

**FINAL ASSESSMENT REPORT FOR
PROPOSAL P293 – NUTRITION HEALTH & RELATED
CLAIMS**

Terminology

Development of terminology and claim descriptors

The terminology used in the draft Standard is the culmination of lengthy consideration; it has taken into account the changes in the proposed regulatory approach for nutrition, health and related claims over the course of Proposal P293, and submitter comments that were made at each stage of the assessment process.

In the Initial Assessment Report, FSANZ sought comment on a number of issues related to the proposed FSANZ Conceptual Framework, including some key terms and their definitions, claim descriptors (for example, *low* or *unsalted*) and other related claims descriptors (for example, ‘function claim’ or ‘biomarker enhancement claim’).

Submitter responses to the Initial Assessment Report yielded many useful comments that were used to further develop the terminology in the Draft Assessment Report. In some cases, existing definitions were amended as the approach for the regulation of claims developed (for example, the definition of ‘claim’ was amended to include ‘implied claims’). New terms and their definitions were also introduced in support of the approach proposed in the Draft Assessment Report (for example, ‘health effect’ and ‘property of a food’). As the draft Standard developed, it contained no reference to any of the related claim descriptors proposed in the Initial Assessment Report and these were subsequently abandoned. Claim descriptors relating to the property of the food are addressed separately within the related nutrition content claim sections of the Draft, Preliminary Final Assessment and Final Assessment Reports.

The purpose of the Preliminary Final Assessment Report was to address specific issues that warranted further consultation. As the proposed regulatory approach changed for some issues, certain terms and definitions were deleted (for example, ‘meals/main dishes’). Other terms elicited many comments from submitters and an amended definition was proposed (for example, for ‘dietary information’). Where terms that already existed in the Code were considered inappropriate for the purposes of the draft Standard, new terms and their definitions were proposed (for example, for ‘fruit’ and ‘vegetable’).

Consideration was also given to the location of some existing terms in the Code. It was proposed in the Draft Assessment Report to relocate some definitions from Standards 1.2.4, 1.2.8 and 1.3.2 to the Standard 1.1.1, as it was thought that they would apply generally across the Code (for example, ‘claimable food’ in Standard 1.3.2). In the Preliminary Final Assessment Report, the recommendation was made to relocate several more terms to Standard 1.1.1 (for example, ‘fat’ and ‘gluten’ in Standard 1.2.8). Following the Preliminary Final Assessment Report, the relocation of most of these definitions was reconsidered and they were positioned back in specific standards, to avoid any potential unintended consequences for other parts of the Code. The definition clauses in Standard 1.2.8 and the draft Standard will be cross referenced. Therefore the definitions contained in clause 1 of each of these Standards will apply to both Standards.

Submitter comments and final recommendations for terms and definitions that remain relevant to the draft Standard in the Final Assessment Report are discussed in Table 1. Terms for which submitters had requested definitions be developed, and the reasons FSANZ has given for not doing so, are included in Table 2.

Table 1. Terms and their definitions that are relevant to the draft Standard, and their recommended locations.

Terms and definitions - Decision	Current location in Code	Recommended location	Submitter comments	Decision history and response to submitter comments
<p>average energy content has the meaning given by clause 1B</p> <p><i>The following method will be inserted after clause 1A:</i></p> <p>average energy content is worked out as follows –</p> <p>(a) multiply the average amount of each food component by 100 g of the food by the energy factor for that food component;</p> <p>(b) add the amounts calculated for each using the following formula -</p> <p>Average energy (kJ/100 g) = $\sum W_i F_i$</p> <p>Where –</p> <p>W_i means the average weight of the food component (g/100 g food); and</p> <p>F_i means the energy factor assigned to that food component (kJ/g).</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report (DAR)</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report (PFAR)</p> <ul style="list-style-type: none"> Some submitters agreed with the relocation proposed at PFAR. 	<ul style="list-style-type: none"> This definition was not subject to review, however, it was decided that the method contained within the definition be separated out, simplified and stated in clause 1A. At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Post-PFAR, the decision was made for this definition to remain connected to the energy factor in sub clause 2(1) and accompanying energy factor table (Table 1 to sub clause 2(2) in Standard 1.2.8.
<p>biologically active substance means a substance, other than a nutrient, with which health effects are associated.</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> At DAR, there was a view that the qualification of ‘other than a nutrient’ may be problematic in relation to biologically active substances. What is currently recognised as a ‘nutrient’ by virtue of its inclusion in 2006 Nutrient Reference Values may simply be a subclass of ‘biologically active substances’. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> The proposed relocation of the definition and the deletion of the editorial note were noted. The deletion was opposed. Considered that the problem with the current 	<ul style="list-style-type: none"> This definition was not subject to review The definition of biologically active substances in the Code serves a useful regulatory purpose The definition is not primarily intended for scientific or academic usage The use of the term ‘nutrient’ in the definition for biologically active substance relies on the common understanding of the term. This is consistent with the approach taken throughout the Code. The policy relating to the addition of substances other than vitamins and minerals remains under development and it would be premature to review the regulatory definition

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			<p>definition is that almost every food ingredient or component has had some research undertaken in relation to possible health effects. Everything from water to an apple would be captured by the definition and a biologically active substance and therefore reference to such things a nutrition content claim.</p> <ul style="list-style-type: none"> Many submitters opposed the recommendation that whole grain nutrition content claims be regulated as for biologically active substances. Some believed that FSANZ was capturing wholegrain under this definition. 	<p>of biologically active substances at this point.</p> <ul style="list-style-type: none"> There are no plans to retain the Editorial Note to this definition The definition refers to a ‘substance’. The common understanding of this term does not include whole foods. Any nutrition content claim made about biologically active substances or any other property of a food must meet the generic conditions for making a nutrition content claim. FSANZ agrees that ‘wholegrain’ is not a substance as the term is commonly understood and therefore not a biologically active substance. At DAR, it was proposed to relocate this definition to Standard 1.1.1. Given that this definition is required for labelling purposes only, the decision was made post-PFAR for this definition to remain in Standard 1.2.8. Refer to Part 2 of Attachment 5 - Nutrition Content Claims for further discussion on biologically active substances, and the approach taken for wholegrain.
<p>biomarker means a measurable biological parameter which, when present at an abnormal level in the human body, is predictive of the risk of a serious disease.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> Some submitters recommended that the definition should be amended to include overweight as a biomarker for obesity, meaning that claims about overweight are regulated as high level health claims. It was questioned why the draft Standard remains silent on how biomarkers for non-serious diseases are to be regulated. It was suggested that the word ‘predictive’ be replaced by the word ‘indicative’, given that one biomarker is rarely the only factor in the cause of a particular disease. ‘Predictive’ may be interpreted as suggesting a causal link whereas ‘indicative’ does not. 	<ul style="list-style-type: none"> This term has been defined for use in the context of the draft Standard. This definition has been defined to clarify whether a health claim that refers to a biomarker is regulated as a high level or general level health claim. Biomarker is defined in terms of serious disease because claims that refer to other biomarkers that relate to non-serious disease are simply regulated as general level health claims. This is not explicit in the draft Standard. However because health claims are either general level and high level health claims, any that are not captured by the definition of a high level health claim default

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			<ul style="list-style-type: none"> It was suggested that as biomarkers can be an indicator for maintaining good health, then claims about biomarkers should not be regulated in the same way as serious diseases, but should be regulated as general level health claims. Alternatively, another submitter suggested that all food biomarker claims should be regulated as high level health claims. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> The definition refers to ‘measurable biological parameter’, ‘abnormal’, and ‘predictive’, without providing detail on the capture of these words. This may lead to considerable debate on boundaries in an enforcement situation. The recommendation that the definition is amended to include overweight as a biomarker for obesity was restated. 	<p>to the definition of general level health claim (excluding any related claims that are defined, such as cause-related marketing).</p> <ul style="list-style-type: none"> This approach is consistent with the definition of a high level health claim, which relates to serious disease only. It would be inconsistent within the Standard to regulate health claims about non-serious disease as general level health claims but about biomarkers of non-serious disease as high level health claims. It is also supported by the Policy Guideline which provides an example of a high level health claim about a biomarker and notes that <i>a biomarker is one indicator of a person’s risk of developing a serious disease.</i> Overweight is considered not to be a biomarker because it is not predictive of a serious disease, in this case, of obesity. FSANZ believes that ‘predictive’ is the correct term in place of ‘indicative’, because a biomarker should have a causal association with the disease outcome and ‘predictive’ describes that required relationship for any of the many factors that can lead to a multifactorial disease. Other queries that relate to ‘measurable biological parameter’ and ‘abnormal’ signal a lack of detail in previous FSANZ documentation about biomarker parameters. This has now been addressed and further details will be given in the section devoted to high level health claims in the <i>Application Handbook</i>.
<p>Carbohydrate means –</p> <p>(a) carbohydrate by difference, calculated by subtracting from 100 the average quantity expressed as a percentage of</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Some submitters called for definitions of ‘low’ 	<ul style="list-style-type: none"> This definition was not subject to review. ‘Low’ or ‘reduced’ are considered as claim descriptors, rather than definitions. The regulatory approach for nutrition content claims in relation to carbohydrate is discussed

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<p>water, protein, fat, dietary fibre, ash, alcohol and, if quantified or added to the food, any other unavailable carbohydrate and the substances listed in column 1 of Table 2 to subclause 2(2); or</p> <p>(b) available carbohydrate, calculated by summing the average quantity of total available sugars and starch and, if quantified or added to the food, any available oligosaccharides, glycogen and maltodextrins.</p>			<p>or ‘reduced’ carbohydrate.</p> <ul style="list-style-type: none"> Some submitters agreed with the relocation proposed at PFAR 	<p>in Part 2 of Attachment 5.</p> <ul style="list-style-type: none"> At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Post-PFAR, the decision was made that this definition should remain in Standard 1.2.8, to keep it together with Table 2 to sub clause 2(2).
<p>cause-related marketing statement for a food means a nutrition content claim or health claim that is presented as a statement that the sale of the food will contribute to fundraising for an organisation.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> It was queried why the name of the organisation had to refer to a serious disease. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments specifically relating to the definition were received. 	<ul style="list-style-type: none"> This term has been defined for use only in the context of this Standard. The definition no longer requires the organisation to refer to a serious disease. The regulatory approach taken for cause-related marketing statements is discussed in Attachment 9.
<p>claim means a statement, representation, design or information in relation to a food or property of the food which is not mandatory in this Code, including an implied claim.</p>	Std. 1.1.1	Std. 1.1.1	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments were received 	<ul style="list-style-type: none"> At DAR, the definition was amended to include: <ul style="list-style-type: none"> implied claims to ensure that they would be captured by the Standard, and property of a food to ensure that in addition to claims about a food, claims about the property of a food would also be captured by the Standard. At PFAR, minor grammatical edits have been made, which do not alter the intent of the definition.
<p>claimable food means a food which consists of at least 90% by weight of –</p> <p>(a) (i) primary foods; (ii) foods mentioned in the Table to clause 3; or</p>	Std. 1.3.2	Deleted	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> A drafting error was identified where the definition incorrectly referred to the Table to clause 2 of Standard 1.3.2 rather than the Table to clause 3. 	<ul style="list-style-type: none"> This definition was not subject to review under Proposal P293. At DAR, it was proposed to relocate this definition to Standard 1.1.1. In the Consultation Paper, it was proposed that the existing approach to apply claimable food

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<p>(b) any of the following:</p> <ul style="list-style-type: none"> (i) a mixture of primary foods; (ii) water; (iii) foods mentioned in the Table to clause 3 other than butter, cream and cream products, edible oils, edible oil spreads and margarine. 			<p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> • No comments were received 	<p>criteria to claims about vitamins and minerals be removed. This became the regulatory approach decided at FAR, and as a consequence, this definition has now been deleted from the Code.</p>
<p>dietary fibre means that fraction of the edible part of plants or their extracts, or synthetic analogues that –</p> <ul style="list-style-type: none"> (a) are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and (b) promote at least one of the following beneficial physiological effects – <ul style="list-style-type: none"> (i) laxation; (ii) reduction in blood cholesterol; (iii) modulation of blood glucose; <p>and includes polysaccharides, oligosaccharides (degree of polymerisation > 2) and lignins.</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> • No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> • A review of the definition was suggested: one recommendation was to consider the latest Codex draft definition of dietary fibre; other submitters opposed the current definition permitting high fibre claims on products deemed inappropriate (for example, the definition would include polydextrose, when added to chocolate bars would then claim ‘high fibre’). • Some submitters agreed with the relocation proposed at PFAR 	<ul style="list-style-type: none"> • This definition was not subject to review. Furthermore, any amendments to the definition may impact on other Proposals. • At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Post- PFAR, the decision was made for this definition to remain in Standard 1.2.8. • Refer to Part 2 of Attachment 5 for further discussion on dietary fibre.
<p>dietary information means general dietary information that –</p> <ul style="list-style-type: none"> (a) does not relate to a health effect; and (b) relates to food or a property of the food; and 	New	Std. 1.2.7	<p>A summary of submitter comments to the Draft Assessment Report¹ is on the FSANZ website. A summary of submitter comments to the Preliminary Final Assessment Report is at Attachment 13.</p>	<ul style="list-style-type: none"> • Refer to Attachment 9 for discussion on the development of the definition of dietary information and how submitter comments have been addressed.

¹ [Food Standards Australia New Zealand: Proposal P293 - Nutrition, Health and Related Claims](#)

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(c) is provided for educational purposes.				
<p>endorsement means a design used, or intended to be used, to distinguish food certified by an endorsing organisation in relation to its nutrition or health features from other foods not so certified, other than –</p> <p>(a) a design that distinguishes food in relation to ethical, religious or environmental features including vegetarian, halal, kosher or organic designs; or</p> <p>(b) a design that includes a reference to a serious disease other than as part of the name of the endorsing organisation.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> It was noted that the definition refers to a ‘design’, which may have implications for claims that might be permitted under certification trademark rules. There was some opposition to the use of ‘serious disease’ in the definition. There was some support for the definition. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> The regulatory difficulty between capturing ‘designs’ in this definition and those designs which are registered trademarks was re-stated. The definition of an endorsement program should include that the process and criteria for endorsement programs are transparent and made readily available to consumers. 	<ul style="list-style-type: none"> The definition included in the Standard meets the regulatory purpose to provide minimum effective regulation and aligns nutritional and health related endorsements with nutrition policy principles. The use of the term ‘serious disease’ in the definition is necessary to allow endorsements by endorsing organisations whose name makes reference to a serious disease (e.g. Coeliac Society of Australia) without it being captured as a high level health claims A design which does not meet the criteria of an endorsement must have an accompanying nutrition or content claim, or must itself be compliant with the criteria and conditions of a nutrition or health claim. The reference to certification trademarks has been removed from the definition. Refer to Attachment 9 for further discussion on the regulatory approach for endorsements.
<p>endorsing organisation means an independent organisation, including a government organisation, formed for nutrition or health purposes, the name of which may include a serious disease, other than an organisation established or controlled by a supplier or their representatives of food or food ingredients.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> Explicit reference in the definition that research and development organisations should be endorsing organisations was suggested. It was queried whether the use of ‘supplier’ is based on the definition of ‘supplier’ in Standard 1.1.1. There was some opposition to the use of ‘serious disease’ in the definition. There was some support for the definition. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> The comment was made that until the definitions are tested, it is unclear whether they would control an influx of ‘independent 	<ul style="list-style-type: none"> The current definition effectively identifies appropriate endorsing organisations whose endorsements are potentially not required to comply with the claims classification system in the draft Standard. The term ‘supplier’ in Standard 1.1.1 is intended to apply across the Code. The use of the term ‘serious disease’ in the definition is necessary to allow organisations whose name makes reference to a serious disease (e.g. Coeliac Society of Australia) to qualify as ‘endorsing organisations’ Under the proposed definition an endorsing organisation has to be independent. Peak Industry bodies are not independent and not

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			<p>endorsing organisations' with indirect industry linkages.</p> <ul style="list-style-type: none"> 'Peak' industry bodies appear to be excluded from the definition. 	<p>structured in a way that guarantees that suppliers of foods carrying the endorsement cannot influence the criteria used by the endorsement program. Therefore, such organisations are not endorsing organisations and their endorsements would need to comply with the claims requirements in the draft Standard.</p> <ul style="list-style-type: none"> The regulatory approach for endorsing organisations and endorsements is discussed in Attachment 9.
fat means total fat.	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Some submitters agreed with the relocation proposed at PFAR 	<ul style="list-style-type: none"> This definition was not subject to review. At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Given that this definition is required for labelling purposes only, the decision was made post-PFAR for this definition to remain in Standard 1.2.8.
<p>food group means, in this Standard, any of the following groups –</p> <p>(a) bread (both leavened or unleavened), grains, rice, pasta and noodles; or</p> <p>(b) fruit, vegetables, herbs, spices and fungi that is one ingredient or more than one ingredient of that class; or</p> <p>(c) milk and milk products as standardised in Part 2.5 and analogues derived from legumes and cereals mentioned in column 1 of the Table to clause 3 in Standard 1.3.2; or</p> <p>(d) meat, fish, eggs and legumes that is one ingredient or more than</p>	New	Std. 1.2.7	<p>A summary of submitter comments to the Draft Assessment Report¹ is on the FSANZ website. A summary of submitter comments to the Preliminary Final Assessment Report is at Attachment 13.</p>	<ul style="list-style-type: none"> Refer to Part 2 of Attachment 5 for discussion on the development of the definition of dietary information and how submitter comments have been addressed.

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(e) one ingredient of that class; or fats including butter, edible oils and edible oil spreads.				
fruit means fruit other than nuts, spices, herbs, fungi, dried pulses and seeds and includes the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole fruit (with or without the peel or water).	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received, as a specific definition was not developed until the PFAR. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Fruit and vegetable definitions are presented separately and are not consistent the fruit and vegetable definitions in Standard 2.3.1. There was also a recommendation to rely on the existing definitions in Schedule 4 of Standard 1.4.2. Strawberries and berries are not captured by the definition of fruit as the seed are on the outside of the fruit. Notes that the definition at DAR would capture tomato. Whilst technically correct, this may cause consumer confusion. Clarification was sought as Standard 1.4.2 defines tomato as a ‘fruiting vegetable other than cucurbits’. 	<ul style="list-style-type: none"> The definition was developed specifically for the draft Standard, as the definition in Standard 2.3.1 does not provide sufficient clarity around what is meant by a fruit for the purposes of Standard 1.2.7. At PFAR, the definition was revised to take into account the dictionary meaning for ‘fruit’. This was because trying to individually define ‘fruit’ using botanical based definitions resulted in the exclusion of some foods commonly known as fruits whilst capturing other cereals and plant foods not normally classified as fruit. In this Report, the definition was amended to clarify that the definition of fruit includes dried fruit.
general level health claim means a health claim that does not, directly or indirectly, refer to a serious disease or a biomarker.	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> In the Draft Assessment Report, General Level Claim was defined and this definition also captured nutrition content claims. A submitter commented that this approach was confusing. It was it questioned how claims relating to non-serious conditions as opposed to ‘diseases’ would be regulated. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments were received specifically about this definition. 	<ul style="list-style-type: none"> This term has been specifically developed for the draft Standard. In the Preliminary Final Assessment Report, the definition was simplified to refer solely to general level health claims and reference to nutrition content claims was removed for simplification of the Standard. The definition relies upon the definitions of ‘biomarker’ (see above), ‘health claim’, and ‘serious disease (see below). In accordance with the ‘step-up’ approach for the classification of different claims (outlined in Section 11.6 of the Final Assessment Report), the distinguishing feature of a general

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				<p>level health claim is that it is a health claim that does not refer to a serious disease or a biomarker of a serious disease, either directly or indirectly.</p> <ul style="list-style-type: none"> As indicated by the definition of ‘serious disease’, a general level health claim does not include a claim about a <i>condition that is not appropriate to diagnose, treat or manage without consultation with or supervision by a health care professional</i>, but would by default, include claims about conditions that do not fall under the ‘serious disease definition. This approach is supported by the Policy Guideline which states <i>general level claims do not reference a serious disease</i>.
<p>gluten means the main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions Coeliac disease and dermatitis herpetiformis.</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Some submitters agreed with the relocation proposed at PFAR. 	<ul style="list-style-type: none"> This definition was not subject to review. At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Given that this definition is required for labelling purposes only, the decision was made post-PFAR for this definition to remain in Standard 1.2.8.
<p>glycemic index (GI) means the property of the carbohydrates in different foods, specifically the blood glucose raising ability of the digestible carbohydrates in a given food.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Definition of Glycemic Index has been proposed as ‘the weight of glucose that would induce a glycemic response equivalent to that induced by a given amount of food’. 	<ul style="list-style-type: none"> The definition for ‘glycemic index’ used in the Code is consistent with the definition used in the Australian Standard AS 4694—2007, Australian Standard® - Glycemic Index of foods The definition for this term was developed at PFAR. Post-PFAR, the phrase ‘[referred to as the GI of the food]’ was deleted because it was superfluous
<p>health claim means a claim that directly or indirectly refers to a relationship between –</p> <p>(a) food or a property of the food; and</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> It was suggested that the definition could be amended to encompass not only the specific claim but the total presentation of the product, including labelling and advertising. 	<ul style="list-style-type: none"> This definition has been specifically developed for the draft Standard. FSANZ considers it is necessary to define ‘health claim’, as the term is likely to be interpreted differently by different stakeholders given the current requirements

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(b) a health effect.			<p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments specifically about this definition were received. 	<p>and use of the term in the Code.</p> <ul style="list-style-type: none"> The main characteristic of a health claim is that it is a claim that indicates a relationship between consumption of a food or a property of a food with a health effect. The definition is based on the definition in the European Regulation. The definition of ‘claim’ upon which this definition relies, and the scope of the Code in general, ensure that the total presentation of the product is taken into account and the claim(s) regulated accordingly, including health claims in advertising. Refer to Attachment 9 for the rationale for removing the exclusion of ‘cause-related marketing statements’ from the definition of health claim. References to ‘dietary information’ and ‘endorsements’ in the definition were removed on the basis that dietary information and endorsements are not excluded from the operation of the draft Standard, however if certain conditions are met, they do not have to meet the requirements of the claims classification system in the draft Standard.
<p>health effect means an effect on the functioning of the human body including a disease state or physical or mental performance or maintenance of a healthy functioning body.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> It was queried whether the word ‘measure’ is appropriate, when many references to the impact of food on the body many not be ‘measurable’ or may not reference a level or value of the effect. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Remove ‘or performance’, as performance claims relating to sports foods should only be permitted providing they are substantiated on foods/beverages under Standard 2.9.4. The word ‘substance’ could be interpreted 	<ul style="list-style-type: none"> In response to submitter comments, the definition of health effect has been simplified post-PFAR for the following reasons: <ul style="list-style-type: none"> Health effect should refer to the <u>outcome</u> part of the food-health or food-disease relationship. In the definition proposed at DAR and PFAR, the use of ‘<u>impact</u> of’ referred to a relationship rather than an outcome and therefore ‘impact’ was not the appropriate word. ‘..a measure of’ health effect is not referred to in the pre-approved high level health claims,

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			<p>more broadly than ‘food’, for example substances legislated by the Therapeutic Goods Act 1989.</p>	<p>therefore these words have been removed.</p> <ul style="list-style-type: none"> – Health effect should not make any reference to the food or property of the food (that is, ‘substance’ or ‘particular dietary intake’) as these are already represented by the food or property component of the definition of health claim. – Revision of the definition has also clarified the context of ‘performance’.
<p>high level health claim means a health claim that directly or indirectly refers to a serious disease or a biomarker.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> • No comments were received specifically about this definition. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> • No comments were received specifically about this definition. 	<ul style="list-style-type: none"> • This term has been defined for use in the context of the draft Standard. • A high level health claim is the highest level of claim in the ‘step up’ approach in the classification of different claims (refer to Section 11.6 of the Final Assessment Report) because it captures only those claims that refer (directly or indirectly) to a serious disease or a biomarker of a serious disease. • This approach is consistent with the Policy Guideline which states that <i>high level claims are those claims which make reference to a serious disease</i>. The Policy Guideline gives examples of high level health claims including those relating to biomarkers or a serious disease. • The definition relies on the definitions of biomarker (see above) and serious disease (see below).
<p>ingredient means any substance, including a food additive, used in the preparation, manufacture or handling of a food</p>	Std.1.2.4	Std. 1.2.4	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> • No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> • No comments were received. 	<ul style="list-style-type: none"> • At DAR, it was proposed to relocate this definition to Standard 1.1.1. Post-PFAR, the decision was made for this definition to remain in Standard 1.2.4. This is because ‘ingredient’ was defined specifically for this Standard. Other references to this term in the Code should rely on the Macquarie dictionary definition.

Terms and definitions - Decision	Current location in Code	Recommended location	Submitter comments	Decision history and response to submitter comments
<p>monounsaturated fatty acids means the total of cis-monounsaturated fatty acids and declared as monounsaturated fat.</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Some submitters agreed with the relocation proposed at PFAR 	<ul style="list-style-type: none"> This definition was not subject to review in the draft Standard. At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Given that this definition is required for labelling purposes only, the decision was made post-PFAR for this definition to remain in Standard 1.2.8.
<p>nutrition content claim means a claim about the presence or absence of a property of the food, other than a claim about alcohol content.</p>	Std 1.2.8 as 'nutrition claim'	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received about this definition. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments were received specifically about this definition. 	<ul style="list-style-type: none"> The definition of 'nutrition claim' currently in the Code has been modified under this Proposal. A nutrition content claim is the first level of claim in the 'step up' approach in the classification of different claims (refer to Section 11.6 of the Final Assessment Report) hence it is a claim about the presence or absence of a property of a food. It is differentiated from a health claim by not including reference to a health effect. The definition relies on the definition of a 'property of a food' (refer below). See Section 2.2 of Attachment 4 for the rationale for excluding claims about alcohol content from this definition. Refer to Attachment 9 for the rationale for removing the exclusion of 'cause-related marketing statements' from the definition of nutrition claim. References to 'dietary information' and 'endorsements' in the definition were removed on the basis that dietary information and endorsements are not excluded from the operation of the draft standard, however if certain conditions are met, they do not have to meet the requirements of the claims classification system in the draft Standard.
<p>polyunsaturated fatty acids means the total of polyunsaturated fatty acids with</p>	Std. 1.2.8	Std. 12.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. 	<ul style="list-style-type: none"> This definition was not subject to review in the draft Standard.

Terms and definitions - Decision	Current location in Code	Recommended location	Submitter comments	Decision history and response to submitter comments
<p>cis-cis-methylene interrupted double bonds acids and declared as polyunsaturated fat.</p>			<p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Some submitters agreed with the relocation proposed at PFAR. 	<ul style="list-style-type: none"> At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Given that this definition is required for labelling purposes only, the decision was made post-PFAR for this definition to remain in Standard 1.2.8.
<p>primary food means fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds or fish.</p>	Std. 1.3.2	Deleted	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> The definition may be problematic as it does not give an account of the extent of manufacture (for example, as in canned fruit or fish). It may be useful to use the trade terms of ‘minimally processed’. Is the definition of a primary food based on the amount of processing, or by what foods are ‘primarily’ consumed by the population? Recommends the definition be reviewed to align with that for ‘food groups’. This complements the categories used in the Australian Dietary Guidelines, Australian Guide to Healthy Eating and the 1995/1996 National Nutrition Survey, and can reflect the dietary intake of Australia’s and New Zealand’s multi-cultural society. Therefore, the definition of a primary food should be replaced by the definition for a food group, but be extended to include water, and fats and oils. There are foods missing from the listing of primary foods, such as a claim cannot be made about water as it is missing. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments were received 	<ul style="list-style-type: none"> The definition of primary food was not subject to review in the draft Standard. At DAR, this definition was used to set boundaries for what constituted a whole food, and consequently it was tied to conditions for whole food claims. At PFAR, the reference to primary food in the context of whole food was removed. However, given that primary food is used within the definition of claimable food, it was proposed that this term should reside in Standard 1.1.1. In the Consultation Paper, it was proposed that the existing approach to apply claimable food criteria to claims about vitamins and minerals be removed. This became the regulatory approach decided at FAR, and as a consequence, this definition has now been deleted from the Code.
<p>property of the food means any of the following, that is associated with a nutrition or health purpose,—</p> <p>(a) energy, a nutrient, or a biologically active substance; or</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> As the definition includes the word ‘ingredient’, a simple ingredient claim may be regulated as a nutrition content claim. 	<ul style="list-style-type: none"> The definition must be clear that an ingredient could be considered a property of the food, if it is associated with a nutrition or health purpose. The reference to ‘ingredient’ should remain, even if it doubles up with ‘feature’ or ‘constituent’. ‘Feature or constituent of the food’ was

Terms and definitions - Decision	Current location in Code	Recommended location	Submitter comments	Decision history and response to submitter comments
<p>(b) a component, ingredient or any other feature or constituent of the food; or</p> <p>(c) glycemic index.</p>			<ul style="list-style-type: none"> The words ‘any other feature’ would capture descriptors such as soda water in a vodka and soda ready to drink product, which may be regulated as a nutrition content claim. Question the meaning of ‘any other feature or constituent of the food’. Unclear what the words ‘associated’ and ‘purpose’ mean in the context of the definition. 	<p>intended to capture any aspect of food not already covered by ‘component’ or ‘ingredient’, for example the food matrix. It was not intended to capture descriptors, such as ‘soda water’.</p> <ul style="list-style-type: none"> At PFAR, the definition was amended to replace ‘health effect’ with ‘a nutrition or health purpose’ in order to capture both nutrition content claims and health claims. Apart from reorganising the structure, the only amendment to the definition as proposed at PFAR was the removal of ‘glycemic load’. This action was taken because the Standard does not specifically mention this term.
<p>reference food means a food that is –</p> <p>(a) of the same type as the food for which a claim is made and that has not been further processed, formulated, reformulated or modified to increase or decrease the energy value or the amount of the nutrient for which the claim is made; or</p> <p>(b) a dietary substitute for the food in the same food group as the food for which a claim is made.</p>	New	Std. 1.2.7	A summary of submitter comments to the Draft Assessment Report ¹ is on the FSANZ website. A summary of submitter comments to the Preliminary Final Assessment Report is at Attachment 13.	<ul style="list-style-type: none"> Refer to Part 2 of Attachment 5 for discussion on the development of the definition of reference food and how submitter comments have been addressed.
<p>Reference quantity means –</p> <p>(a) for a food mentioned in the Table to clause 3 of Standard 1.3.2 –</p> <p>(i) the quantity specified in the Table for the food or,</p>	Std. 1.3.2	Std. 1.3.2	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> A drafting error was identified where the definition incorrectly referred to the Table to clause 2 of Standard 1.3.2 rather than the Table to clause 3. <p>Preliminary Final Assessment Report</p>	<ul style="list-style-type: none"> This definition was not subject to review in the draft Standard. At DAR, it was proposed to relocate this definition to Standard 1.1.1, as it is used across several standards. Minor drafting changes were made for simplification and correct reference to the

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<p>(ii) for a food that requires dilution or reconstitution according to directions – the quantity of the food that, when diluted or reconstituted, produces the quantity mentioned in column 2 of the Table; or</p> <p>(b) for all other foods –</p> <p>(i) a normal serving; or</p> <p>(ii) for a food that requires dilution, reconstitution, draining or preparation according to directions, the quantity of the food which when diluted, reconstituted, drained or prepared produces a normal serving.</p>			<ul style="list-style-type: none"> No comments were received. 	<p>Table to clause 2 of Standard 1.3.2 and it was decided after the PFAR to return this definition to Standard 1.3.2 because the clauses that this definition relates to reside in Standard 1.3.2.</p>
<p>reference value means RDI, ESADDI or a reference value under the Table to subclause 7(8) of Standard 1.2.8.</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments were received. 	<ul style="list-style-type: none"> The definition for reference value was developed at DAR. The decision was made for this term to reside in Standard 1.2.7, with a cross reference to clause 1A of Standard 1.2.8.
<p>saturated fatty acids means the total of fatty acids containing no double bonds acids and declared as saturated fat.</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Some submitters agreed with the relocation proposed at PFAR 	<ul style="list-style-type: none"> This definition was not subject to review in the draft Standard. At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Given that this definition is required for labelling purposes only, the decision was made post-PFAR for this definition to remain in Standard 1.2.8.
<p>serious disease means a disease, ailment, defect or condition for which it is not appropriate to diagnose, treat or manage without consultation with or supervision by a health care</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> Concern was raised regarding the reference to ‘health care professional’ because of uncertainty as to which professionals are recognised by the definition. 	<ul style="list-style-type: none"> This term has been developed for use in the context of the draft Standard. This definition is based on the definition used in the Australian Therapeutic Goods Advertising Code, with some amendments to

Terms and definitions - Decision	Current location in Code	Recommended location	Submitter comments	Decision history and response to submitter comments
professional, and includes obesity, but does not include being overweight.			<ul style="list-style-type: none"> It was suggested that ‘ailments’ is not included, as a serious ailment would manifest itself as a disorder or condition. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Further detail on the term ‘not appropriate’ within this definition, was requested. 	<p>take into account the specific needs of food regulation, e.g. including reference to ‘condition’ and excluding reference to ‘injury’.</p> <ul style="list-style-type: none"> The definition specifically includes reference to obesity but not overweight. This is intended to clarify the appropriate regulatory position of such claims and is not intended to indicate that overweight is not a condition with significant public health outcomes at a population level. The term ‘professional’ implies someone with suitable, broadly recognised qualifications, in the community, in the area of health care. ‘Ailment’ has been added to broaden the definition and capture at least some injuries. This helps to clarify the definition in terms of what types of conditions or disorders it may or may not capture. The Policy Guideline includes ‘ailment’ in an example definition of ‘serious disease or condition’. ‘Not appropriate’ can be explained in the context of the definition as referring to a potential level of risk incurred by a person if self diagnosis, management or treatment is undergone or such services are provided by those other than a health care professional.
sugars means monosaccharides and disaccharides.	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> The comment was made that this term covers a variety of mono and disaccharides which can be significantly different from each other. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Because of its non-cariogenic properties, the exemption of isomaltulose from the definition was suggested as an option to distinguish it from other forms of sugar. 	<ul style="list-style-type: none"> At DAR, sugars were not defined for the purposes of this Standard. ‘Sugars’ is defined twice in the Code in Standards 1.2.8 and 2.8.1. At PFAR, it was proposed to relocate the definition in Standard 1.2.8 to Standard 1.2.7. Post-PFAR, the decision was made for this definition to remain in Standard 1.2.8. The definition itself was not subject to review. Isomaltulose would be captured by this definition, as it is a disaccharide.
trans fatty acids means the total of unsaturated fatty acids where one or	Std. 1.2.8	Std. 1.2.8	A summary of submitter comments to the Draft Assessment Report is on the FSANZ website ¹ . A	<ul style="list-style-type: none"> This definition was not subject to review in the draft Standard. However comments that were

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<p>more of the double bonds are in the trans configuration acids and declared as trans fat.</p>			<p>summary of submitter comments to the Preliminary Final Assessment Report is at Attachment 13.</p>	<p>received were addressed in Part 2 of Attachment 5.</p> <ul style="list-style-type: none"> At PFAR, it was proposed to relocate this definition to Standard 1.1.1. Given that this definition is required for labelling purposes only, the decision was made post-PFAR for this definition to remain in Standard 1.2.8.
<p>unit quantity means, in the case of a solid or semi-solid food, 100 grams or, in the case of a beverage or other liquid food, 100 millilitres.</p>	Std. 1.2.8	Std. 1.2.8	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> No comments were received. 	<ul style="list-style-type: none"> This definition was not subject to review in the draft Standard; however minor changes were made which do not change the intent of the definition. This definition relates to prescribed declarations in the nutrition information panel, which also remain in Standard 1.2.8.
<p>vegetable means vegetable other than nuts, spices, herbs, fungi, dried pulses and seeds and includes the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole vegetable (with or without the peel or water).</p>	New	Std. 1.2.7	<p>Draft Assessment Report</p> <ul style="list-style-type: none"> No comments were received, as a specific definition was not developed until the PFAR. <p>Preliminary Final Assessment Report</p> <ul style="list-style-type: none"> Fruit and vegetable definitions are presented separately and are not consistent the fruit and vegetable definitions in Standard 2.3.1. There was also a recommendation to rely on the existing definitions in Schedule 4 of Standard 1.4.2. The definition does not include legumes and fungi. 	<ul style="list-style-type: none"> This definition has been specifically developed for the draft Standard, as the definition Standard 2.3.1 does not provide sufficient clarity around what is meant by a fruit for the purposes of Standard 1.2.7. At PFAR, the definition was revised to take into account the dictionary meaning for 'vegetable'. This was because trying to individually define 'vegetable' using botanical based definitions resulted in the exclusion of some foods commonly known as vegetables whilst capturing other cereals and plant foods not normally classified as vegetables. Legumes and fungi were explicitly excluded from the definition. In this Report, the definition was amended to clarify that the definition of vegetable includes dried vegetable.

Table 2. Terms for which definitions were recommended, but not developed

Requested Term	Submitter comments	Rationale for not developing a definition
Nutrient	<ul style="list-style-type: none"> Suggest a definition of ‘nutrient’ is added to Standard 1.1.1, as the definition of biologically active substance (proposal to insert definition Standard 1.1.1, Division 1(2)) refers to a ‘substance other than a nutrient’. An extensive, but non-exclusive list of biologically active substances appears in Attachment 6 to the Draft Assessment Report, collated from submitters’ comments to the IAR. Note that many of these biologically active substances are also nutrients. 	<ul style="list-style-type: none"> It was decided not to define ‘nutrient’ in the context of the draft Standard, as this definition would have far-reaching implications for other parts of the Code. However, FSANZ may find an opportunity in future planned work to consider a definition of nutrient that is suitable for use throughout the Code.
Therapeutic	<ul style="list-style-type: none"> Strong recommendation for a definition of ‘therapeutic’ to be included, as the lack of a definition has been a major difficulty in enforcing the current transitional standard. The definition in the Therapeutic Goods Act was considered unhelpful as it is for ‘therapeutic use’ and is meant to address the use of medications, not food. 	<ul style="list-style-type: none"> In the Draft Assessment Report, it was decided that to define ‘therapeutic’ in relation to ‘therapeutic claim’ would be problematic. Wording in subclause 3(2) of the draft Standard is intended to prohibit therapeutic claims; these words reflect the wording used in paragraph (a) of the definition of ‘therapeutic use’ in the Therapeutic Goods Act 1989, where <i>‘therapeutic use’ means use in or in connection with:</i> (a) <i>preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals.</i> The approach taken at Final Assessment Report is the same as the approach taken in the Draft Assessment Report and Preliminary Final Assessment Report.
Supplier	<ul style="list-style-type: none"> In the draft Standard in the Draft Assessment Report, Clause 5(1)(a) referred to permission for a nutrition content claim to be made if the supplier of the food has records substantiating the claim. It was noted that the ‘supplier’ of the food is taken to mean each person who supplies the food. This would include the manufacturer, wholesaler, importer and retailer. The suggestion was made to define ‘supplier’ to mean the person who initiates the claim. The definition of ‘supplier’, as it relates to the holding of evidence for the substantiation of health claims, allows NSW enforcement officers the power to obtain information from premises outside the physical boundaries of NSW. Currently the visitation powers of enforcement officers under the <i>NSW Food Act 2003</i> are limited to the physical boundaries of NSW. 	<ul style="list-style-type: none"> The submitters’ interpretation of ‘supplier of the food’ is in close agreement with the term ‘supplier’, as defined in Standard 1.1.1 Division 1(2), where <i>Supplier means the packer, manufacturer, vendor or importer of the food in question.</i> Consider a change to be unnecessary, as any of these parties could make a claim on the food label or in an advertisement and must therefore meet the requirements listed in the proposed Standard. Where there is a provable nexus, substantiating evidence can be accessed inter-state. Uncertainties around the form of the substantiating evidence that would be accessible (i.e. files or information other than books) must be addressed through individual State legislation. Where substantiating evidence is held overseas, it would be the responsibility of the supplier of the food that is the distributor based in Australia/New Zealand (the importer, vendor or both) to obtain the required substantiation. This is a matter for the relevant enforcement agencies to consider as part of food law enforcement and capacity to compel information to be provided to the enforcement body.

