subsection (4), the name to be stated must be:
- (a) the name listed for that food in Column 1 of the table to section S9—3; or
 - (b) any other name by which that food is commonly known.

1.2.3—7

Form of a mandatory declaration

- (1) A *required name in a statement of ingredients 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 *required name in a statement of ingredients must be listed:
- (a) separately for each ingredient that is or contains the relevant food; and
 - Example** kamut (**wheat**), maltodextrin (**wheat**)
 - (b) as a separate word or as separate words if the required name is contained in the name of the ingredient that is or contains the relevant food; and
 - Examples** milk powder, **sesame** seeds, but not buttermilk
 - (c) separately from but next to the name of the ingredient that is or contains the relevant food unless the required name:
 - (i) is identical to the name of the ingredient; or
 - (ii) is contained in the name of the ingredient.
 - Examples** sodium caseinate (**milk**) or sodium caseinate (from **milk**); pasta (**wheat**, **egg**)
- (3) A summary statement must:
- (a) commence with the word 'Contains' and then list the *required name of each food to be declared; and
 - (b) contain no other words.
- (4) A summary statement must:
- (a) appear on the label of the food for sale:
 - (i) in the same field of view as the statement of ingredients; and
 - (ii) directly next to the statement of ingredients; and
 - (b) be distinctly separated from the statement of ingredients.

- (5) 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 any other text in the statement of ingredients which is not a required name.
- (6) In this section, a **summary statement** means a summary statement required by paragraph 1.2.3—6(2)(b).

1.2.3—8 Compliance with requirement for required name

If a provision of this Division requires a *required name to be declared or stated, that required name may be declared or stated in either the singular or plural form as required.

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

[5.1] omitting paragraph 2.9.5—9(1)(d), substituting

(d) any required advisory statements, *warning statements, other statements, and declarations (see section 2.9.5—10);

[5.2] omitting the heading for section 2.9.5—10, substituting

2.9.5—10 Mandatory statements and declarations—food for special medical purposes

[5.3] omitting subsection 2.9.5—10(2), substituting

(2) For paragraph 2.9.5—9(1)(d), the required advisory statements and declarations are any that are required by:

- (a) items 1, 4, 6 or 9 of the table to section S9—2; or
- (b) subsection 1.2.3—2(2); or
- (c) section 1.2.3—4.

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 to section S9—3 is a reference 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; and
 - (c) **mollusc** means a marine mollusc.
- (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 in a statement of ingredients</i>	<i>Required name for other declarations</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
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: <ol style="list-style-type: none"> (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.	wheat	(a) wheat; and (b) if gluten is present - gluten.
4	Any of the following tree nuts:			

<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 in a statement of ingredients</i>	<i>Required name for other declarations</i>
	almond		almond	almond
	Brazil nut		Brazil nut	Brazil nut
	cashew		cashew	cashew
	hazelnut		hazelnut	hazelnut
	macadamia		macadamia	macadamia
	pecan		pecan	pecan
	pine nut		pine nut	pine nut
	pistachio		pistachio	pistachio
	walnut		walnut	walnut
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

Schedule 10

[7] Schedule 10 is varied by

[7.1] omitting section S10—1A

[7.2] omitting the following condition for use for ‘cereals’ from the table to section S10—2

If the cereal is wheat, rye, barley, oats or spelt or a hybridised strain of one of those cereals, the specific name of the cereal must be declared.

[7.3] omitting paragraph (a) of the condition for use for ‘fats or oils’ from the table to section S10—2, substituting

(a) The statement of ingredients must declare:

- (i) whether the source is animal or vegetable; and
- (ii) if the food is a dairy product, including ice cream—the specific source of animal fats or oils.

[7.4] omitting the following condition for use for ‘fish’ from the table to section S10—2

If crustacea, the specific name of the crustacea must be declared.

substituting

The definition of *fish* in subsection 1.1.2—3(2) does not apply for the purposes of this table.

[7.5] omitting from the table to section S10—2

nuts

The specific name of the nut must be declared.

[7.6] omitting paragraphs (a) and (b) of the condition for use for 'starch' from the table to section S10—2, substituting

The name 'starch' may be used for any unmodified starch or any starch which has been modified by either physical means or enzymes.

Attachment B – 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.

The Authority 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 approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the Legislation Act 2003.

2. Purpose

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 what terminology to use when making the declarations.

The Authority has approved a draft variation amending 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 approved draft variation also amends Standards 1.1.1, 1.1.2, 1.2.4, and 2.9.5; and Schedule 10. These amendments are consequential and related to the primary amendments.

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 included two rounds of public consultation following an assessment, targeted communication with key stakeholders, and the preparation of a draft Standard and associated assessment summaries.

A First Call for Submissions was made between March 2018 and May 2018, followed by a Second Call for Submissions between November 2019 and February 2020. Also, in August 2020, FSANZ conducted targeted consultations with key consumer, public health and industry stakeholders.

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 existing 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 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 in a manner listed in subsection 1.2.3—4(5), a declaration that that food is present must be made.

A Note to subsection 1.2.3—4(1) states that the labelling provisions related to this requirement are set out in Standard 1.2.1, subparagraph 1.2.4—5(6)(b)(i), and paragraph 2.9.5—9(1)(d) of the Code.

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.

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) provides that, for the purposes of subsection (1), a food to which section 1.2.3—4 applies must 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.

A food that is not present in a food for sale in one of the above ways is not subject to the requirements imposed by Division 3.

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 certain foods (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:

- when listed 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));
- all other cases—the corresponding required name(s) in Column 4 of the table to section S9—3 (paragraph 1.2.3—5(b)).

New section 1.2.3—6

Subsection 1.2.3—6(1) provides that a declaration other than a declaration to which subsection (2) or (4) applies (see below) must be made by stating the required name of the food to be declared.

This requirement applies to declarations made in relation to the following foods:

- food for sale that is not required to have a statement of ingredients on its label (see subsections 1.2.4—2(2) and (3)); and
- food that is not required to bear a label (see subsections 1.2.1—9(3) and (7)); and
- food that is sold to caterers (see section 1.2.1—15); and
- food sold in individual portion packs (see subsection 1.2.1—8(3)).

Subsection 1.2.3—6(2) sets out how declarations made for the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i) must be made. That is, these declarations must be made by:

- listing in the statement of ingredients of the food for sale—the required name, and, if the food to be declared is a substance used as a processing aid or an ingredient or component of such a substance, the words ‘processing aid’ in conjunction with that required name; 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) states that the requirements in subsection 1.2.3—6(2) do not apply to food for sale that is not required to have a statement of ingredients on its label due to the operation of subsection 1.2.4—2(2) or (3) of the Code.

A Note to subsection 1.2.3—6(3) explains that subsections 1.2.4—2(2) and (3) provide that certain foods are not required to have a statement of ingredients on their label.

Subsection 1.2.3—6(4) sets out requirements for declarations made in relation to the following food for sale:

- a food for special medical purposes; or
- an infant formula product that is:
 - specifically formulated for premature or low birthweight infants; or
 - specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions; or
 - represented as lactose free formula or low lactose formula; or
 - based on a protein substitute.

The subsection states that a declaration made in relation to any of the above foods must be made by stating the name of the food to which subsection 1.2.3—4(1) applies and that is present in the food for sale. See also subsection 1.2.3—6(5).

There are two (2) Notes to subsection 1.2.3—6(4) explaining the application and operation of paragraph 2.9.5—9(10)(d) and Division 4 of Standard 2.9.1.

Note 1 explains that paragraph 2.9.5—9(1)(d) applies to food for special medical purposes and provides that a label that is required for such food must make (among other things) any mandatory declarations required by section 1.2.3—4.

Note 2 explains that Division 4 of Standard 2.9.1 applies to infant formula products for special dietary use, and sets out compositional and labelling requirements for such food.

Subsection 1.2.3—6(5) provides that the name to be stated for the purposes of subsection 1.2.3—6(4) must be either:

- the name listed for that food in Column 1 of the table to section S9—3; or
- any other name by which that food is commonly known.

New section 1.2.3—7

Section 1.2.3—7 sets out how a declaration that is 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 how a required name must be listed in a statement of ingredients. The required name must be listed:

- separately for each ingredient that is or contains the food to be declared (for example, ‘kamut (**wheat**), maltodextrin (**wheat**)’);
- as a separate word or as separate words if the required name is contained in the name of the ingredient that is or contains the food to be declared (for example, ‘**milk** powder’, ‘**sesame** seeds’ but not ‘buttermilk’);
- separately from but next to the name of the ingredient that is or contains the food to be declared, unless the required name:
 - is identical to the name of the ingredient; or
 - is contained in the name of the ingredient, (for example, ‘sodium caseinate (**milk**)’ or ‘sodium caseinate (from **milk**)’; ‘pasta (**wheat, egg**)’).

Subsection 1.2.3—7(3) 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. However, a summary statement must not contain any other words.

Subsection 1.2.3—7(4) sets out where a summary statement must appear on the label of a food for sale. The summary statement must appear on the label of a food for sale in the same field of view as and directly next to the statement of ingredients. The summary statement must also be distinctly separated from the statement of ingredients.

Subsection 1.2.3—7(5) 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 any other text in the statement of ingredients which is not a required name.

Subsection 1.2.3—7(6) 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 clarifies that a required name may be declared or stated in either the singular or plural form, as required. For example: as required by the context, ‘almond’ or ‘almonds’ could be used as the required name to declare the presence of ‘almond’

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] varies Standard 2.9.5. It makes consequential amendments to sections 2.9.5—9 and 2.9.5—10 as a result of amendments to Standard 1.2.3 and Schedule 9.

Sub-item [5.1] amends paragraph 2.9.5—9(1)(d) by including ‘declarations’ to the list in that paragraph (with associated grammatical amendments).

Sub-item [5.2] replaces the heading of section 2.9.5—10 with ‘2.9.5—10 Mandatory statements and declarations—food for special medical purposes’ to reflect that this section deals with requirements for both mandatory statements and mandatory declarations.

Sub-item [5.3] replaces subsection 2.9.5—10(2) with a revised subsection that states that, for the purposes of paragraph 2.9.5—9(1)(d) (see **sub-item [5.1]** above), the required advisory statements and declarations are any that are required by:

- (a) items 1, 4, 6 or 9 of the table to section S9—2; or
- (b) subsection 1.2.3—2(2); or
- (c) section 1.2.3—4.

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 new mandatory declarations requirements in Division 3 of Standard 1.2.3.

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

Subsection S9—3(2) clarifies the meaning of terms used in the table to subsection S9—3(3).

Paragraphs S9—3(2)(a) and (b) state 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 this subsection (paragraph (a)) and that ‘fish’ in this table does not include crustacea and molluscs (paragraph (b)). This amendment is required because:

- the definition of ‘fish’⁸ in Standard 1.1.2 was not developed for the purpose of allergen declarations, and could capture, in addition to finfish, molluscs and crustacea as ‘shellfish’; and
- there are separate and distinct references to (and different declaration requirements for) ‘fish’, ‘crustacea’ and ‘molluscs’ in the table to subsection S9—3(3).

Paragraph S9—3(2)(c) states that ‘mollusc’ means a marine mollusc for the purposes of the table to subsection S9—3(3). This amendment is required because the ordinary meaning of ‘mollusc’ includes land molluscs and, therefore, has a broader meaning than what was originally intended in the Code (i.e. molluscs as aquatic invertebrates).

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 made in a statement of ingredients (see **sub-item [3.5]**—paragraph 1.2.3—5(a) above).

Column 4: lists the ‘required name’ for the corresponding food in Column 1, for other declarations made. This includes declarations made in a summary statement; and declarations made in relation to:

- food for sale that is not required to have a statement of ingredients on its label; and
- food that is not required to bear a label; and
- food that is sold to caterers; and
- food sold in individual portion packs (see **sub-item [3.5]**—paragraph 1.2.3—5(b) above).

⁸ **Fish** means a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish, but not including amphibians or reptiles (subsection 1.1.2—3(2) of Standard 1.1.2 – Definitions used throughout the Code).

Note: The first letter of required names listed in the Table to subsection S9—3(3) are not capitalised, with the exception of ‘Brazil nuts’. However, it is noted that none of the amendments made by the approved draft variation requires a required name to be stated with its first letter in either upper or lower case. Consequently, either upper or lower case may be used for the first letter of a required name.

Examples: maltodextrin (**wheat**) or maltodextrin (**Wheat**).

Item [7] varies Schedule 10 by omitting section S10—1A and amending the table to section S10—2.

Sub-item [7.1] omits section S10—1A. Section S10—1A is redundant in that 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.

Sub-items [7.2] – [7.6] amend 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 mostly 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 [7.2] 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, or oats; 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.

‘Spelt’ was one of the cereals listed in the omitted condition for use for ‘cereals’ in the table to section S10—2. As spelt is one of several species of wheat from the genus *Triticum*, ‘spelt’ is not included in the list of required names in the table to section S9—3. However, in accordance with ingredient naming requirements in section 1.2.4—4, if spelt is an ingredient in a food for sale, ‘spelt’ may still be listed as the ingredient in the statement of ingredients, however a declaration using the required name of ‘wheat’ will also be required for the purposes of Division 3 of Standard 1.2.3.

Sub-item [7.3] 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 [7.4] changes the condition of use for ‘fish’ from the table to section S10—2 from ‘If crustacea, the specific name of the crustacea must be declared’ to ‘The definition of fish in subsection 1.1.2—3(2) does not apply for the purposes of this table’.

The amendment reflects the new declaration requirements in relation to a food for sale that is or contains crustacean—the definition of fish in subsection 1.1.2—3(2) does not apply and ‘fish’ does not include crustacea and molluscs. In other words, crustacea and molluscs must be separately declared (see **sub-item[6.4]** above).

In particular, where a food for sale contains any ‘crustacea’ as an ingredient, the required name ‘crustacean’ (or ‘crustacea’ as permitted by section 1.2.3—8) 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 [7.5] 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 [7.6] 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 an initial transitional arrangement where during a three year transition period commencing on the instrument's 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 subsequent transitional arrangement where during a subsequent two year transition period commencing on the day after the initial transition period ends, a food product that was packaged and labelled before the end of initial three year transition period, may be sold 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.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* provided at Second Call for Submissions



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:
 - (c) **transition period** means the period commencing on the variation's date of commencement and ending 24 months after the date of commencement;
 - (d) **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

- (4) For Division 3 of Standard 1.2.3, a reference to the table in section S9—3 is to the table to subsection (3).
- (5) 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.
- (6) 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	(d) the wheat or its hybridised strain that is present in beer or spirits; (e) glucose syrups made from wheat starch and that:	wheat	(c) wheat; and (d) 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>
		(iii) have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable; and (iv) have a gluten protein content that does not exceed 20 mg/kg; (f) 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	(c) soybean oil that has been degummed, neutralised, bleached and deodorised; (d) soybean derivatives that are tocopherol or phytosterol.	soy, soya or soybean	soy

Schedule 10

[7] Schedule 10 is varied by

[7.1] omitting the following condition of use for 'cereals' from the table to section S10—2

If the cereal is wheat, rye, barley, oats or spelt or a hybridised strain of one of those cereals, the specific name of the cereal must be declared.

[7.2] omitting paragraph (a) of the condition for use for 'fats or oils' from the table to section S10—2, substituting

(b) The statement of ingredients must declare:

(iii) whether the source is animal or vegetable; and

(iv) if the food is a dairy product, including ice cream—the specific source of animal fats or oils.

[7.3] omitting the following condition of use for 'fish' from the table to section S10—2

If crustacea, the specific name of the crustacea must be declared.

[7.4] omitting from the table to section S10—2

nuts

The specific name of the nut must be declared.

[7.5] omitting paragraphs (a) and (b) of the condition for use for 'starch' from the table to section S10—2, substituting

The name 'starch' may be used for any unmodified starch or any starch which has been modified by either physical means or enzymes.