ATTACHMENT 9

DEVELOPMENT OF TERMINOLOGY

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Chapter 1: Background to claim definitions and other terminology

At Initial Assessment, FSANZ sought comment on a number of issues related to the proposed FSANZ Conceptual Framework, including FSANZ Claim Descriptors and Other Related Claim Descriptors. FSANZ had developed a list of descriptors, to give effect to the FSANZ Conceptual Framework discussed in the Initial Assessment Report. It was unclear at this time whether or not these terms required further definition in the Standard for nutrition, health and related claims.

At Draft Assessment:

- the terminology used, such as 'definition' and 'descriptors' has been clarified; and
- some of the terms discussed under Other Related Descriptors at Initial Assessment have been defined.

Chapter 2 deals with Claim Definitions. These are definitions included in the draft Standard 1.2.7. As necessary, they will be further explained in supporting documentation in order to ensure absolute certainty around terminology used within the context of this standard. Chapter 3 deals with Claim Descriptors. These are descriptors that do not require definition in the Standard, but may be used in the Standard to describe a claim (e.g. 'low', 'reduced'), or in supporting explanatory materials.

Due to terms being divided into descriptors and definitions, the numbered sequence of questions that appeared in the IAR has changed.

Chapter 4 deals with other terminology. These are terms used throughout the Draft Assessment Report and any supporting materials and defined for purposes of clarity (e.g. guideline, user guide) but not for regulatory purposes.

Consideration was also given to various definitions currently located in Standards 1.2.4, 1.2.8 and 1.3.2, which at present only apply to those standards, but will also need to apply to Standard 1.2.7. These have been consolidated and moved into Standard 1.1.1 and will apply generally across the Code. The following terms are affected:

- biologically active substance;
- claimable food;
- ingredient;
- primary food;
- reference quantity.

Furthermore, the fundamental definition of 'claim' under Standard 1.1.1 is proposed to be amended to put it beyond doubt that it encompasses implied claims. Implied claims mean those claims that direct the attention or thoughts of an average consumer to a matter, although that matter is not expressly stated as part of the claim. As this meaning is consistent with common dictionary definitions, it is not necessary to define 'implied claims' under Standard 1.1.1. This is consistent with general drafting practice in the Code.

The following analysis sets out the issues raised by submitters in relation to these matters, FSANZ's assessment of these issues and the preferred approach at Draft Assessment.

Chapter 2: FSANZ Claim Definitions

2.1 Claim

2.1.1 Current definition at Initial Assessment

Term	Current definition in Standard 1.1.1 in the Code
claim	means any statement, representation, information, design, words or reference in relation to food, which is not mandatory in this Code.

FSANZ did not expressly seek comment on the current definition for claim in Standard 1.1.1.

FSANZ proposes to amend the current definition for claim in Standard 1.1.1 in the Code.

2.1.2 Proposed definition at Draft Assessment

Term	Proposed amended definition for inclusion in Standard 1.1.1
claim	means any statement, representation, information, design, words or reference in relation to food, which is not mandatory in this Code, and includes implied claims.

2.1.3 Rationale

The definition of a 'claim' is very broad, encompassing any voluntary representations made in relation to a food. This covers words or other artwork on food labels, or conveyed through other mediums such as advertisements.[1] It covers verbal representations in relation to food.

The term 'claim' provides a basic threshold for the categories of claims in the Claims Classification Framework. For example, in order for something to constitute a general level claim or a high level claim, it must first meet the criteria for being a claim.

FSANZ considers that the current definition of 'claim' in the Code provides a basis for defining the categories of claims. The current definition of claim, which makes reference to 'representation' and 'words or reference in relation to a food' captures implied claims. However, for the purpose of clarity and to facilitate compliance and enforcement, FSANZ considers it is appropriate to amend the current definition in Standard 1.1.1 to put it beyond doubt that claims may be expressed or implied.

[1] Advertising is defined in the Model Food Act as 'any words, whether written or spoken, or any pictorial representation or design, or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale food'.

2.2 General Level Claim

2.2.1 Proposed definition at Initial Assessment

Term	Proposed FSANZ working definition at Initial Assessment
general level claim	is a claim, which does not reference a biomarker, or a serious disease or condition and [includes] [content] claims, function claims, enhanced function claims and risk reduction claims that reference a non-serious disease or non-serious condition.

2.2.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if they thought that the working definition of a 'general level claim' captures all the possible types of claims, which would not reference a biomarker or a serious disease or condition.

Many submitters responded to this question and while there was a measure of support for the wording of the proposed definition for a general level claim, a number of submitters noted that the ability to interpret the proposed definition was affected by the proposed definitions for 'claim'; 'serious disease'; 'biomarker' and 'non-serious disease'; and 'non-serious condition'.

A number of industry submitters suggested prefacing the proposed definition with the phrase *...is a type of nutrition, health and related claim….* Other submitters questioned whether there was a need to include the subcategories of general level claims within the proposed definition and whether those subcategories of claims listed in the definition represented all the possible types of general level claims.

A number of industry submitters considered that content claims in relation to biologically active substances should be permitted and regulated as general level claims.

There were a number of comments from submitters regarding how the proposed definition might apply in certain contexts, including whether certain representations of claims would or should be considered general level claims. There was a consideration that claims such as 'gluten free' and 'sugar free' should be permitted to be accompanied by a health message such as 'suitable for coeliacs' or 'suitable for diabetics' without being regulated as high level claims.

Some industry submitters sought clarification about whether dietary advice, including advice from industry to health professionals, would be a considered a type of nutrition, health and related claim and if so, was it appropriate to require this advice to be pre-approved if it included a reference to a biomarker or a serious disease or condition.

A large number of submitters supported the development of a user guide for general level claims that would provide examples of the different types of general level claims and model claims.

2.2.3 Proposed definition at Draft Assessment

Term	Proposed definition at Draft Assessment
general level claim	means (a) a nutrition content claim; or (b) a health claim that does not, either directly or indirectly, refer to a serious disease or a biomarker.

2.2.4 Assessment and Rationale

FSANZ acknowledges that individual definitions cannot be considered in isolation and that the ability to delineate between the different categories of claims is affected by other relevant definitions including the proposed definitions for serious disease and biomarker.

As the distinguishing feature of a general level claim is that it does not reference a biomarker or serious disease, FSANZ considers that this should be the main concept reflected in the definition. As a consequence, FSANZ proposes not to list the sub-categories of general level claims within the definition. However, FSANZ will provide guidance around the different types of general level claims and how these claims might be represented in an Interpretative Guide to the Standard.

In relation to the proposal by submitters to preface the definition of a general level claim with the phrase *...is a type of nutrition, health and related claim…*, FSANZ considers that the scope of 'general level claim' might be better defined by referring to more specific terms, namely as 'nutrition content claim' and 'health claim', which will be clearly defined in the standard, rather than a catch-all term. In order to achieve this outcome, FSANZ intends to develop a definition for a 'nutrition content claim' and a 'health claim'. Refer to Section 2.3 Nutrition content claim and Section 2.4 Health Claim.

2.3 Nutrition content claim

2.3.1 Proposed descriptor at Initial Assessment

Term	Proposed descriptor at Initial Assessment
content claim	is a general level claim, which describes or indicates [explicitly or implicitly] the presence or absence of energy or a nutrient [or a biologically active substance] in a food.
For example, 'This food is reduced in fat' or 'This food is a good source of calcium'.	

2.3.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked whether the descriptor for a 'content claim' should refer to biologically active substances or other substances in addition to nutrients and energy.

Many submitters responded to this question and the most agreed that the descriptor for a 'content claim' should refer to biologically active substances or other substances in addition to nutrients and energy. Justification for this reference included the growing evidence base for ingredients, such as phytosterols and stanols, which exert beneficial biological effects.

In addition, several submitters suggested that that consumers were interested in these substances and their view of food had changed from a medium that simply delivered nutrients, that the proposed definition of 'health claim' had included reference to 'food or one of its constituents', and that the terms nutrient and biologically active substance had been differentiated in Standard 1.2.8.

Many submitters added clarifying statements and additional comments to their responses, in relation to the definition, reference levels, implied health benefits and regulation of biologically active substances. Some submitters recommended that the term 'content claim' be changed to 'nutrition content claim'.

Only a few submitters, from public health and industry, expressed their opposition to the inclusion of biologically active substances or other substances in addition to nutrients and energy. Reasons for opposition included: poor consumer understanding of what biologically active substances are and their effects; that allowing such claims in addition to nutrients and energy would be confusing and misleading; concern that a further expansion of claims made under the category of 'content claim' would further increase the capacity of food marketers to make misleading claims; and a comment that all nutrients and most substances found in food or added intentionally to food are biologically active at some level.

2.3.3 Proposed definition at Draft Assessment

Term	**Proposed definition at Draft Assessment**
nutrition content claim	means a claim about the presence or absence of a property of a food, but does not include an endorsement, dietary information or a cause related marketing statement.

2.3.4 Assessment and Rationale

FSANZ has clarified the term 'nutrition content claim'. As discussed in sub-section 2.2.4, FSANZ proposes to define a nutrition content claim in order to give effect to the proposed definition for a general level claim. Nutrition content claims are the most basic level of claims. They cover the presence or absence of a property of a food; a broad concept that has been designed to capture traditional claims as well as newer or emerging forms of claims. The concept of 'property of a food' has been defined further in Section 2.5, and includes claims about biologically active substances. The view of the most submitters, that such content claims should include biologically active substances or other substances in addition to nutrients and energy, is in agreement with this approach.

2.4 Health Claim

2.4.1 Proposed descriptor at Initial Assessment

Term	**Proposed descriptor at Initial Assessment**
health claim	a claim, other than a therapeutic claim, that describes or indicates [explicitly or implicitly] that a relationship exists between the consumption of a food, a category of food or one of its constituents and health.

2.4.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked whether they agreed that in accordance with the FSANZ Claims Classification Framework all claims other than content claims are health claims.

Of those submitters that responded to this question, most agreed that in accordance with the FSANZ claims Classification Framework all claims other than content claims were health claims. It was noted that health was not just treating or reducing disease risk, but also involved maintenance of normal body responses. Another point raised was that this approach was consistent with the Policy Guideline, whereby all claims other than content claims would be considered in the context of the total diet. In addition, it was noted that the proposed classification would be consistent with the Codex Guidelines for Use of Nutrition and Health Claims (2004).

Several submitters from industry either opposed the concept of having a separate definition of a health claim or disagreed that all claims other than a content claim were health claims. Points raised in opposition included: that the proposed definition of health claims was ambiguous as the term 'health' was left open to interpretation; that content claims and some function claims were not necessarily health claims, as they did not always denote a health outcomes (e.g. mint freshens your breath or glucose assists with brain function / concentration); and that the definition was not fully explanatory as the word 'health' was defined.

2.4.3 Proposed definition at Draft Assessment

Term	**Proposed definition at Draft Assessment**
health claim	means a claim that directly or indirectly refers to a relationship between – a) a food; or b) a category of food; or c) a property of food; and a health effect, but does not include an endorsement, dietary information or a cause related marketing statement.

2.4.4 Assessment and Rationale

As described in sub-section 1.3.2 previously, FSANZ considers there is a need to define the term 'health claim' in the new Standard. The intention is to link the definitions for a general level claim and a high level claim to the concept of a health claim, with the main characteristic of a health claim being that it indicates a relationship between consumption of a food, a category of a food or a property of a food and a health effect. Refer to Section 2.6 Health effect for the proposed definition of this term. The concept of a health claim is outlined below.

FSANZ recognises that a nutrition content claim is not a health claim.

General level claims		High level claims
Nutrition content claims	*Other general level claims*	
Absolute claims Comparative claims	Function claims Enhanced function claims Risk reduction claims (ref. A non-serious disease or condition)	Biomarker maintenance claims Biomarker improvement claims Risk reduction claims (ref. A serious disease or condition)
	Health claim indicates a relationship between the consumption of a food, a category of food, or a component in a food and a health outcome, whether expressed affirmatively or negatively.	

2.5 Property of a food

As a consequence of the decision by FSANZ to clarify the scope of general level claims by using more specific terms 'nutrition content claim' and 'health claims' (Refer to Section 2.3 Nutrition content claim and Section 2.4. Health claim), new terminology that has been used in the Draft Assessment must also be clarified.

2.5.1 Proposed definition at Draft Assessment

Term	Proposed definition at Draft Assessment
property of a food	means energy, a nutrient, or a biologically active substance, or – (a) a component; or (b) an ingredient; or (c) any other feature or constituent of the food; that is associated with a health effect, including glycaemic index and glycaemic load.

2.5.2 Rationale

The term 'property of a food' is used in part to describe 'nutrition content claim' and 'health claim'. A 'property of a food' covers energy, a nutrient, a component (see Standard 1.1.1), an ingredient (see Standard 1.2.4), or any other feature or constituent of the food including a biologically active substance (see Standard 1.1.1). Properties must, however, have a linkage with a 'health effect'. Otherwise, the definition of nutrition content claim has the potential to capture many claims about the content of food, which do not have health or nutrition overtones. The term 'health effect' is defined in Section 2.6.

2.6 Health effect

The definition of 'health effect' is designed to encompass such measures of health status as morbidity, life expectancy, birth defects, cancer incidence or recurrence, obesity rates, and nutritional status. Health effects can be positive or negative, and are physiological in nature.

2.6.1 Proposed definition at Draft Assessment

Term	Proposed definition at Draft Assessment
health effect	means – (a) a measure of the impact of a substance on the healthy functioning of the human body; or (b) a measure of the impact on the health or performance of a specific population, where the impact is associated with a particular dietary intake; and for the purposes of this definition, 'impact' includes maintenance.

2.6.2 Rationale

At Initial Assessment, the evidence required to substantiate an effect of consumption of a food or food component needed to relate to a claimed outcome. Neither 'outcome' or 'health outcome' were defined at that time.

FSANZ now considers that 'health effect' is a more appropriate and encompassing term that allows for intermediate end points as the subject of claims, as well as the absolute, clear-cut endpoint of the results of dietary intake.

The meaning of 'health effect' therefore includes intermediate endpoints that relate to healthy functioning of the human body such as claims about nutrition function that refer to biochemical or physiological effects. The term also refers to other impacts on health and includes impacts on mental or physical performance associated with particular dietary intake. Because of interest in health maintenance claims, the definition has been formulated to make it clear that the meaning of 'impact' not only includes dynamic change, but also maintenance.

2.7 High Level Claim

2.7.1 Proposed definition at Initial Assessment

Term	Proposed working definition at Initial Assessment
high level claim	is a claim, which references a biomarker, or a serious disease or condition and [includes] biomarker maintenance claims, biomarker enhancement claims and risk reduction claims, which reference a serious disease or condition.

2.7.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if they thought that the working definition of a 'high level claim' captures all the possible types of claims, which would reference a biomarker or a serious disease or condition.

Many responded to this question and as for the definition of a general level claim it was noted that the ability to interpret the proposed definition was affected by the proposed definitions for 'claim'; 'serious disease'; 'biomarker' and 'non-serious disease'; and 'non-serious condition'.

While there was a measure of support for the wording of the proposed definition for a high level claim, a number of industry submitters suggested prefacing the proposed definition with the phrase *...is a type of nutrition, health and related claim….* Other submitters questioned whether there was a need to list the subcategories of high level claims within the proposed definition and whether the listed subcategories of claims represented all possible types of high level claims.

There was also some concern expressed by submitters that the proposed definition of a high level claim was too broad and might not clearly delineate between prohibited therapeutic claims and permitted high level claims. Some of those submitters sought clarification on what the phrase 'reference a serious disease….' meant, particularly when a 'reference' to a serious disease would constitute a therapeutic claim rather than a high level claim. There was also a request from some submitters for the inclusion of the concept *within the context of the total diet* in the proposed definition to avoid confusion with a therapeutic claim.

Some submitters commented that the definition for a high level claim should be clearly linked to human nutrition. FSANZ assumes these comments mean that it should be clear that process type claims or statements in relation to 'organic', 'Halal' or 'kosher' foods, would not fall within the scope of the requirements for nutrition, health and related claims.

There was also concern from some submitters that industry might generalise the representation of certain claims thereby avoiding the pre-approval process for what might be considered higher risk claims. No examples were provided of how these claims might be represented.

There was some disagreement whether or not biomarker maintenance claims should be considered a type of high level claim.

2.7.3 Proposed definition at Draft Assessment

Term	**Proposed definition at Draft Assessment**
high level claim	means a health claim that directly or indirectly refers to a serious disease or a biomarker.

2.7.4 Assessment and Rationale

As the distinguishing feature of a high level claim is that it includes a reference to a biomarker or serious disease, FSANZ considers that this should be the main concept reflected in the definition. Therefore, as proposed for a general level claim, FSANZ proposes not to list the sub-categories of high level claims within the definition and intends to provide guidance around the different types of high level claims and how they might be represented in an Interpretative Guide to the Standard.

To maintain consistency with the definition of a general level claim, the definition for a high level claim will also be based on the concept of a health claim. This should address the concern expressed by some submitters that process type claims such as those in relation to 'organic food', unless they directly or indirectly indicated a health effect, would not fall within the scope of the Standard for Nutrition, Health and Related Claims.

In response to the request to include the phrase *within the context of the total diet* in the proposed definition for a high level claim, FSANZ intends to make this a condition of making a health claim, and as such it need not be included in the definition.

2.8 Therapeutic Claim

2.8.1 Proposed definition at Initial Assessment

Term	Proposed working definition at Initial Assessment
therapeutic claim	is a claim [outside the context of the total diet], which refers to the prevention, treatment, alleviation or cure of a disease, ailment, defect or injury.
For example, 'This food is high in iron for the treatment and prevention of anaemia.'	

2.8.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if there were any circumstances not adequately captured by the proposed wording of FSANZ's working definition of 'therapeutic claim'.

Many submitters responded to this question and raised a number of issues related to both the wording of the proposed definition and its application. In relation to the wording of the definition, views were divided among submitters regarding whether or not the reference to *outside the context of the total diet* should be included in the proposed definition. There was some suggestion that the substantiation framework should be relied upon to manage claims that made reference to the 'prevention, treatment, alleviation or cure of a disease' whether made inside or outside the context of the total diet. Other submitters expressed the view that claims that included a reference to the 'prevention, treatment, alleviation or cure of a disease', whether made inside or outside the context of the total diet, should be prohibited.

In relation to the application of the proposed definition, some submitters sought guidance on the use of terms such as 'helps reduce' and 'may prevent' in a claim and whether or not they were considered synonymous. A number of submitters indicated the need for consistency between the definitions of 'therapeutic claim' as it applied to therapeutic goods and the proposed definition, which would apply to food.

Submitters to the Initial Assessment Report were asked whether the definition of a therapeutic claim should explicitly include claims that can be interpreted as medical advice or whether this is already implied in the definition. Alternatively, they were asked if such claims should be treated separately.

Many submitters responded to this question in relation to whether the proposed definition should explicitly refer to 'medical advice'. While a large number of submitters indicated that the proposed definition for therapeutic claim did not need to explicitly refer to claims that could be interpreted as medical advice, there were also a number of submitters who expressed concern about the clarity of the proposed definition. Those submitters, who supported the current definition, did so on the basis that the proposed wording implied advice of a medical nature.

Other submitters indicated that the new standard should not be ambiguous on this issue and that advice of a medical nature should either be explicitly referred to in the definition for a therapeutic claim or defined separately in the Standard and prohibited. It was suggested that all nutrition, health and related claims could be interpreted as medical advice.

Submitters to the Initial Assessment report were asked if whether the terminology of 'disease, ailment, defect or injury' in the definition of a therapeutic claim, in contrast to the high level claim definition which centres on disease, conditions or biomarkers, might cause specific problems.

Many submitters responded to this question in relation to use of the terminology of 'disease, ailment, defect and injury' in the definition for a therapeutic claim. A number of submitters considered that the proposed terminology sufficiently differentiated a therapeutic claim from a high level claim and that at this stage neither definition appeared problematic. However, other submitters suggested that references within the two definitions should be consistent in order to avoid any potential confusion. On this point a number of submitters requested there be close liaison between FSANZ and the regulators of therapeutic goods to ensure parity and consistency in any definitions, which would apply to foods and therapeutics. A small number of submitters requested greater clarity be provided in the definition to ensure that the two claim types could be differentiated, however, submitters did not suggest how this might be achieved.

2.8.3 Preferred approach at Draft Assessment

FSANZ proposes not to define a 'therapeutic claim' and instead intends to prohibit claims that might be considered therapeutic in nature, based on the definition of 'therapeutic use' under the *Therapeutic Goods Act 1989*.

2.8.4 Assessment and Rationale

FSANZ proposed a definition for 'therapeutic claim' at Initial Assessment firstly to illustrate the continuum of nutrition, health and related claims, and secondly to seek advice on whether therapeutic claims could be differentiated from high level claims on the basis of whether or not they were made in the context of the total diet.

On the basis of comments received from submitters, FSANZ considers that the proposed definition for a therapeutic claim is problematic and that rather than defining the term 'therapeutic claim' it may be preferable to prohibit claims from referring to *prevention, treatment, alleviation or cure*. It was noted that the *Therapeutic Goods Act 1989* provides a definition of 'therapeutic use', not 'therapeutic claim'. In this Act, paragraph (b) of the definition of 'therapeutic use' refers to influencing, inhibiting or modifying a physiological process in persons. This is not appropriate for food, as in the context of food it may be seen as capturing many health claims. Similarly, other paragraphs within this definition are not appropriate in the context of food.

The benefit of this approach is that it:

- overcomes the need to define a therapeutic claim in the standard;
- avoids capturing too many claims that would otherwise be permitted as health claims;

- avoids the need to differentiate between a therapeutic claim and a high level claim on the basis of basis of whether or not the claim is made in the context of the total diet; and
- avoids the problem of inconsistent language, specifically the use of 'disease, ailment, defect or injury', which is used for therapeutic goods and 'serious disease or biomarker' which is referred to in the Policy Guideline for Nutrition, Health and Related Claims.

The approach outlined above will have no impact on the use of required labelling statements, including those prescribed in Standard 2.9.4 –Formulated Supplementary Sports Foods. Mandatory statements are not claims for the purposes of the Code.

In relation to the issue of medical advice, FSANZ considers that claims, which directly or indirectly refer to 'prevention, treatment, alleviation or cure', are those most likely to be interpreted as medical advice. Consequently, prohibiting a claim from including such a reference should ensure that claims of a medical nature are not made in relation to a food. Given this, it would appear unnecessary in the Standard to expressly prohibited claims that might be interpreted as medical advice.

FSANZ intends to provide advice in an Interpretative Guide to the Standard on what words and phrases might not indicate prevention, treatment, alleviation or cure if used in a claim.

2.9 Serious disease

2.9.1 Proposed definition at Initial Assessment

Term	Proposed working definition at Initial Assessment
serious disease, disorder, condition or defect	is one generally accepted as not being appropriate to be diagnosed or treated without consulting a suitably qualified health care professional, or one that is beyond the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified health care professional.

2.9.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if a reference to 'disorders, conditions or defects' should be included in the definition of serious disease.

Many submitters responded to this question, of which more than half supported the inclusion of 'disorders, conditions or defects' in the definition of serious disease. A third had opposed the inclusion. Many submitters commented that reference to disorders, conditions and defects should be included as this is consistent with the *Therapeutic Goods Act 1989* definition of disease. Comment was made on the definition of disease, disorders, conditions and defects. Some submitters had noted that the Oxford Dictionary definition of disease is inclusive of disorder and condition and therefore it might not be necessary to reference these terms, while others stated that inclusion of the reference to disorders, conditions and defects would help to remove ambiguity. Several submitters from government, public health and industry groups suggested that it would be helpful to provide examples of professional groups that are considered to be suitably qualified health care professionals to diagnose and treat conditions.

Submitters to the Initial Assessment Report were asked whether or not it would be useful to include a list of serious diseases/conditions in a guideline document, and if they had any suggestions about the proposed list of serious disease/conditions.

Many submitters responded to this question and most supported the inclusion of a list of serous diseases and conditions, and some specified that the list should be part of a user guide. Some submitters inferred that they did not agree with the inclusion of a list in either a user guide or in the Standard. It was also noted that it would be difficult to find a list that is fully comprehensive. Another submitter from industry stated that a list of common ailments (not considered serious disease) should be provided in the Standard.

Many submitters, mostly from public health, highlighted specific issues that would need to be considered if a list was developed. These issues included: the prevalence of the disease or burden in the population, the substantiated link between diet and disease, that the list is determined in consultation with health professionals, that the list is concise and illustrative and should be regularly updated, that diseases should be limited to those in the National Health and Medical Research Council dietary guidelines; that terminology used to describe these diseases should reference standard medical practise rather than every day expression; and that obesity should be considered as serious disease.

Submitters to the Initial Assessment Report were asked if claims in relation to cancer should be permitted in food regulation.

Many submitters responded to this question and more than two-thirds had supported permissions for health claims relating to cancer. A few had implied they supported health claims pertaining to cancer. Some submitters, representing public health, industry, government and consumer groups, did not support health claims referring to cancer. Several conditions (e.g. level of evidence, claim wording, claims around specific rather than generic cancer) were considered necessary before a cancer claim could be made.

For those submitters that opposed such claims, the reasons were: that consistency across standards should be encouraged (i.e. the Therapeutic Goods Advertising Code does not currently permit references to cancer on labels of non-prescription medicines, such as fibre tablets); that there is insufficient evidence to make health claims relating to cancer; that there is insufficient evidence to convincingly support an association between cancer and specific nutrients or food components; and that cancer is a serious disease and requires specialist medical treatment. Many submitters commented on the level of evidence for a relationship between particular/specific foods and cancer(s) and the difficulties in undertaking research proving a protective effect.

2.9.3 Proposed definition at Draft Assessment

Term	**Proposed definition at Draft Assessment**
serious disease	means a disease, ailment, defect or condition that is not appropriate to diagnose, treat or manage without consultation with or supervision by a health care professional, and includes obesity, but does not include overweight.

2.9.4 Assessment and Rationale

At Initial Assessment, a definition consistent with requirements of the Therapeutic Goods Advertising Code was proposed and comment was sought on whether or not a reference to 'disorders, conditions or defects' should be included in the definition of serious disease, and if there is a need to include a list of diseases, defects, ailments of conditions considered to be serious. Further comment was sought on whether or not claims referring to cancer should be permitted on foods.

In this Draft Assessment a definition of serious disease has been developed with reference to the definition used in the Therapeutic Goods Advertising Code, recognising the need for a degree of consistency at the foods-medicine interface, but also taking into account the specific needs of food regulation (for example by including reference to 'condition' but omitting reference to 'injury'). 'Ailment' has been included, as it appears sufficiently broad to cover at least some injuries. Accordingly, the definition of serious disease refers to 'disease, ailment, defect or condition'. For simplicity, the definition used in therapeutic goods regulation has been condensed by the inclusion of the concept of management with diagnosis and treatment. In addition, reference to a health care professional being 'suitably qualified' has been omitted as use of the term 'professional' implies a person with suitable, broadly recognised, qualifications.

A prescribed list of serious diseases is considered impractical due to the need for frequent amendment of such a list. It is proposed instead that a short list of conditions considered to be non-serious will be included in guideline documents developed before finalisation of the Standard.

Cancer claims on foods will not be prohibited. Given that cancers are serious diseases, any claim referring to cancers will be a high level claim and require FSANZ pre-approval. There is potential public health benefit from permission for substantiated claims about diet and cancer, given that diet is believed to be a significant environmental factor associated with some cancers. At present, FSANZ has not pre-approved any high level claims relating to cancer.

The proposed 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.

2.10 Non-serious disease

2.10.1 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if there is a need to define 'non-serious disease' in the Standard for Nutrition, Health and Related Claims.

Many submitters responded to this question, with most from across most stakeholder groups having agreed or implied that there is a need to define 'non-serious disease'. Many of these considered that the inclusion of the definition would help to avoid misinterpretation and confusion. There was some support for consistency with the definition of serious disease, whilst other submitters from industry and public health considered that a more defined and explicit definition would make it easier to enforce.

Many submitters were also of the opinion that if the definitions of serious disease and biomarker claims are clearly defined, the remaining claims are general level and would not need to be defined. It was noted that the definition of non-serious disease might be more appropriate than the definition of serious disease.

Some submitters did not support the inclusion of the definition. Opinion was spilt as to whether the list should go into a standard or a guideline. Regardless of the opinion on the inclusion of a definition for non-serious diseases, many submitters made comment on examples of non-serious diseases either in the Guideline document or in the Standard.

Submitters to the Initial Assessment Report were asked to provide examples of what might constitute a non-serious disease or condition.

Submitters provided a list of over 60 non-serious diseases ranging from constipation, irritable bowel syndrome, overweight, migraines and heartburn to bruises, coughs, headaches and acne. There was much discussion and comment surrounding the wide spectrum of severity of disease and the difference of disease severity according to individuals. It was noted that health professionals treat some non-serious diseases or conditions. In addition, there was concern that non-serious diseases may also become serious or be indicative of serious disease for some individuals.

2.10.2 Preferred approach at Draft Assessment

It was decided that the term 'non-serious' disease should not be defined further, and claims other than 'serious disease' will default to a 'non-serious' disease.

2.10.3 Assessment and Rationale

At Initial Assessment, comment was sought on the need to define 'non-serious disease'. Given that a definition for 'serious disease' has been proposed, a separate definition of 'non-serious' disease was considered to be superfluous. It is proposed that a short list of conditions considered to be non-serious will be included in guideline documents developed before finalisation of the Standard.

2.11 Biomarker

2.11.1 Proposed definition at Initial Assessment

Term	Proposed working definition at Initial Assessment
biomarker	is a measurable biological parameter that predicts the risk of human disease, disorders, conditions or defects. The biomarker itself is not a measure of disease, disorder or condition

2.11.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if they preferred the term 'biomarker' to that of 'surrogate outcome'.

Most of the submitters that responded to this question preferred the term 'biomarker' to 'surrogate outcome'.

Reasons given for preferring the first term were that: the term 'biomarker' has already been extensively used; the observation that while consumers do not generally understand the term, it is common terminology in scientific health research compared with 'surrogate outcomes'; and that the term 'surrogate' also means substitute and was considered to be unsuitable.

Only a few submitters did not prefer 'biomarker', whilst it was also noted that both terms should be used. Several comments were made about the wording of the definition of biomarker, particularly concerning the use of the word 'predicts' and its appropriateness.

Submitters to the Initial Assessment Report were asked what they saw to be the practical implications from the proposed definition.

Of those submitters that responded to this question, some had commented on the appropriateness of the word 'predicts' in the definition of biomarker and thought that the term 'predictive of the risk' better expresses the relationship between the biomarker and risk of human disease, disorder, condition or defect. There was also discussion pertaining to the ability of a biomarker to measure disease, as is the case with blood glucose and diabetes. Most submitters considered that FSANZ should provide a list of biomarkers either in the Standard or Guideline document.

Submitters to the Initial Assessment Report were asked what they saw to be the practical implications from the proposed criteria for use of biomarkers in substantiation.

Several submitters that responded to this question acknowledged the importance of having a list of approved biomarkers in the criteria for substantiating a health claim. Many submitters commented that it is important to only use biomarkers where a causal link with disease has been established or at least an assessment of the weight of evidence by an independent panel of experts. Several submitters commented on possible consumer perceptions of biomarkers: some believed that consumers would understand the meaning of biomarker claims and their relevance to public health; while others were of the opinion that this would not be the case, and referred to research that consumers do not discriminate between serious disease – risk reduction claims and biomarker claims. It was also stated that the applicability of health claims to consumers will vary considerably given the relationship between health risk and benefit to consumers will differ based on physiological and environmental factors.

From an industry viewpoint, it was believed that the costs associated with validating a biomarker would be financially out of reach of small companies. However, it was also noted that companies would be able to conduct biomarker research, retain the intellectual property and have subsequent health claims assessed by government.

2.11.2 Proposed definition at Draft Assessment

Term	**Proposed definition at Draft Assessment**
biomarker	means a measurable biological parameter which, when present in an abnormal level in the human body, is predictive of the risk of a serious disease.

2.11.3 Assessment and Rationale

The classification of high level claims considers biomarkers in terms of their use as surrogate outcome measures. At Initial Assessment, most submitters preferred the term biomarker to surrogate outcome. 'Biomarker' is taken to be the preferred term.

To address issues raised during consultation at Initial Assessment, the definition of biomarker has been changed in the following ways:

- the term 'predictive of risk' has replaced the term 'predicts the risk' on the basis that the former implies a less absolute relationship between the biomarker and disease outcome and that this is a truer reflection of the nature of the relationship;

- the following has been deleted from the proposed definition – 'The biomarker itself is not a measure of the disease, disorder or condition'. There are occasions where biomarkers are measures of disease (e.g. body mass index is a measure of obesity);

- because the definition of serious disease encompasses 'a disease, ailment, defect or condition', and biomarker is defined for the purposes of the standard in terms of serious disease, the separate terms 'disease, disorders, conditions or defects' have been dropped from the definition of biomarker.

- biomarkers are measured in the human body across a range of values. When a measured parameter is outside the normal range, intervention by a health care professional is needed to diagnose, treat or manage the disease, ailment, defect or condition related to the biomarker. Under such circumstances, the biomarker is acting as a surrogate outcome measure of serious disease. Hence, the following qualification has been added to the definition of biomarker – '…a measurable biological parameter which, <u>when present at an abnormal level in the human body</u>…'

Biomarker is defined in terms of serious disease because other biomarkers that relate to non-serious disease are simply regulated as a form of general level claim and do not require differentiation. If all biomarkers, including those for non-serious disease, were treated as high level claims this would lead to an anomalous situation whereby biomarkers for non-serious disease would be subject to FSANZ assessment and pre-approval, but claims in relation to non-serious disease would not be – they would simply be regulated as general level claims. Therefore, for regulatory purposes the standard uses 'biomarker' as shorthand for biomarkers in relation to serious disease. This should not be understood as affecting other biomarkers for non-serious disease.

An indicative list of biomarkers that are likely to be acceptable for use in substantiating diet-health relationships proposed, as the basis for high level claims is included in the Substantiation Framework at Attachment 8. The Substantiation Framework also details the criteria that a biomarker should meet. In the process of reviewing the scientific evidence for diet-disease relationships for pre-approved high level health claims, FSANZ instructed reviewers to investigate where the evidence substantiates a relationship with any biomarkers of the disease state that was the subject of the review. This information is contained in the high level claim reviews available on the FSANZ website.

Chapter 3: Claim Descriptors

3.1 Function claim

3.1.1 Proposed descriptors at Initial Assessment

Term	Related claim descriptor
function claim	a general level claim, which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in [normal] growth, development, maintenance and other like functions of the body.
For example, 'Linoleic acid, one of the family of Omega-6 fatty acids is essential for healthy skin' or 'Calcium aids in the development of strong bones and teeth'.	
enhanced function claim	a general level claim, which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] beyond [normal] growth, development, maintenance and other like functions of the body.
For example, 'A high fibre diet may help to improve bowel function'.	

3.1.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked whether or not claims other than content claims (that is, health claims) should be made in relation to biologically active substances.

Most of the submitters that responded to this question agreed that claims other than content claims (i.e. health claims) should be made in relation to biologically active substances. The reasons ranged from statements that they should simply be part of it to statements that biologically active substances may potentially and positively influence health and as such, should be regulated within the Health Claims Framework. It was noted that biologically active substances were defined in Standard 1.2.8 as a substance 'other than a nutrient' with which health effects are associated. Therefore, it was argued that it is appropriate to be able to claim those substantiated health effects for these substances. Most submitters added provisos with regard to substantiation or gave clarifying statements to their responses.

Submitters to the Initial Assessment Report were asked if they agreed with the descriptors for 'function claim' and 'enhanced function claim'

Almost a third of submitters that responded to this question agreed with the descriptors for a function claim and an enhanced function claim. In addition, many submitters agreed subject to provisos, which mostly related to the addition, deletion or replacement of words in the brackets of the descriptors. Other submitters agreed with the proposed definition, although they also questioned the practical value in differentiating between the two descriptors. Some submitters did not agree with the descriptors for a function and an enhanced function claim. Most submitters who agreed with the definitions focused mostly on the descriptors themselves, while those who disagreed, focused on wider issues and opposed the need for function and enhanced function sub-categories.

3.1.3 Preferred approach at Draft Assessment

FSANZ's preferred approach is yet to be determined in context of use in supporting documents such as a user guide.

3.2 Risk reduction claims in relation to a non-serious disease

3.2.1 Proposed descriptor at Initial Assessment

Term	Related claim descriptor
risk reduction claim in relation to a non-serious disease or condition	a general level claim, which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in [significantly] reducing the risk of developing a non-serious disease or condition.
For example, 'This food is high in fibre which may reduce constipation'.	

3.2.2 Issues raised by submitters

3.2.1.1 Submitters to the Initial Assessment Report were asked if the descriptor for a risk reduction claim should include the word 'significantly'.

Almost two-thirds of submitters that responded to this question opposed the inclusion of the word 'significantly' in the descriptor for a risk reduction claim. Reasons for opposing the inclusion of the word 'significantly' related to its lack of clarity and difficulty to measure. It was also considered superfluous by some submitters, as the substantiation process and fair trading laws already covered any requirement for statistical significance. Some submitters from across most stakeholder groups agreed that the descriptor for a risk reduction claim should include the word 'significantly'. Most reasons for the inclusion of 'significantly' related to strengthening the claim and that claim pre-requisites/conditions would ensure that the risk reduction claims were true and not misleading. Many of the submitters who responded made additional comments and recommendations.

Submitters to the Initial Assessment Report were asked if there are likely to be claims which reference a non-serious disease or condition which would not be expressed as 'risk reduction claims'. If this was considered likely, they were asked if there is a need to identify another sub-category of claim in the Claims Classification Framework.

Almost half of the submitters that responded to this question agreed that it was likely that there would be claims that reference a non-serious disease or condition which would not be expressed as 'risk reduction claims'. Some had identified other sub-categories of claims in the Claims Classification Framework. These included: risk increase claims for use in nutrition education or health maintenance claims; over-consumption of a food which may pose a problem for consumers with a specific health problem; many enhanced function claims which are likely to refer to a non-serious disease or condition; weight management claims; a general level claim that describes a wellness, well-being or performance improvement outcome; a non-serious disease which is vague; and reference to many examples from claims and indications in Listed Medicines.

Other submitters did not express a clear position or were uncertain as to the need for more sub-categories. Some submitters from industry and public health did not agree that it was likely that there would be claims which reference a non-serious disease or condition, which would not be expressed as 'risk reduction claims'.

3.2.3 Proposed descriptor at Draft Assessment

FSANZ's preferred approach is yet to be determined in context of use in supporting documents such as a user guide.

3.3 Biomarker claims

3.3.1 Proposed descriptors at Initial Assessment

Term	**Related claim descriptor**
biomarker maintenance claim	is a high level claim, which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in maintaining a normal level of a [recognised] biomarker.
For example, 'This food is low in saturated fat which, as part of a diet low in saturated fat, may help to maintain a healthy blood cholesterol level'.	
biomarker enhancement claim	is a high level claim, which describes [explicitly or implicitly] the biological role of a food, energy or a nutrient [or a biologically active substance] in reducing or increasing the level of a [recognised] biomarker.
For example, 'This food is high in calcium which helps improve bone density when eaten as part of a varied diet high in calcium'.	

3.3.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if the descriptor for a biomarker maintenance claim and biomarker enhancement claims should include the phrase 'recognised biomarker'.

More than half of the submitters that responded to this question disagreed that the descriptors for a biomarker maintenance claim and a biomarker enhancement claim should include the phrase 'recognised biomarker'. Their reasons for excluding 'recognised biomarker' mostly referred to the fact that it was unnecessary to include this term in the definition because biomarker was already defined or the processes of approval and substantiation would determine the suitability of a biomarker.

A few disagreed, unless specific terms were satisfied, while another several submitters agreed, subject to similar provisos. Of these, it was suggested that there should be an adequate explanation of the biomarker provided in the claim if it is not well recognised. There was also some disagreement with the term unless the effect of the biomarker was defined, and disagreement over a list or schedule of recognised biomarkers.

A few submitters considered it irrelevant as to whether these claims included 'recognised' or not.

Several submitters agreed to the inclusion of 'recognised biomarker' in the descriptors, for reasons that related to scientific evidence, which would limit the chances of any misleading claims from being made.

3.3.3 Proposed descriptors at Draft Assessment

FSANZ's preferred approach is yet to be determined in context of use in supporting documents such as a user guide.

3.4 Risk reduction claims in relation to a serious disease

3.4.1 Proposed descriptor at Initial Assessment

Term	Related claim descriptor
risk reduction claim in relation to a serious disease or condition	is a high level claim, which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in [significantly] reducing the risk of developing a serious disease or condition.
For example, 'A healthy diet that may lower the risk of certain cancers is one that is low in fats and includes fibre from a number of sources including a variety of fruits and vegetables, and wholegrain bran and cereals. This food is high in dietary fibre.'	

3.4.2 Issues raised by submitters

Submitters to the Initial Assessment Report were asked if the descriptor for a risk reduction claim in relation to a serious disease or condition should include the word 'significantly'.

Slightly more than half of the submitters that responded to this question opposed the inclusion of the word 'significantly' in the descriptor for a risk reduction claim in relation to a serious disease or condition. These submitters opposed the inclusion of the word for reasons relating to its lack of clarity and difficulty to measure. Several submitters considered it to be unnecessary given that the substantiation process will enable the significance of a risk reduction claim to be determined.

Some submitters, that were mostly from government and public health, agreed that the descriptor for a risk reduction claim (serious) should include the word 'significantly'. Reasons for supporting its inclusion related to strengthening the claim and that claim prerequisites/conditions would ensure that the risk reduction claims were true and not misleading. Other submitters agreed, subject to provisos which included: the interpretation, whereby it means statistically significant' because biological significance is fundamental to the science underlying the impact of a food/nutrient/active compound on a disease; that it is adequately defined; and that the significant reduction of risk is a fact as decided upon by the evaluation process. The inclusion of 'significantly' was also regarded as irrelevant. Many of the submitters expressed their reasons, added comment or made recommendations.

Submitters to the Initial Assessment Report were asked if there are likely to be claims that reference a serious disease or condition, which will not be expressed as 'risk reduction claims'.

Almost a third of submitters that responded to this question did not agree that it was likely that there would be claims which reference a serious disease or condition, which would not be expressed as 'risk reduction claims'. Reasons given were: that other claims were most likely to be health claims or therapeutic claims; and if the claims regulatory system was well defined, there would be no need to regulate for exceptions.

Several submitters were unable to either determine or provide examples of such likely claims. Some suggested that there was a need to thoroughly test the claims classification framework in the development of Standard 1.2.7 before implementation. One view was that it was not possible to comment until a list of serious diseases was developed. Some submitters agreed or implied agreement that it was likely that there would be claims that reference a serious disease or condition, which would not be expressed as 'risk reduction claims'. Most of these submitters identified examples of other claims, which included: risk increase claims; comparative claims; claims that do not explicitly include the term 'risk'; claims that relate to weight loss; slimming, image and obesity claims; maintenance claims; improvement claims; management claims; and endorsements from non-government organisations.

3.4.3 Proposed descriptor at Draft Assessment

FSANZ's preferred approach is yet to be determined in context of use in supporting documents such as a user guide.

Chapter 4: Claim descriptors for the property of a food

Claim descriptors for the property of a food are listed in the table below. They must comply with nutrition content claim conditions: descriptors and nutrition content claim conditions will both be listed in the standard. FSANZ proposes to develop an illustrative list of synonyms for some descriptors for inclusion in the guideline documents.

Descriptor	**Applicable to the following properties of a food**
Free	Cholesterol, Gluten, Lactose
% Free	Fatty acid, Sugar or Sugars
Low	Cholesterol, Energy, Fatty acid, Gluten, Lactose, Salt/Sodium, Saturated and trans fatty acid, Saturated fatty acid, Sugar or Sugars
Reduced	Cholesterol, Energy, Fatty acid, Salt/Sodium, Saturated and trans fatty acid, Saturated fatty acid, Sugar or Sugars
Increased	Dietary Fibre
Diet	Energy
No added	Salt/Sodium, Sugar or Sugars
Unsalted	Salt/Sodium
Unsweetened	Sugar or Sugars

Descriptor	Applicable to the following properties of a food
Source	Dietary Fibre, Protein, Vitamins or Minerals[1]
Good source	Dietary Fibre, Omega-3 fatty acid, Protein, Vitamins or Minerals[1], Wholegrain

[1] if the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1

Chapter 5: Other Terminology

cause related marketing statement	Means a statement that the sale of the food will contribute to fundraising for an organisation, the name of which refers to a serious disease
claim criteria	FSANZ considers that 'claim criteria' are specific requirements regarding the food or its composition that must be met before a claim can be made. This would also include criteria around the eligibility of a food. Claim criteria apply once a claim is considered to be an eligible claim.
claim prerequisites	Claim prerequisites are preconditions that must be met before a claim can be considered an eligible nutrition, health and related claim. Claim prerequisites apply to all claims irrespective of whether they are general level claims or high level claims. An example of a claim prerequisite is that all claims must be scientifically substantiated.
claims classification framework	A framework outlining the categories of claims (general level claims and high level claims) and examples of each. The framework is based on the FSANZ interpretation of the Claims Classification Framework in the Policy Guideline.
condition	FSANZ considers that a 'condition' is an additional mandatory statement, required to clarify the context of the claim, in order to protect public health and safety and/or prevent misleading and deceptive conduct.
CoPoNC	Code of Practice on Nutrient Claims in Food Labels and Advertisements.
dietary information	General dietary information, and includes information from national nutrition guidelines, but does not include information that refers to a specific brand of food and a health effect.
FSANZ conceptual framework	Consists of three inter-related elements: the Claims Classification Framework, the FSANZ Claim Descriptors and the FSANZ Regulatory Model The Conceptual Framework proposes a system for categorising nutrition, health and related claims and how they might be regulated.

endorsement	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, and includes a certification trade mark, but does not include – (a) a design that distinguishes food in relation to ethical, religious or environmental features including vegetarian, Halal, kosher or organic designs; or (b) a design that includes a reference to a serious disease other than as part of the name of the endorsing organisation.
endorsing organisation	Means an independent, non-profit or not-for-profit organisation formed for nutrition, health, community or government purposes, the name of which may include a serious disease, but does not include an organisation established by suppliers or their representatives.
FSANZ regulatory model	Is a model developed by FSANZ that identifies how claims can be regulated in relation to claim prerequisites, claim criteria and conditions according to their position in the Claims Classification Framework.
guideline	In relation to the FSANZ Regulatory Model and the preliminary Impact Analysis, a Guideline is a form of quasi-regulation.[2] A Guideline is an alternative to a food standard. It is not legally binding and is not legally enforceable.
national nutrition guidelines	Means – (a) National Health and Medical Research Council (2003) Dietary Guidelines for Australian Adults; (b) National Health and Medical Research Council (2003) Dietary Guidelines for Children and Adolescents in Australia; (c) New Zealand Ministry of Health 2003. Food and Nutrition Guidelines for Healthy Adults; (d) NZ Ministry of Health 1997. Food and Nutrition Guidelines for Health Children aged 2-12 years; (e) NZ Ministry of Health 1997. Guidelines for Healthy Pregnant Women; (f) NZ Ministry of Health 1997. Guidelines for Healthy Breastfeeding Women; (g) NZ Ministry of Health 1996. Guidelines for Health Older People; (h) NZ Ministry of Health 1998. Food and Nutrition Guidelines for Health Adolescents.
nutrition, health and related claims	In the context of this Proposal, this is a collective term for any claim, which refers to nutrients, nutrition or diet and health.
reference food	Means a food that is – (a) equivalent to the food in relation to which the claims is being made; and (b) a regular product in the same category of food as that food in relation to which a claim is being made.

[2] 'A wide range of rules or arrangements by which governments influence businesses to comply, but which do not form part of explicit government regulation', Office of Regulation Review 1998, *A Guide to Regulation*.

substantiate	In accordance with [insert document name and date]
substantiation framework	Establishes the principles and procedures for the scientific substantiation of nutrition, health and related claims.
user guide	In relation to the FSANZ Regulatory Model and the preliminary Impact Analysis, a user guide is an interpretive document that provides guidance on matters set out in a food standard. May also be referred to as an 'interpretive user guide'.