

# Explanatory Statement

## 1. Authority

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

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

FSANZ prepared Proposal P293 to implement the then Australia and New Zealand Food Regulation Ministerial Council<sup>1</sup> Policy Guideline for the development of the regulatory framework for the management of nutrition, health and related claims. The Authority considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and has approved a draft Standard.

On 6 June 2008, the then Australia and New Zealand Food Regulation Ministerial Council asked FSANZ to review its decision in relation to the new Standard. FSANZ has reviewed its decision and has re-affirmed the approval of Standard 1.2.7 subject to amendments in response to the review request and to additional advice in July 2012 from the COAG Legislative and Governance Forum on Food Regulation<sup>2</sup>, regarding the regulatory approach for general level health claims.

Following consideration by the COAG Legislative and Governance 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 *Legislative Instruments Act 2003*.

## 2. Purpose and operation

The Authority has approved a new Standard 1.2.7 – Nutrition, Health and Related Claims. The purpose of this Standard is to regulate the use of nutrition content claims and health claims on food labels and in advertisements for food. It will consolidate a number of requirements relating to such claims that were previously spread across several Standards, such as Standards 1.2.8 and 1.3.2. The Standard will replace the transitional standard – Standard 1.1A.2 – Transitional Standard – Health Claims.

## 3. Documents incorporated by reference

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

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<sup>1</sup> Now known as the COAG Legislative and Governance Forum on Food Regulation

<sup>2</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

## 4. Consultation

The Authority's consideration of P293 has included six rounds of public consultation following assessments, the preparation of a draft Standard, a draft variation and associated reports. Public submissions were called for in 2004, 2005, 2007, 2009 and 2012. In addition, targeted consultation about the regulation of general level health claims was undertaken in 2011 and 2012 with key stakeholders.

A Standards Development Advisory Committee (SDAC) was established with representatives from the industry sector, the relevant State and Territory government agencies and consumer organisations to provide ongoing advice to the Authority throughout the standard development process. The SDAC contributed a broad spectrum of knowledge and expertise covering industry, government, research and consumers. The SDAC was involved in the initial development of the new Standard, however it was not active during the review of the Standard that commenced in 2008.

A Regulation Impact Statement was required because the proposed variation, Standard 1.2.7, is likely to have an impact on businesses and individuals.

### 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. Commencement

Standard 1.2.7 commences on 18 January 2013. There will be a transition period of three years, starting when Standard 1.2.7 commences and ending when Standard 1.1A.2 is repealed. During that period Standard 1.1A.2 will operate concurrently with Standard 1.2.7.

During the transition period, if Standard 1.1A.2 is relied on, the changes made to other Standards under Proposal P293 have no effect. For a particular food, either Standard 1.2.7 and the changes made to other Standards, or the Code (including Standard 1.1A.2) as it was immediately prior to the commencement of Standard 1.2.7 can be relied on, but not a combination of both.

Three years after the gazettal of Standard 1.2.7 and associated variations, the Transitional Standard 1.1A.2 ceases to operate and the conditions in Standard 1.2.7 must be met. All food labels and advertising in the marketplace at that time must comply with Standard 1.2.7 and the variations to other standards made under Proposal P293.

## 7. Variations

### ***Part 1 — Purpose and interpretation***

Clause 1 outlines the purpose of the Standard.

Clause 2 sets out definitions for terms used in the Standard. In particular, a nutrition content claim is defined as a claim about the presence or absence of certain properties of food (the properties are listed in the definition). A health claim is a claim that a food or property of food has or may have a health effect. These definitions depend on the definition of a 'claim' as defined in Standard 1.1.1, which includes implied claims.

## **Part 2 — Claims framework and general principles**

Clause 3 prohibits nutrition content claims and health claims from being made about kava (as standardised in Standard 2.6.3), an infant formula product (as standardised in Standard 2.9.1) and food containing more than 1.15% alcohol by volume. However a nutrition content claim about the energy content or carbohydrate content of a food containing more than 1.15% alcohol by volume is permitted.

Clause 4 lists the foods that do not need to comply with the Standard. For example, food delivered to a vulnerable person by a delivered meal organisation does not need to comply with the Standard. The definition of 'vulnerable person' in Standard 3.3.1 does not apply to the use of this term in Standard 1.2.7.

Clause 5 makes it clear that the Standard does not apply to certain claims or declarations, for example, claims permitted by other standards in the Code.

Clause 6 describes how the requirements of the Standard apply to different forms of food. The Table to clause 6 sets out different types of food and the form of the food to which the requirements of the Standard apply. To determine the form of the food to which the requirements of the Standard apply, the following should be taken into account:

- the information on the label for the food, including the directions for use
- any information provided in an advertisement for the food.

Clause 7 prohibits therapeutic claims. A prohibition on therapeutic claims assists to clarify the interface between foods and goods for therapeutic use, given that therapeutic claims are characteristically a feature of goods for therapeutic use. This prohibition maintains the existing prohibition on making claims of therapeutic or prophylactic action currently in the transitional standard 1.1A.2.

A claim that compares a food with a good that is represented to be for therapeutic use, or is likely to be taken to be for therapeutic use, is also not permitted. An exception to this prohibition exists if a statement is permitted by another provision of the Code. Subclause 8(3) of Standard 2.6.2 permits a claim about the treatment of a condition (namely, mild dehydration). This is currently the only express permission for a statement that refers to the alleviation of a condition.

Clause 8 is designed to prohibit any claim that compares the vitamin or mineral content of one food with that of any other food. This is an existing provision in Standard 1.3.2 that has been moved to Standard 1.2.7.

Clause 9 clarifies that there is flexibility in the actual wording that can be used in a nutrition content claim or health claim, i.e. the wording of a claim is not prescribed. The statements or information that are required to be on a label or in an advertisement can be worded as desired, as long as the effect of the required statement or information, as described in the Standard, is not altered or contradicted.

## **Part 3 – Requirements for nutrition content claims and health claims**

### **Division 1 – Nutrition content claims**

A nutrition content claim, as defined in clause 2, is a claim about the presence or absence of certain properties of food, which are listed in the definition.

Clause 10 provides that, if a nutrition content claim is made, it must be presented together with a description of the form of the food to which the claim relates, unless the claim relates to the food in the form in which it is sold. This requirement relates back to clause 6 which describes how the requirements of the Standard apply to different forms of food.

Clause 11 deals with nutrition content claims about the properties of food set out in Schedule 1, e.g. nutrition content claims about the fat content of a food.

Schedule 1 has two types of conditions in it: general claim conditions and specific claim conditions. Subclause 11(2) provides that foods carrying nutrition content claims about a property of food listed in Column 1 must meet the general claim conditions in Column 2 that correspond with that property of food, if there are any. Subclause 11(3) provides that foods carrying nutrition content claims using a specific descriptor (e.g. 'good source', 'free', 'reduced') listed in Column 3 (or a similar descriptor) must meet the general claim conditions in Column 2 as well as the specific claim conditions in Column 4 that align with the descriptor and the property of food that is the subject of the claim.

Subclause 11(4) makes it clear that if there are inconsistent obligations imposed by a general claim condition in Column 2 of Schedule 1 and a specific claim condition in Column 4, the specific claim condition prevails. For example, for a claim that a food is an 'excellent source of dietary fibre', the general claim conditions say that a serve of the food must contain at least 2 g of dietary fibre, whereas the specific claim condition says that a serve of the food must contain at least 7 g. In this example, subclause 11(4) makes it clear that the 7 g requirement prevails.

Subclause 11(5) provides that only certain nutrition content claims about lactose and trans fatty acids can be made. Only the descriptors listed in Column 3 of Schedule 1 (or similar descriptors) corresponding to lactose or trans fatty acids, as applicable, can be used. For example, the claims 'free of trans fatty acids' and 'no trans fatty acids' can be made but 'low in trans fatty acids' is prohibited.

Subclause 11(6) has the effect that descriptors, for example 'high', 'low' or 'medium', cannot be used in relation to glycaemic load claims, however numbers of the measure can be used, for example, GL = 30.

Subclause 11(7) has the effect that the only nutrition content claims that can be made about gluten are 'low', 'free', 'high' and 'contains' (or claims using similar wording).

Subclause 11(8) makes it clear that in addition to the descriptors listed in Column 3 of Schedule 1, any other descriptor can also be used in a nutrition content claim to describe the amount of a property of food listed in Schedule 1. However the restrictions mentioned in earlier subclauses still apply. For example, a 'high energy' claim is permitted even though the descriptor 'high' or similar is not listed in Column 3 adjacent to energy. If descriptors other than those listed in Column 3 (or similar descriptors to those in Column 3) are used, the general claim conditions adjacent to the property of food that is the subject of the claim must be met (if any), but there are no specific conditions that apply. For example, a 'good source of polyunsaturated fatty acids' claim could be made if the food meets the conditions in Column 2 that apply to claims about polyunsaturated fatty acids.

Clause 12 sets out the conditions for making nutrition content claims about properties of food that are not mentioned in Schedule 1, e.g. biologically active substances. The descriptors listed in Column 3 of Schedule 1 cannot be used in these nutrition content claims, e.g. 'good source of x', 'increased x'; except for descriptors indicating the food does not contain the property of the food, e.g. 'free'.

Claims that the food contains (e.g. 'source of x', 'contains x') or does not contain (e.g. 'free of x') the property of food can be made. In addition, paragraph 12(1)(b) permits nutrition content claims that specify the presence of a certain amount of the property of food in a specified amount of the food, e.g. 'contains 10 g of x per serving'.

Clause 13 permits certain nutrition content claims about choline, fluoride or folic acid to be made about a food, but only if a health claim about that substance is made about that same food. Claims that the food contains choline, fluoride or folic acid (e.g. 'source of choline') can be made in this instance. In addition, paragraph 13(1)(b) permits nutrition content claims that specify the presence of a certain amount of choline, fluoride or folic acid in a specified amount of the food. The descriptors listed in Column 3 of Schedule 1 cannot be used in these nutrition content claims, e.g. 'good source', 'increased'. Specific permission for nutrition content claims about choline, fluoride and folic acid (a synthetic form of the vitamin folate) is necessary because they are not permitted by the conditions for making nutrition content claims about vitamins and minerals in Schedule 1 (as they are vitamins or minerals but are not listed in Column 1 of the Schedule to Standard 1.1.1). However nutrition content claims about folate are permitted by the conditions for making nutrition content claims about vitamins in Schedule 1.

Clause 14 provides that words which imply slimming cannot be used in a nutrition content claim about energy, instead of the descriptor 'diet'. 'Diet' claims have been permitted under the transitional standard and it is not intended to prohibit the use of 'diet' as a descriptor if the conditions of use are satisfied. However, the use of other terms that suggest slimming properties is not permitted.

Clause 15 deals with nutrition content claims that are 'comparative'. Subclauses (1) and (2) describe what comparative claims are. Subclause (3) sets out some additional labelling information that must be provided with a comparative claim.

## ***Division 2 – Health claims***

Health claims are claims (including implied claims) that a food or property of food has or may have a health effect. A health effect means an effect on the human body. A high level health claim is a health claim that refers to a serious disease or a biomarker of a serious disease. A general level health claim is any other health claim that is not a high level health claim. These definitions are in clause 2.

Clause 16 has the effect that an application or proposal to add a new general level health claim to Schedule 3 will be subject to the provisions in the FSANZ Act that apply to high level health claims variations.

Subclause 17(1) requires that for all health claims, the conditions in subclause 17(2) must be met. In addition, for high level health claims, the conditions in subclause 17(3) must be met, and for general level health claims, the conditions in subclause 17(4) must be met.

Subclause 17(2) requires that if a health claim is made about a food, that food must meet the nutrient profiling scoring criterion (NPSC). This requirement does not apply to foods standardised in Part 2.9 of the Code (Special Purpose Foods) (subclause 17(5)). Instructions on how to calculate the nutrient profiling score of a food are provided in Schedule 5. In order to meet the NPSC, the score of a food must meet the nutrient profiling score specified in Schedule 4.

Subclause 17(3) prohibits high level health claims unless they are derived from a relationship between a food or property of food and a corresponding health effect listed in Schedule 2.

The food about which the high level health claim is made must meet any applicable conditions that are specified in Column 5 of Schedule 2. For example, for a health claim about salt and blood pressure, the food must meet the conditions for salt or sodium nutrition content claims specified in Column 4 of Schedule 1 corresponding to 'low'.

For general level health claims, subclause 17(4) specifies the two ways in which a claim is permitted to be made. The general level health claim can be derived from a relationship between a food or property of food and a corresponding health effect listed in Schedule 3. The food about which the general level health claim is made must meet any applicable conditions that are specified in Column 5 of Schedule 3.

Alternatively, a general level health claim can be based on a relationship between a food or property of food and a health effect that has been established by a process of systematic review. Under this option, paragraph 17(4)(b) requires that the person responsible for making the general level health claim must have notified the Chief Executive Officer (CEO) of Food Standards Australia New Zealand (FSANZ) of the actual relationship that has been established between a food or property of food and a health effect (upon which the general level health claim is based). The notified relationship must have been established by the process for systematic review as outlined in Schedule 6.

Clause 18 sets out the requirements that must be met if a general level health claim is based on a relationship between a food or property of food and a health effect that has been notified to the CEO of FSANZ under paragraph 17(4)(b). The person giving this notification must provide their name and the Australian or New Zealand address of that person, and certify that the relationship that has been notified has been established by a process of systematic review as described in Schedule 6. Further, if requested by a relevant authority, records must be provided to it that demonstrate the systematic review was conducted in accordance with the requirements for systematic review outlined in Schedule 6. Those records must also demonstrate that the notified relationship is a reasonable conclusion of the systematic review. 'Relevant authority' is defined in clause 2 of Standard 1.1.1 as the authority responsible for the enforcement of the Code.

Subclause 18(2) clarifies that if the certificate required by subclause 18(1)(c) is provided for a body corporate, the certificate must be signed by a senior officer of that body corporate.

Clause 19 sets out what a health claim must say and the statements that must be made together with the health claim.

Subclause 19(1) applies to high level health claims and general level health claims based on relationships between a food or a property of food and a health effect listed in Schedules 2 and 3 respectively. The health claim must state the food or property of food and the specific health effect claimed for that food or property of food, as mentioned in the applicable Schedule. Paragraph 19(1)(b) requires that the relevant population group from Column 3 of the applicable Schedule (if any) must be stated together with the health claim.

Subclause 19(2) applies to general level health claims that are based on a relationship between a food or property of food and a health effect that has been notified to the CEO of FSANZ. The general level health claim must state the food or property of food and the specific health effect, based on the notified relationship. It must also state the relevant population group, if a target population group is identified in the conclusion of the systematic review.

Subclause 19(3) provides that the health claim must also be presented together with a dietary context statement and a description of the form of the food to which the claim relates.

Subclause 19(5) provides an exemption from the dietary context statement if the health claim is on a label of a small package. Subclause 19(6) specifies that the form of the food does not need to be stated if the claim relates to the food in the form in which it is sold.

Subclause 19(4) outlines what must be included in the dietary context statement. The dietary context statement must state that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and must be appropriate for the claim being made. For health claims based on a relationship described in Schedules 2 or 3, words to the effect of the relevant dietary context statement in Column 4 of those Schedules must also be used. For general level health claims based on a relationship notified to the CEO of FSANZ, the dietary context statement must be consistent with the conclusions of the systematic review.

As outlined in clause 9, the actual wording that is used in the health claim can be modified from the wording mentioned in Schedules 2 or 3 as long as the effect is not altered.

Clause 20 allows some elements of a health claim to be presented as a separate statement in what is called a split health claim. However, those elements must appear on the same label or in the same advertisement as the complete statement required by clause 19. An indication of where the complete statement is located must be provided with the separate elements. For example, the split health claim 'calcium for normal bone and teeth structure' can be presented on the main panel of a food package, accompanied by a directive statement such as 'see back of pack', with the complete claim 'calcium for normal bone and teeth structure when consumed as part of a healthy diet including a variety of foods' provided on the back of the same package.

The effect of clause 21 is that an additional 'healthy diet' context statement is not required if a health claim about phytosterols, phytostanols or their esters is presented together with the advisory statement required by clause 2 of Standard 1.2.3.

### ***Division 3 – Endorsements***

Endorsements are nutrition content claims or health claims that are made with the permission of an endorsing body.

Clause 22 imposes conditions on endorsing bodies. The terms 'endorsing body' and 'endorsement' are defined in clause 2.

Clause 23 sets out the requirements for an endorsement to be validly made. An endorsing body must satisfy criteria set out in clause 22. Endorsements are exempt from the other requirements of the Standard (except clause 7), to allow for endorsement programs which use the criteria set by the endorsing body. Clause 23 also contains record-keeping requirements for suppliers who use endorsements. Required records must be kept for a certain period of time and presented to the relevant authority (defined in clause 2 of Standard 1.1.1) on request. Subclause (2) is designed to deal with an endorsement that is placed on a label prior to importation. It provides that the importer of the food must comply with the record-keeping requirements of this clause.

### ***Division 4 – Additional labelling of food required to meet the NPSC***

Clause 24 indicates where the method for calculating the NPSC is described.

Clause 25 sets out some additional labelling requirements for food that is required to meet the NPSC in order to make a claim.

Subclause (5) outlines how this additional information must be provided if the food in question is exempt from the requirement to bear a label under clause 2 of Standard 1.2.1.

Clause 26 provides exemptions from these additional labelling requirements for food in small packages.