

# 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’<sup>1</sup> 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).

**Note:** The first letter of required names listed in the Table to subsection S9—3(3) are not

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<sup>1</sup> **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).

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.