

# Getting Your Claims Right

A guide to complying with the Nutrition, Health and Related Claims Standard of the Australia New Zealand Food Standards Code

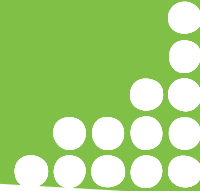


## **Disclaimer**

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## 1. Introduction

This document, developed by the Implementation Subcommittee for Food Regulation (ISFR), provides advice on how to comply with the Nutrition, Health and Related Claims Standard (Standard 1.2.7) in the Australia New Zealand Food Standards Code (the Food Standards Code).

ISFR is made up of representatives from government agencies and departments in Australia and New Zealand that are responsible for monitoring the implementation of food laws and enforcing those laws. These agencies and departments work together through ISFR to ensure food laws are implemented and enforced consistently.

Food sold in Australia and New Zealand is required to comply with Parts 1 and 2 of the Food Standards Code.

All food businesses in Australia and New Zealand must comply with Standard 1.2.7 when making nutrition content claims and health claims on food labels, in advertisements and in endorsements on food from 18 January 2016.

Standard 1.2.7 applies to food labels and advertising materials for foods that are sold or prepared for sale in Australia or New Zealand and imported into Australia and New Zealand.

This document is not a legal document. The legal document is Standard 1.2.7 of the Food Standards Code. Food businesses using this document should also refer to Standard 1.2.7 and the associated explanatory information. Where guidance is offered in this document about a clause or schedule in Standard 1.2.7 or a paragraph, the number of the clause and paragraph or schedule is provided in **bold text**.

The diagram on page 4 can help you consider whether Standard 1.2.7 applies to any claims made. This is followed by explanatory text about general conditions and requirements for making claims.

A glossary of key terms (based on definitions in Standard 1.2.7) is on page 45.

You can find Standard 1.2.7 online at:

[www.comlaw.gov.au/Details/F2013L00054](http://www.comlaw.gov.au/Details/F2013L00054)

The explanatory statement, which provides detail about the purpose and intent of the Standard and its associated clauses, can be found online at:

[www.comlaw.gov.au/Details/F2013L00054/Explanatory%20Statement/Text](http://www.comlaw.gov.au/Details/F2013L00054/Explanatory%20Statement/Text)

For information about establishing food-health relationships by systematic review, refer to the Food Standards Australia New Zealand (FSANZ) document '*Guidance on establishing food-health relationships for general level health claims*' (as described in **Schedule 6** of Standard 1.2.7). This can be found online at:

[www.foodstandards.gov.au/publications/Pages/Guidance-on-establishing-food-health-relationships-for-general-level-health-claims.aspx](http://www.foodstandards.gov.au/publications/Pages/Guidance-on-establishing-food-health-relationships-for-general-level-health-claims.aspx)

Guidance on calculating scores for the nutrient profiling scoring criterion is also available on the FSANZ website at:

[www.foodstandards.gov.au/industry/labelling/pages/notifyingaselfsubsta5781.aspx](http://www.foodstandards.gov.au/industry/labelling/pages/notifyingaselfsubsta5781.aspx)

This guidance document should be read in conjunction with associated checklists:

- Checklist for Nutrition Content Claims
- Checklist for General Level Health Claims (pre-approved)
- Checklist for General Level Health Claims (systematic review)
- Checklist for High Level Health Claims.

State and territory government departments and local government in Australia, the Department of Agriculture (for imported food) and the New Zealand Ministry for Primary Industries are responsible for monitoring the implementation of food laws and enforcing those laws.

Standards are adopted by law into state and territory and New Zealand legislation. These food laws give regulators a range of tools they can use in responding to non-compliance. Generally, when a business supplies a product that does not meet the legal requirements, the regulator will look at what steps the business has taken to comply with the Standard when deciding on appropriate enforcement action.

Food businesses should contact the relevant food regulator in their state or territory or in New Zealand if further guidance is required about complying with Standard 1.2.7 or any other requirements of the Food Standards Code.

Full details of state and territory and New Zealand agencies responsible for administering and enforcing the Food Standards Code can be found on the FSANZ website at:

[www.foodstandards.gov.au/about/foodenforcementcontacts/Pages/default.aspx](http://www.foodstandards.gov.au/about/foodenforcementcontacts/Pages/default.aspx)

Food businesses must not make false or misleading claims. It is an offence for food businesses to engage in conduct that is misleading or deceptive in relation to the advertising, packaging or labelling of food for sale or intended for sale.

Fair trading laws and food laws in Australia and New Zealand require that goods sold do not misinform through false, misleading or deceptive representations. In Australia, the Australian Competition and Consumer Commission (ACCC) and state and territory consumer authorities enforce Australian Consumer Law. In New Zealand, the Commerce Commission is responsible for enforcing the *Fair Trading Act 1986*.

More information is available from:

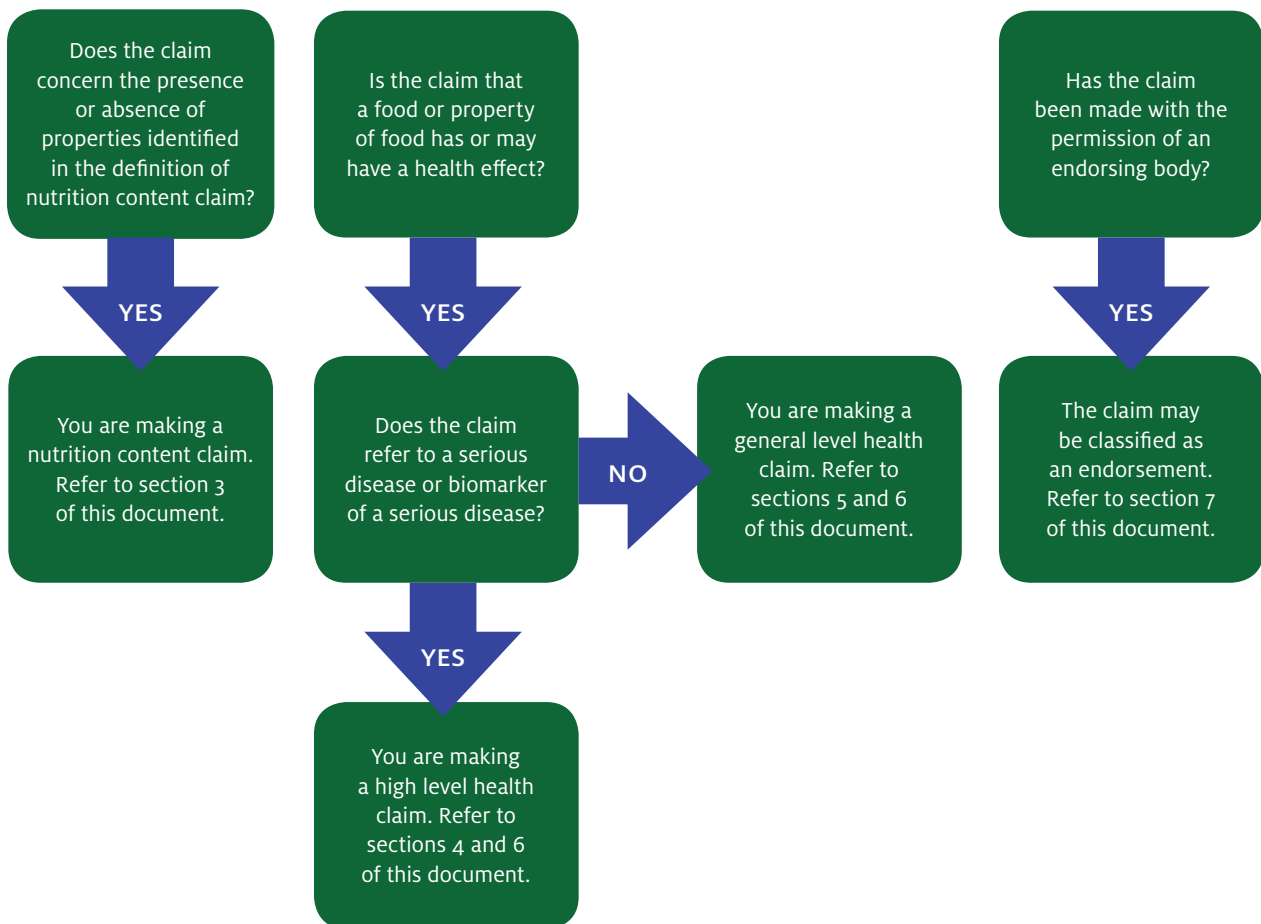
[www.accc.gov.au](http://www.accc.gov.au) – Australian Competition and Consumer Commission (ACCC)

[www.comcom.govt.nz](http://www.comcom.govt.nz) – New Zealand Commerce Commission

[www.consumeraffairs.govt.nz](http://www.consumeraffairs.govt.nz) – New Zealand Ministry of Business, Innovation and Employment (MBIE) (formerly Ministry of Consumer Affairs).

## Are you making a nutrition content, health or related claim?

The purpose of this diagram is to direct the user to the appropriate section(s) of this document. Please note that the general conditions and restrictions for making claims as outlined in section 2 of this guidance document apply. Please also use this diagram in conjunction with the associated checklists (checklist for nutrition content claims, checklist for general level health claims (pre-approved), checklist for general level health claims (systematic review) and checklist for high level health claims).





## 2. General conditions and restrictions for making claims

Claims are defined in Standard 1.1.1 of the Food Standards Code as an express or implied statement, representation, design or information in relation to a food or property of food which is not mandatory in the Code (Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions).

Standard 1.2.7 regulates the following types of claims:

- nutrition content claims (claims about the presence or absence of certain nutritional properties of food)
- high level health claims (claims that a food or a property of food, has or may have a health effect and refers to a serious disease or biomarker of a serious disease)
- general level health claims (claims that a food or a property of food has or may have a health effect and that are not a high level health claim).

These claims are regulated whether they are made on a label, in advertisements or by way of a third party endorsement e.g. a logo licensing scheme.

Claims that are not regulated by Standard 1.2.7 include those made about non-nutrient characteristics of the food e.g. 'pure', 'fresh', or 'natural' or process claims e.g. 'pasteurised' and 'halal'.

You can find more information about the different types of claims at:

[www.foodstandards.gov.au/healthclaims](http://www.foodstandards.gov.au/healthclaims)

Restrictions and conditions on making claims under Standard 1.2.7 are outlined below.

### 2.1 General restrictions

Nutrition content and health claims cannot be made for **(Clause 3)**:

- kava
- a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about energy or carbohydrate content
- an infant formula product.

Nutrition content and health claims must not:

- refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition **(Clause 7)**

- compare a food with a good that is represented in any way to be for therapeutic use; or likely to be taken for therapeutic use, whether because of the way in which the food or substance is presented or for any other reason **(Clause 7)**
- compare the vitamin or mineral content of a food with another food **(Clause 8)** unless permitted by the Food Standards Code.

A health claim (and certain nutrition content claims as indicated in **Schedule 1** of Standard 1.2.7) must not be made about a food that does not comply with the nutrient profiling scoring criterion (NPSC) **(subclause 17(2))**. However, special purpose foods (standardised in Part 2.9 of the Food Standards Code) do not need to meet the NPSC for health claims. A guideline on calculating NPSC scores can be found at: [www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm](http://www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm)

Standard 1.2.7 does not apply to **(Clauses 4 and 5)**:

- food, other than food in a package, provided to a patient in a hospital or other similar institution
- meals provided to a vulnerable person by a delivered meal organisation
- foods intended for further processing, packaging or labelling before retail sale
- a claim that is expressly permitted by another standard
- a claim about the risks or dangers of alcohol intake or about moderating alcohol intake
- a declaration that is required by the Act as defined in Standard 1.1.1 – see **glossary**.

## 2.2 Form of the food **(Clause 6)**

The requirements for nutrition content claims and health claims must be applied to the appropriate form of the food, as set out in **Clause 6**. This does not prevent claims being made on foods that someone needs to prepare (e.g. heating or reconstituting) or that may be used with other foods, so long as the claim applies to one of the forms of the food as determined in accordance with the **Table to Clause 6**. To determine the form of the food you should take into account:

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

When making a nutrition content or health claim, the form of the food must be stated together with the claim, unless the claim relates to the form of the food as sold **(Clause 10 and subclauses 19(3)(b) and 19(6))**.

## 2.3 Claim wording

Standard 1.2.7 does not prescribe the words to be used when making a claim. Any statement or information required by Standard 1.2.7 may be modified if the modification does not alter or contradict the effect of the required statement or information (**Clause 9**).

## 2.4 Information to support compliance

Food businesses may wish to maintain documentation to demonstrate that claims made on their food products comply with the conditions and requirements of Standard 1.2.7.

This information may include:

- test results
- documents demonstrating that a product complies with appropriate clauses in Standard 1.2.7 and content in **Schedule 1, 2, 3, 4, 5 or 6** of Standard 1.2.7
- checklists and templates you have filled out in accordance with due diligence.

## 2.5 Nutrition Information Panel

Food for retail sale must bear a label setting out all the information prescribed in the Food Standards Code, including a nutrition information panel (NIP), as outlined in Standard 1.2.8 – Nutrition Information Requirements. Exceptions from the requirement to bear a label are in **paragraphs 2(1) (a) to (h)** of Standard 1.2.1. When a nutrition content or health claim is made about foods exempt from the requirement to bear a label, this exemption no longer applies, and a NIP must be displayed on or in connection with the display of the food or provided to the purchaser on request (**subclause 4(3)** of Standard 1.2.8).

There are also exemptions for foods that are required to bear a label, to be labelled with a NIP (**clause 3** of Standard 1.2.8). However, if a nutrition content or health claim is made about these foods, the exemptions in **clause 3** do not apply, and a NIP must be provided on the label (**subclause 4(2)** of Standard 1.2.8).

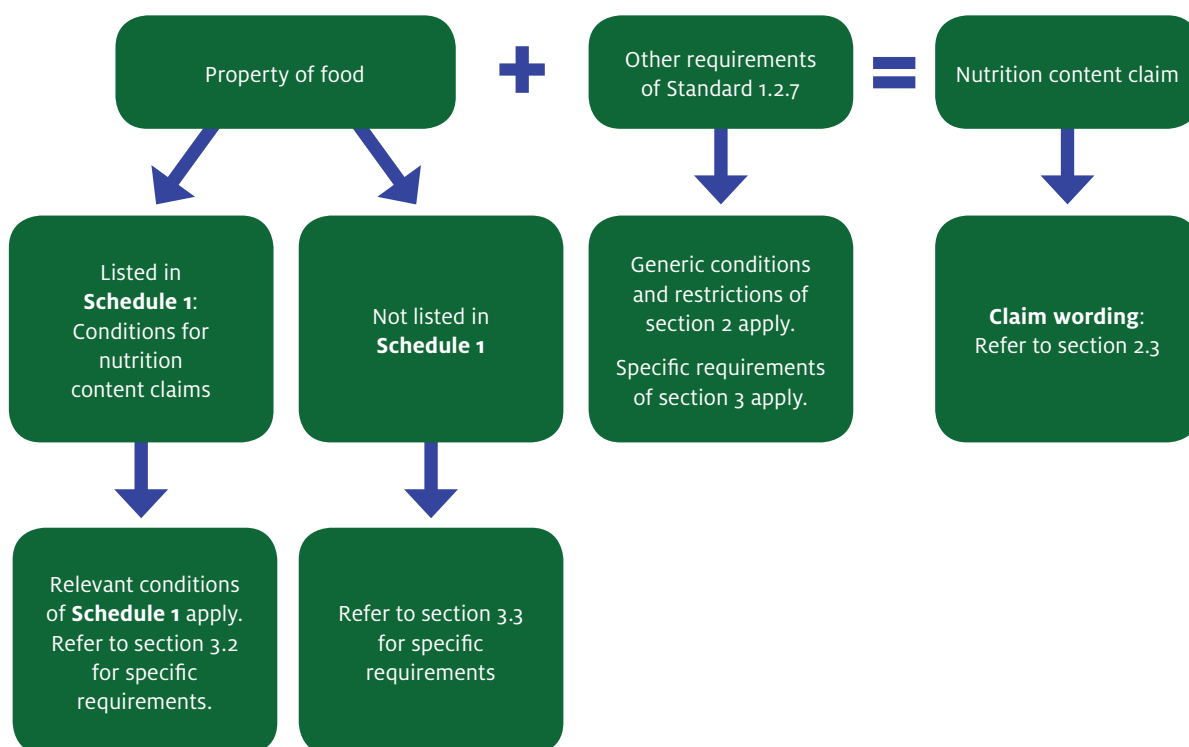
**Clause 5** of Standard 1.2.8 sets out what is required in a NIP, including the name and the average quantity of any nutrient or biologically active substance that a nutrition content or health claim refers to.

Standard 1.2.8 does exempt food in small packages (see **glossary**) from having an NIP, but additional labelling requirements must still be met when certain claims are made (**subclause 4(4) and clauses 8 and 8A** of Standard 1.2.8).

### 3. Making a nutrition content claim

#### 3.1 Building a nutrition content claim

The purpose of this diagram is to direct the user to the relevant sections of this guidance document.



**Schedule 1** may be amended by application to FSANZ:  
[www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx](http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx)

A nutrition content claim is a claim about the presence or absence of certain properties of food. These properties are listed in the definition of nutrition content claim provided in the **glossary**.

The requirements outlined in Section 2 of this document also apply when making a nutrition content claim.

Different requirements apply to claims depending on whether or not the nutrition content claim refers to a substance listed in Column 1 of **Schedule 1** of Standard 1.2.7.

### 3.2 Nutrition content claims about properties of food listed in Schedule 1 (Clause 11)

**Schedule 1** of Standard 1.2.7 provides conditions for making nutrition content claims about the properties of food listed in Column 1 of **Schedule 1**.

If a claim is made about a property of food listed in Column 1, the food and/or claim must comply with any general conditions in Column 2.

If the claim has the same effect as a qualifier (descriptor) listed in Column 3, the food and/or claim must also comply with any additional conditions in Column 4. If there is an inconsistency between the conditions in Columns 2 and 4, the specific conditions in Column 4 override those in Column 2 (**subclause 11(4)**).

A claim about a property listed in Column 1 can be made without qualifiers (descriptors) (for example, a “contains” or “source of” claim), in which case only the general conditions in Column 2 apply, together with other prohibitions in the Standard.

A claim about a property of food listed in Column 1 may also be made with a qualifier (descriptor) that is **not** mentioned in Column 3, including quantification claims specifying the amount of the property in the food (**subclause 11(8)**). In this case, the general conditions in Column 2 apply together with other prohibitions in the Standard.

Building a nutrition content claim based on **Schedule 1**:

- Protein: is listed in **Schedule 1**.
- Column 1 (Property of food): Protein.
- Column 2 (General claim conditions that must be met): The food contains at least 5g of protein per serving unless the claim is about low or reduced protein.
- Column 3 (Specific descriptor or synonym): ‘Good source’, ‘Increased’.
- Column 4 (Conditions that must be met if using specific descriptor in Column 3): ‘Good source’ – the food contains at least 10g of protein per serving. ‘Increased’ – the food contains at least 25% more protein than in the same quantity of reference food; and the reference food meets the general conditions for a nutrition content claim about protein.

### *Nutrition content claims about vitamins and minerals*

There are also conditions for making nutrition content claims about vitamins and minerals in other standards in the Food Standards Code. Standard 1.3.2 – Vitamins and Minerals prescribes the maximum claims that can be made about foods that contain added vitamins or minerals. Specific conditions for making nutrition content claims about special purpose foods are in Part 2.9 – Special Purpose Foods. If a claim is expressly permitted by another Standard, Standard 1.2.7 does not apply (**clause 5(a)**).

Claims that directly or indirectly compare the vitamin or mineral content of a food with that of another food must not be made unless such a claim is permitted by the Food Standards Code (**clause 8**).

### **3.3 Nutrition content claims about properties of food not listed in Schedule 1 (Clause 12)**

Food businesses are not limited to the properties of food listed in **Schedule 1** for making nutrition content claims. If a business makes a nutrition content claim about a property of food not listed in **Schedule 1**, the claim may:

- only state that the food does or does not contain the property of food; or
- state that a specified amount of the food contains a specified amount of the property of food; or
- a combination of the above.

For example, a nutrition content claim that is a comparative claim (such as ‘reduced’) cannot be made about a property of food unless the property is listed in **Schedule 1**.

### **3.4 Conditions for certain nutrition content claims**

#### *Lactose or trans/fatty acids (Subclause 11(5))*

If you are making nutrition content claims about lactose or trans fatty acids, only the descriptors in Column 3 relating to lactose or trans fatty acids, or synonyms of those descriptors from **Schedule 1**, may be used.

#### *Glycaemic index and glycaemic load (Subclause 11(6))*

If nutrition content claims are made about glycaemic index (GI) or glycaemic load, the food must meet the nutrient profiling scoring criterion (NPSC). For claims about GI, the numerical value of the GI of the food must be included either in the claim or in the NIP, however the GI descriptor (low, medium, high) is not required to be included as part of the GI claim. For claims about glycaemic load, no descriptors other than a number or a descriptor expressed in numeric form may be used.

### *Gluten (Subclause 11(7))*

If nutrition content claims are made about gluten, only the descriptors in Column 3 of **Schedule 1** relating to gluten may be used (or a synonym of that descriptor). Alternatively, the claim may state that a food contains gluten or is high in gluten.

### *Folic acid, choline or fluoride (Clause 13)*

No nutrition content claim about folic acid, choline or fluoride may be made unless a health claim is also made in relation to the property. When a health claim is made, no descriptors (e.g. high, low, rich) can be used when making the nutrition content claim.

### *Must not imply slimming effects (Clause 14)*

Claims about energy that meet the conditions to use the descriptor 'diet' must not use another descriptor that directly or indirectly imply a 'slimming' effect (or a synonym for 'slimming'). Claims using the descriptor 'diet' must also meet the specific conditions for this descriptor as set out in Column 4 of **Schedule 1**.


In addition, and among other conditions covered in later sections of this document, claims using the descriptor 'diet' can only be used on foods meeting the NPSC.

### *Comparative claims (Clause 15)*

A comparative claim is a nutrition content claim that directly or indirectly compares the nutrition content of one food or brand of food with another, and includes claims that use the following descriptors: 'light', 'lite', 'reduced', 'increased' (**subclause 15(1)**). In addition, a 'diet' nutrition content claim is deemed to be a comparative claim if it meets the conditions for making the diet claim by having at least 40% less energy than the same quantity of reference food (**subclause 15(2)**).

Additional wording is required to be included with comparative claims. The identity of the reference food (see **glossary**) and the difference between the amount of the property of food in the claimed food and the reference food must be included together with the comparative claim (**subclause 15(3)**).

Conditions for making comparative claims about certain properties are included in Column 4 of **Schedule 1**.



Note that descriptors listed in Column 3 of **Schedule 1**, such as ‘increased’ and ‘reduced’, cannot be used in a nutrition content claim about a property of food that is not mentioned in **Schedule 1 (clause 12)**. Claims that directly or indirectly compare the vitamin or mineral content of a food with that of another food must not be made unless such a claim is permitted by the Food Standards Code (**Clause 8**).

A template is provided to help food businesses build a nutrition content claim; and demonstrate due diligence in attempting to comply with the Food Standards Code.

This template should be used with the associated ‘Checklist for Nutrition Content Claims’.

A separate template and associated check list should be used for each claim.



## Compliance template—nutrition content claims

This template may help food businesses build a nutrition content claim; and demonstrate due diligence in attempting to comply with the Food Standards Code.

See sections 2 and 3 of this document for the conditions for making nutrition content claims.

### General information

1. What is the wording of your proposed nutrition content claim?

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2. What food will you be applying the nutrition content claim to?

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3. Has the form of the food to which the claim relates been determined in accordance with the Table to **clause 6** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted.

4. Does the nutrition content claim state the form of the food to which the claim applies together with the claim as required by **clause 10** of Standard 1.2.7 unless the form of the food is as sold?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

5. Do words in the nutrition content claim refer to the prevention, diagnosis, cure, or alleviation of a disease, disorder or condition or compare a food with a good that is represented in any way to be for therapeutic use or likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason?

Yes  No

If **YES**, the claim is **NOT** permitted.

6. Do any words used in the nutrition content claim alter or contradict the effect of a statement or information required by Standard 1.2.7?

Yes  No

If **YES**, the claim is **NOT** permitted.

7. Do the details of the nutrient or biologically active substance used to make the nutrition content claim appear in the nutrition information panel (NIP) on the label of the package of the food as required by **clause 5** of Standard 1.2.8?

Yes  No

If **NO**, the particulars of the nutrient or biologically active substance **MUST BE** declared in the NIP, or if no label is required under **subclause 2(1)** of Standard 1.2.1, the NIP (with the particulars of the claimed nutrient or biologically active substance) should be displayed on or in connection with the display of the food or provided to the purchaser on request. This requirement does not apply to food in small packages; however certain information must be included on the label of the small package (**clauses 8 and 8A** of Standard 1.2.8).

8. What property of food (e.g. a vitamin, fat, energy or beta glucan) will the nutrition content claim be about?

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9. Is the property of food listed in Column 1 of **Schedule 1** of Standard 1.2.7?

Yes  No

If **NO**, proceed to question 19.

10. Does the food and claim meet the applicable conditions in Column 2 (if any) for the property of food in Column 1 identified above, and if a descriptor or synonym of a descriptor in Column 3 is used in the claim, does the food and claim meet the applicable conditions in Column 4?

Yes  No

If **YES**, go to question 11. If **NO**, claim is **NOT** permitted.

11. Demonstrate, as appropriate, how the nutrition content claim complies with all relevant conditions from **Schedule 1** of Standard 1.2.7 (e.g. amount of substance in food, testing results).

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If the claim is not about gluten, glycaemic index, glycaemic load or trans fatty acids, proceed to question 24 (comparative claims).

**Specific substances: gluten, lactose, glycaemic index, glycaemic load or trans fatty acids**

12. Is your nutrition content claim made about lactose or trans fatty acids?

Yes  No

If **NO**, proceed to question 15.

13. If yes, what descriptors (if any) are applied?

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14. Are the descriptors derived from Column 3 of **Schedule 1** corresponding to the appropriate substance, or are they synonyms of those descriptors provided in Column 3 of **Schedule 1**?

Yes  No

If **NO**, the claim is **NOT** permitted.

If **YES**, proceed to question 24.

15. Is your nutrition content claim about gluten?

Yes  No

If **NO**, proceed to question 17.

16. If yes, are descriptors from Column 3 of **Schedule 1** relating to gluten or synonyms of those descriptors used, or does your claim state that the food contains gluten or is high in gluten?

Yes  No

If **NO**, the claim is **NOT** permitted.

If **YES**, you have finished.

17. Is your nutrition content claim about:

a) glycaemic index?

Yes  No

If **NO**, proceed to question 19.

If **YES**, proceed to question 19 **AND** complete questions 33 and 34.

b) glycaemic load?

Yes  No

If **NO**, proceed to question 19.

If **YES**, proceed to question 18 **AND** complete questions 33 and 34.

18. Does the nutrition content claim use a descriptor other than a number or a descriptor expressed in numeric form?

Yes  No

If **YES**, the claim is **NOT** permitted.

19. Is a nutrition content claim made about folic acid, choline or fluoride?

Yes  No

If **NO**, proceed to question 21.

20. If yes, does the food also carry a health claim about folic acid, choline or fluoride (as applicable, as referred to in the nutrition content claim)?

Yes  No

If **NO**, nutrition content claim **MAY NOT** be made about that food.

If **YES**, you have finished. The nutrition content **CLAIM MAY ONLY BE MADE** about presence of folic acid, choline or fluoride or the amount of folic acid, choline or fluoride in a specified amount of the food. No descriptors in Column 3 of **Schedule 1** (or any other descriptor) may be used for nutrition content claims made about folic acid, choline or fluoride.

***If your claim is in Schedule 1, go to question 24 (comparative claims)***

21. Is a nutrition content claim made about a property of food not mentioned in **Schedule 1**?

Yes  No

If **NO**, proceed to question 24.

22. If yes, does the claim use a descriptor listed in Column 3 of **Schedule 1** or any other descriptor except for a descriptor that indicates the food does not contain the property of food?

Yes  No

If **YES**, the claim is **NOT** permitted. If **NO**, proceed to question 23.

23. Does the claim refer to the presence or absence of that substance, the specific amount of that property of food in a specified amount of the food or a descriptor that indicates the food does not contain the property of food?

Yes  No

If **NO**, the claim is **NOT** permitted.

If **YES**, you have finished.

**Specific conditions for nutrition content claims: comparative claims**

24. Does the nutrition content claim compare the nutrition content of one food with another or is the word 'diet' used in a nutrition content claim?

Yes  No

If **NO**, you do not need to address any further questions.

25. If yes, are the descriptors, 'light' or 'lite', 'increased', or 'reduced' used in the nutrition content claim?

Yes  No

If yes, which of these terms is used?

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26. If the above words are not used, but the nutrition content claim compares the nutrition content of one food with another, what words are used to describe the comparison between the claimed food and the reference food?

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27. Does the comparative claim state the identity of the reference food and the difference between the amount of the relevant property in the claimed food and reference food?

Yes  No

If **NO**, the claim is **NOT** permitted.

28. Does the claim directly or indirectly compare the vitamin or mineral content of a food with that of another food?

Yes  No

If **YES**, the claim is **NOT** permitted unless the claim is permitted by another Standard in the Food Standards Code.

29. Is the word 'diet' used in a nutrition content claim?

Yes  No

If **YES**, proceed to question 30 **AND** address questions 33 and 34.  
If **NO**, you have finished.

30. If yes, is the 'diet' claim a comparative claim, i.e. does the food meet the conditions for making the 'diet' claim by having at least 40% less energy than the same quantity of reference food?

Yes  No

If **NO**, proceed to question 32.

31. If yes, is the identity of the reference food and the difference between the energy content in the reference food compared to the claimed food provided together with the claim?

Yes  No

If **NO**, the claim is **NOT** permitted.

32. For claims using the word 'diet' as a descriptor (i.e. claims that comply with the conditions for use of the 'diet' descriptor), are other descriptors used that directly or indirectly refer to 'slimming' or synonyms of slimming used?

Yes  No

If **YES**, the claim is **NOT** permitted.

**Questions 33 and 34 apply only if you are making a glycaemic index, glycaemic load or diet claim**

33. What category does the food belong to in the Nutrient Profiling Scoring Criterion (NPSC) as listed in the 'Category' column of **Schedule 4** of Standard 1.2.7?

Category 1  Category 2  Category 3

34. What is the final nutrient profiling score of the food in its specific category, as listed in the 'NPSC category' column of **Schedule 4** of Standard 1.2.7?

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*For information on calculating the nutrient profiling score see:*

[www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm](http://www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm)

*If food is Category 1, nutrient profiling score must be less than 1 to qualify for the claim.*

*If food is Category 2, nutrient profiling score must be less than 4 to qualify for the claim.*

*If food is Category 3, nutrient profiling score must be less than 28 to qualify for the claim.*

If the food **does not** meet the NPSC the glycaemic index, glycaemic load or diet claim is **NOT** permitted.

## 4. Making a health claim

A health claim is any claim that states, suggests or implies that a food or property of food has or may have a health effect. See the **glossary** on page 45 for definitions of property of food, health claim and health effect.

There are two types of health claims, general level health claims and high level health claims. This document provides guidance on making both types of health claim.

A food-health relationship is the relationship between a food or property of food and a health effect. All health claims require a food-health relationship to be established. A high level health claim must be based on a food-health relationship provided in **Schedule 2** of Standard 1.2.7. A food-health relationship for general level health claims can be established in one of two ways:

- it is listed in **Schedule 3** of Standard 1.2.7 or
- following a process of systematic review as described in **Schedule 6** of Standard 1.2.7.

Guidance on establishing a food-health relationship for a general level health claim by systematic review is available at:

[www.foodstandards.gov.au/publications/Pages/Guidance-on-establishing-food-health-relationships-for-general-level-health-claims.aspx](http://www.foodstandards.gov.au/publications/Pages/Guidance-on-establishing-food-health-relationships-for-general-level-health-claims.aspx)

A health claim must not be made on a food that does not meet the NPSC described in **Schedule 4** of Standard 1.2.7. This requirement does not apply to foods standardised in Part 2.9 of the Food Standards Code. The method to calculate a food's nutrient profiling score is described in **Schedule 5** of Standard 1.2.7. You can find a Nutrient Profiling Scoring Calculator to help you determine if a food meets the NPSC at:

[www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm](http://www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm).

A health claim must state the food or the property of food and the specific health effect (derived from the established food-health relationship). If the health effect only applies to a specific sector of the population rather than the whole population this information must be included as part of the health claim.

Dietary context statements must be included with the health claim (**paragraph 19(3) (a)**). The dietary context statement must state that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and must be appropriate for the claim being made (**paragraph 19(3)(a) and**



**subclause 19(4)).** In addition, for health claims based on a pre-approved food-health relationship (a relationship described in **Schedules 2 or 3**), words to the effect of the relevant dietary context statement in Column 4 of those Schedules must also be used. For general level health claims based on a food-health relationship established by following the process of systematic view (**Schedule 6**), the dietary context statement must be consistent with the conclusions of the systematic review.

There is an exemption from the dietary context statement if the health claim is on a label of a small package (see **glossary**) (**subclause 19(5)**).

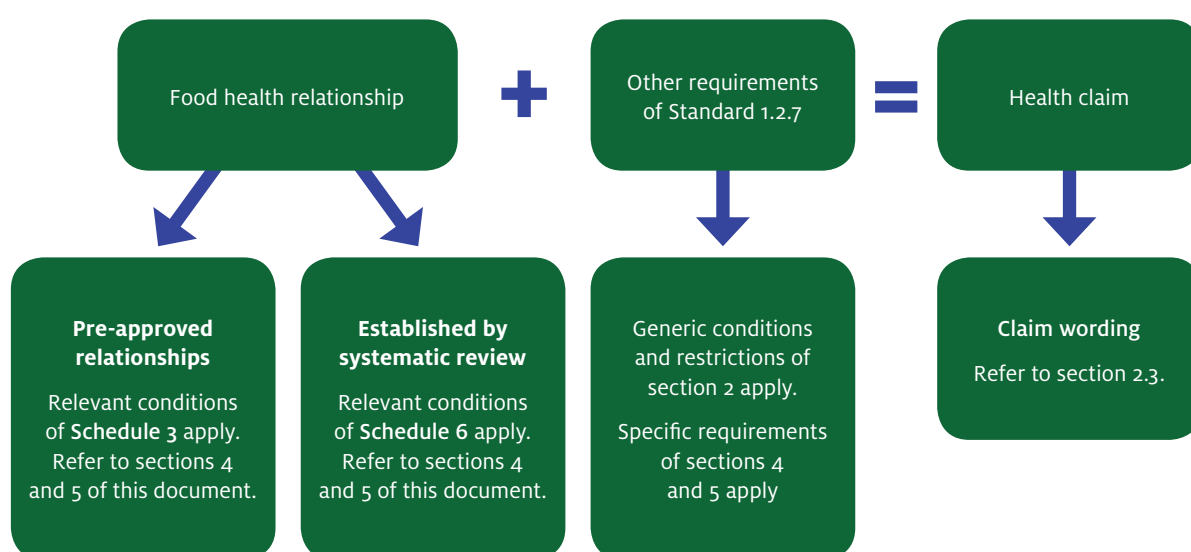
The food or property of food and the health effect may be presented as a separate, shortened statement in what is called a split health claim. However, the shortened statement must appear on the same label or in the same advertisement as the complete statement that includes all the claim elements required by Standard 1.2.7. An indication of where the complete statement is located must be provided with the shortened statement (**clause 20**).

If a health claim is made about phytosterols, phytosterols and their esters and it is presented with the advisory statements required by **clause 2** of Standard 1.2.3 then a statement that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods as part of a dietary context statement is not required (**clause 21**).

## 5. Making a general level health claim

### Building a general level health claim

The purpose of this diagram is to direct users to the relevant sections of this guidance document.



**Schedule 3** may be amended by application to FSANZ:  
[www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx](http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx)

For establishing a food-health relationship by systematic review in accordance with **Schedule 6**, refer to FSANZ guidance document:  
[www.foodstandards.gov.au/publications/Pages/Guidance-on-establishing-food-health-relationships-for-general-level-health-claims.aspx](http://www.foodstandards.gov.au/publications/Pages/Guidance-on-establishing-food-health-relationships-for-general-level-health-claims.aspx)

A general level health claim is defined as a health claim that is not a high level health claim (see **glossary**).

The requirements outlined in Sections 2 and 4 of this document also apply when making a general level health claim.

There are two ways to establish food-health relationships that underpin a general level health claim:

- pre-approved relationships as listed in **Schedule 3** of Standard 1.2.7
- by following the process of systematic review as described in **Schedule 6** of Standard 1.2.7.

Any of the relationships listed in **Schedule 3** may be used for making general level health claims. If a relationship from **Schedule 3** is used, all necessary conditions relating to that relationship need to be met.

If a food-health relationship is established by systematic review, the person responsible for making the claim must notify the FSANZ CEO of the details of the relationship between the food or property of food and the health effect. FSANZ has provided information to consider when notifying self-substantiated food-health relationship in accordance with Standard 1.2.7:

[www.foodstandards.gov.au/industry/labelling/pages/notifyingaselfsubsta5781.aspx](http://www.foodstandards.gov.au/industry/labelling/pages/notifyingaselfsubsta5781.aspx)

Building a general level health claim based on **Schedule 3**:

- Calcium is listed in **Schedule 3**.
- Column 1 (Food or property of food): Calcium.
- Column 2 (Specific health effect): Necessary for normal teeth and bone structure.
- Column 3 (Relevant population): No relevant population required.
- Column 4 (Dietary Context): No additional dietary context required.
- Column 5 (Conditions): The food must meet the general claim conditions for making a nutrition content claim about calcium.

Templates are provided to help food businesses build a general level health claim based on either a pre-approved food-health relationship or systematic review; and demonstrate due diligence in attempting to comply with the Food Standards Code.

These templates should be used with the associated 'Checklist for General Level Health Claims (pre-approved)' and 'Checklist for General Level Health Claims (systematic review)'.

A separate template and associated checklist should be used for each claim.

## Compliance template—general level health claims (Schedule 3 pre-approved food-health relationship)

This template may help food businesses to build a general level health claim based on a pre-approved food-health relationship; and demonstrate due diligence in attempting to comply with the Food Standards Code.

See sections 2, 4 and 5 of this document for conditions on making of general level health claims.

### General information

1. What is the wording of the proposed general level health claim?

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2. What food will the general level health claim be applied to?

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3. Has the form of the food to which the claim relates been determined in accordance with the Table to **clause 6** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted.

4. Does the general level health claim state the form of the food to which the claim applies together with the claim as required by **subclause 19(3)(b)** of Standard 1.2.7 unless the form of the food is as sold?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

5. Do the words in the general level health claim refer to the prevention, diagnosis, cure, or alleviation of a disease, disorder or condition or compare a food with a good that is represented in any way to be for therapeutic use or likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason?

Yes  No

If **YES**, the claim is **NOT** permitted.

6. Do words used in the general level health claim alter or contradict the effect of a statement or information required by Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

7. Does the claim refer to a serious disease or a biomarker of a serious disease?

Yes  No

If **YES**, the claim is **NOT** permitted as a general level health claim.

8. What category does the food belong to in the Nutrient Profiling Scoring Criterion (NPSC) as listed in the 'Category' column of **Schedule 4** of Standard 1.2.7?

Category 1  Category 2  Category 3

*Note: Foods defined in Part 2.9 of the Food Standards Code do not need to comply with the NPSC.*

9. What is the final nutrient profiling score of the food (see the 'NPSC category' column of **Schedule 4** of Standard 1.2.7)?

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*For information on calculating the nutrient profiling score see:*

[www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm](http://www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm)

*If food is Category 1, nutrient profiling score must be less than 1 to qualify for health claim.*

*If food is Category 2, nutrient profiling score must be less than 4 to qualify for health claim.*

*If food is Category 3, nutrient profiling score must be less than 28 to qualify for health claim.*

If the food does not meet the NPSC the health claim is **NOT** permitted.

10. What is the food-health relationship identified in **Schedule 3** of Standard 1.2.7 that is used as the basis for making the general level health claim?

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11. Does the claim meet the conditions identified in Column 3 (relevant population) or Column 4 (dietary context) of **Schedule 3** applicable to the food-health relationship identified above?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

12. Are the conditions in Column 5 of **Schedule 3** applicable to the food-health relationship identified above, met?

Yes  No

If **NO**, the claim is **NOT** permitted.

13. Demonstrate how the general level health claim complies with all relevant criteria identified in **Schedule 3** of Standard 1.2.7.

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14. Does the general level health claim advise consumers that the claimed health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and is the dietary context statement appropriate for the claim being made as required by **subclause 19(4) (a) and (b)** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form (unless the food is contained in a small package).

*Health claims about phytosterols, phytostanols and their esters do not require a statement that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods as part of a dietary context statement to be made in conjunction with the health claim if the claim is presented together with the advisory statements required by **clause 2** of Standard 1.2.3.*

15. Is the general level health claim being made as a split claim? If so, is a statement available with the stated food or property of food and the health effect on the label of the food or advertisement, indicating where all required elements of the general level health claim may be found on the label or advertisement, as required by **clause 20** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

16. Do the details of the nutrients or biologically active substances used to make the general level health claim appear in the nutrition information panel (NIP) on the label of the package of the food as required by **clause 5** of Standard 1.2.8?

Yes  No

If **NO**, the particulars of the nutrient or biologically active substance must be declared in the NIP, or if no label is required under **subclause 2(1)** of Standard 1.2.1, the NIP (with the particulars of the claimed nutrient or biologically active substance) should be displayed on or in connection with the display of the food or provided to the purchaser upon request. This requirement does not apply to food in small packages however certain information must be included on the label of the small package (**clauses 8 and 8A** of Standard 1.2.8).

## Compliance template—general level health claims (systematic review)

This template may help food businesses build a general level health claim based on a food-health relationship established by systematic review; and demonstrate due diligence in attempting to comply with the Food Standards Code.

See sections 2, 4 and 5 of this document for conditions on making general level health claims.

### General information

1. What is the wording of the proposed general level health claim?

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2. What food will the general level health claim be applied to?

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3. Has the form of the food to which the claim relates been determined in accordance with the Table to **clause 6** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted.

4. Does the general level health claim state the form of the food to which the claim applies together with the claim as required by **subclause 19(3)(b)** of Standard 1.2.7, unless the form of the food is as sold?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.



5. Do the words in the general level health claim refer to the prevention, diagnosis, cure, or alleviation of a disease, disorder or condition or compare a food with a good that is represented in any way to be for therapeutic use or likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason?

Yes  No

If **YES**, the claim is **NOT** permitted.

6. Do words used in the general level health claim alter or contradict the effect of a statement or information required by Standard 1.2.7?

Yes  No

If **YES**, the claim is **NOT** permitted.

7. Does the claim refer to a serious disease or a biomarker of a serious disease?

Yes  No

If **YES**, the claim is **NOT** permitted as a general level health claim.

8. What category does the food belong to in the Nutrient Profiling Scoring Criterion (NPSC) as listed in the 'Category' column of **Schedule 4** of Standard 1.2.7?

Category 1  Category 2  Category 3

9. What is the final nutrient profiling score of the food in its specific category, as listed in the 'NPSC category' column of **Schedule 4** of Standard 1.2.7?

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*For information on calculating the nutrient profiling score see:*

[www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm](http://www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm)

*If food is Category 1, nutrient profiling score must be less than 1 to qualify for health claim.*

*If food is Category 2, nutrient profiling score must be less than 4 to qualify for health claim.*

*If food is Category 3, nutrient profiling score must be less than 28 to qualify for health claim.*

*Foods defined in Part 2.9 of the Food Standards Code do not need to comply with the NPSC.*

If the food **DOES NOT** meet the NPSC the health claim is **NOT** permitted.

10. Does the general level health claim advise consumers that the claimed health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and include words to the effect of a relevant dietary context statement that is a reasonable conclusion of the systematic review and is the dietary context statement appropriate for the claim being made, as required by **paragraph 19(3) (a)** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form (unless the food is contained in a small package).

*Health claims about phytosterols, phytosterols and their esters do not require a statement that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods as part of a dietary context statement to be made in conjunction with the health claim if the claim is presented together with the advisory statement required by **Clause 2** of Standard 1.2.3.*

11. Is the general level health claim being made as a split claim? If so, is a statement available with the stated food or property of food and the health effect on the label of the food or advertisement indicating where all required elements of the general level health claim may be found on the label or advertisement, as required by **clause 20** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

12. Do the details of the nutrients or biologically active substances used to make the general level health claim appear in the nutrition information panel (NIP) on the label of the package of the food as required by **clause 5** of Standard 1.2.8?

Yes  No

If **NO**, the particulars of the nutrient or biologically active substance **MUST BE** declared in the NIP, or if no label is required under **subclause 2(1)** of Standard 1.2.1, the NIP (with the particulars of the claimed nutrient or biologically active substance) should be displayed on or in connection with the display of the food or provided to the purchaser upon request. This requirement does not apply to food in small packages however certain information must be included on the label of the small package (**clauses 8 and 8A** of Standard 1.2.8).

13. If the general level health claim is based on a relationship between a food or property of food and a health effect that has been established by a process of systematic review described in **Schedule 6** of Standard 1.2.7, has the person responsible for making the claim notified the CEO of FSANZ of the details of that relationship?

Yes  No

If **NO**, the claim does **NOT** comply with Standard 1.2.7.

14. Has a person giving notice in question 13 above to the CEO of FSANZ provided:

(i) The name of the person giving the notice and the address in Australia or New Zealand of that person, and Yes  No

(ii) Consent to the publication by the Authority of information concerning the relationship that is the subject of the notice plus information in (i) above, and; Yes  No

(iii) Certification that the relationship that is the subject of the notice provided in question 13 above has been established by a process of systematic review that is described in **Schedule 6**. Yes  No

If **NO** to any of the above, the claim **DOES NOT COMPLY** with Standard 1.2.7.

15. Would the person giving notice in question 13 above to the CEO of the Authority, if requested by a relevant authority, be able to provide records to the relevant authority that demonstrate that:

(i) The systematic review was conducted in accordance with the process of systematic review described in **Schedule 6**; and Yes  No

(ii) The notified relationship is a reasonable conclusion of the systematic review. Yes  No

#### *Required elements of a systematic review*

16. Do you intend to undertake a systematic review by reviewing the original (primary) literature or starting with an existing systematic review and updating it?

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If undertaking a systematic review by reviewing the original (primary) literature, answer questions 17–24.

If starting with an existing systematic review and updating it answer questions 17–24 for the updated systematic review including any relevant scientific data not included in the existing systematic review.

17. Has a statement been made that describes the food or property of food, the health effect and the proposed relationship between the food or property of food and the health effect?

Yes  No

If **NO**, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**.

18. Has a search strategy been provided that describes how scientific evidence has been captured relevant to the proposed relationship between the food or property of food and the health effect, including the inclusion and exclusion criteria?

Yes  No

If **NO**, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**.

19. Has a final list of studies, based on the inclusion and exclusion criteria, been provided to support the proposed relationship?

Yes  No

If **NO**, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**.

20. If yes to question 19, are there studies among this list that involve studies in humans?

Yes  No

If **NO**, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**. **Studies in humans are essential.**

21. Has a table with key information from each included study been provided?

This table must include information on:

- |   |     |                          |    |                          |
|---|-----|--------------------------|----|--------------------------|
| (a) the study reference   | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (b) the study design  | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (c) the objectives  | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (d) the sample size in the study groups and loss to follow-up or non-response     | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (e) the participant characteristics   | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (f) method used to measure the food or property of food including amount consumed | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (g) confounders measured  | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (h) the method used to measure the health effect                                  | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (i) the study results, including effect size and statistical significance         | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (j) any adverse effects.  | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

If **NO** to any of the above, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**.

22. Has an assessment of the quality of each included study been undertaken, based on consideration of, as a minimum:

- |   |     |                          |    |                          |
|---|-----|--------------------------|----|--------------------------|
| (a) a clearly stated hypothesis   | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (b) minimisation of bias  | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (c) adequate control for confounding  | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (d) the study participants' background diets and other relevant lifestyle factors | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (e) study duration and follow-up adequate to demonstrate the health effect        | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| (f) the statistical power to test the hypothesis.                                 | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

If **NO** to any of the above, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**.

23. Has an assessment of the results of the included studies as a group been provided, that considers whether:

- (a) is a consistent association between the food or property of food and the health effect across all high quality studies. Yes  No
- (b) there is a causal association between the consumption of the food or property of food and the health effect that is independent of other factors (with most weight given to well-designed experimental studies in humans). Yes  No
- (c) the proposed relationship between the food or property of food and the health effect is biologically plausible. Yes  No
- (d) the amount of the food or property of food to achieve the health effect can be consumed as part of a normal diet of the Australian and New Zealand populations. Yes  No

If **NO** to any of the above, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**.

24. Has a conclusion been provided based on the results of the studies that includes:

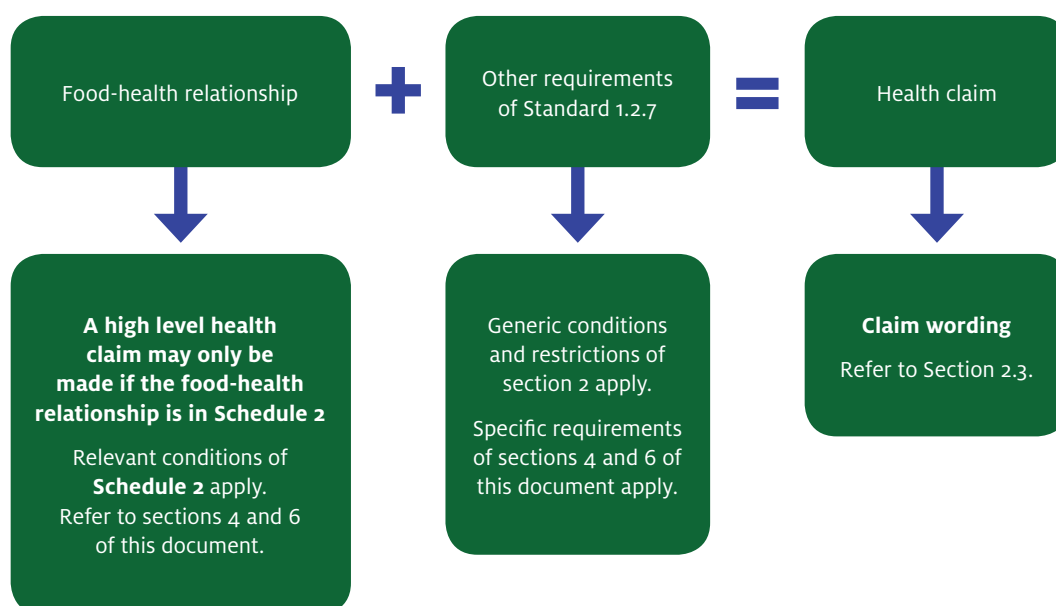
- (a) whether a causal relationship has been established between the food or property of food and the health effect based on the totality and weight of evidence. Yes  No
- (b) where there is a causal relationship between the food or property of food and the health effect:
  - (i) the amount of the food or property of food required to achieve the health effect Yes  No
  - (ii) whether the amount of the food or property of food to achieve the health effect is likely to be consumed in the diet of the Australian and New Zealand populations or by the target population group, where relevant. Yes  No

If **NO** to any of the above, the systematic review **HAS NOT BEEN CONDUCTED** in accordance with the process described in **Schedule 6**.

## 6 Making a high level health claim

### Building a high level health claim

The purpose of this diagram is to direct users to the relevant sections of this guidance document.



**Schedule 2** may be amended by application to FSANZ:  
[www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx](http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx)

A high level health claim means a health claim that refers to a serious disease or a biomarker of a serious disease.

The requirements outlined in Sections 2 and 4 of this document also apply when making a high level health claim.

Only food-health relationships described in **Schedule 2** of Standard 1.2.7 may be used for the making of high level health claims.

Building a high level health claim based on **Schedule 2**:

- Calcium is listed in **Schedule 2**.
- Column 1 (Food or property of food): Calcium.
- Column 2 (Specific health effect): Reduced risk of osteoporosis.
- Column 3 (Relevant population): Persons 65 years and over.
- Column 4 (Dietary context): Diet high in calcium, and adequate Vitamin D status.
- Column 5 (Conditions): The food contains no less than 290mg of calcium per serving.

A high level health claim made about calcium and reduced risk of osteoporosis must comply with all above stated conditions.

A template is provided to assist food businesses to: build a high level health claim; and demonstrate due diligence in attempting to comply with the Food Standards Code.

This template should be used with the associated 'Checklist for High Level Health Claims'.

A separate template and associated checklist should be used for each claim.



## Compliance template—high level health claims

This template may help food businesses build a high level health claim; and demonstrate due diligence in attempting to comply with the Food Standards Code.

See sections 2, 4 and 6 of this document for conditions on making health claims.

### General information

1. What is the wording of the proposed high level health claim?

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*Examples of serious diseases are coronary heart disease, osteoporosis, osteoporotic fracture and neural tube defects. Examples of biomarkers of serious disease are blood cholesterol and blood pressure.*

2. What food will the high level health claim be applied to?

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3. Has the form of the food to which the claim relates been determined in accordance with the Table to **clause 6** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted.

4. Does the high level health claim state the form of the food to which the claim applies together with the claim as required by **subclause 19(3)(b)** of Standard 1.2.7 unless the form of the food is as sold?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

5. Do words used in the high level health claim alter or contradict the effect of a statement or information required by Standard 1.2.7?

Yes  No

If **YES**, the claim is **NOT** permitted.

6. What is the serious disease or biomarker of a serious disease referred to in the claim?

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7. What category does the food belong to in the Nutrient Profiling Scoring Criterion (NPSC) as listed in the 'Category' column of **Schedule 4** of Standard 1.2.7?

Category 1  Category 2  Category 3

8. What is the final nutrient profiling score of the food in its specific category, as listed in the 'NPSC category' column of **Schedule 4** of Standard 1.2.7?

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*For information on calculating the nutrient profiling score, see:*

[www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm](http://www.foodstandards.gov.au/consumerinformation/nutritionhealthandrelatedclaims/nutrientprofilingcal3499.cfm)

*If food is Category 1, nutrient profiling score must be less than 1 to qualify for health claim.*

*If food is Category 2, nutrient profiling score must be less than 4 to qualify for health claim.*

*If food is Category 3, nutrient profiling score must be less than 28 to qualify for health claim.*

*Foods defined in Part 2.9 of the Food Standards Code do not need to comply with the NPSC.*

If the food **DOES NOT MEET THE NPSC** the health claim is **NOT** permitted.

9. Do the words in the high level health claim refer to the prevention, diagnosis, cure, or alleviation of a disease, disorder or condition or compare a food with a good that is represented in any way to be for therapeutic use or likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason?

Yes  No

If **YES**, the claim is **NOT** permitted.

10. What is the food-health relationship listed in Columns 1 and 2 of **Schedule 2** of Standard 1.2.7 that is to be used for making the high level health claim?

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If a **food-health relationship is not in Schedule 2** the claim is **NOT** permitted.

11. Does the claim meet the conditions identified in Column 3 (relevant population) or Column 4 (dietary context) of **Schedule 2**, applicable to the food-health relationship identified above?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

12. Are the conditions in Column 5 of **Schedule 2** applicable to the food-health relationship identified above, met?

Yes  No

If **NO**, the claim is **NOT** permitted.

13. Demonstrate how the high level health claim complies with all relevant criteria identified in **Schedule 2** of Standard 1.2.7.

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14. Does the high level health claim advise consumers that the claimed health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and is it appropriate for the claim being made as required by **subclause 19(4) (a) and (b)** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form (unless the food is contained in a small package).

*Health claims about phytosterols, phytostanols and their esters do not require a statement that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods as part of a dietary context statement to be made in conjunction with the health claim if the claim is presented together with the advisory statement required by **clause 2** of Standard 1.2.3.*

15. Do the details of the nutrients or biologically active substances used to make the high level health claim appear in the nutrition information panel (NIP) on the label of the package of the food as required by **clause 5** of Standard 1.2.8?

Yes  No

If **NO**, the particulars of the nutrient or biologically active substance **must be declared** in the NIP, or if no label is required under **subclause 2(1)** of Standard 1.2.1, the NIP (with the particulars of the claimed nutrient or biologically active substance) should be displayed on or in connection with the display of the food or provided or declared to the purchaser upon request. This requirement does not apply to food in small packages however certain information must be included on the label of the small package (**clauses 8 and 8A** of Standard 1.2.8).

16. Is the high level health claim being made as a split claim? If so, is a statement available with the stated food or property of food and the health effect on the label of the food or advertisement indicating where all required elements of the high level health claim may be found on the label or advertisement, as required by **clause 20** of Standard 1.2.7?

Yes  No

If **NO**, the claim is **NOT** permitted in its current form.

## 7. Endorsing bodies and endorsements

Endorsements are nutrition content claims or health claims made with the permission of an endorsing body. Endorsements are not subject to Part 2 of Standard 1.2.7 (excluding **clause 7**) and Part 3 – Divisions 1, 2 and 4. Endorsements can only be made if the requirements below are met (**clauses 22 and 23** of Standard 1.2.7).

**Subclause 22 (1)** states that endorsing bodies must:

- not be related to the supplier (**subclause 22(2)** outlines when an endorsing body is related to a supplier)
- be independent of the supplier
- be free from influence by the supplier.

In this subclause, ‘supplier’ is the supplier of the food in relation to which an endorsement is made.

The supplier using the endorsement must (during sale or advertising for sale and for 2 years after the product was supplied or advertised) keep and make available to the relevant authority, if requested, records demonstrating that (**clause 23**):

- it has the permission of the endorsing body to use the endorsement; (e.g. a certificate of accreditation)
- the endorsing body has a nutrition or health-related function or purpose (articles of association outlining the function of the endorsing body may demonstrate this)
- the endorsing body is a not-for-profit entity not related to the supplier using the endorsement (company documents may demonstrate this).

Endorsements must comply with **clause 7** (claims must not be therapeutic in nature) and not refer to a serious disease except when referring to the endorsing body if the serious disease is part of the name of the endorsing body.

If these requirements are not met, endorsements are treated as nutrition content or health claims and must comply with all relevant requirements in the Standard.

A template is provided to help suppliers, that make nutrient content claims or health claims with the permission of an endorsing body, demonstrate due diligence in attempting to comply with the Food Standards Code.

## Compliance template—Endorsements

This template is to help suppliers (including importers, see glossary) making nutrition content claims or health claims with the permission of an endorsing body.

Part 2 (other than clause 7) and Part 3 Divisions 1, 2 and 4 of Standard 1.2.7 do not apply to an endorsement.

### General information

1. Describe the endorsement (refer to **glossary**) and how it is made.

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2. Describe the food that carries the endorsement?

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3. What is the name of the endorsing body?

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### Endorsing bodies

4. Is the endorsing body a not-for-profit entity that has a nutrition or health-related function or purpose?

Yes  No

If **NO**, the endorsement **CANNOT** be made by the supplier.

5. Has the endorsing body given the supplier permission to use the endorsement?

Yes  No

If **NO**, the endorsement **CANNOT** be made by the supplier.

### Relationship between endorsing body and supplier

6. Is the endorsing body related in any way to the supplier?

Yes  No

If **YES**, the endorsement **CANNOT** be made by the supplier.

7. Is the endorsing body independent of, and free from influence by, the supplier of the food?

Yes  No

If **NO**, the endorsement **CANNOT** be made by the supplier.

8. Does the supplier have any financial interest in the endorsing body?

Yes  No

If **YES**, the endorsement **CANNOT** be made by the supplier.

9. Did the supplier establish the endorsing body, whether by itself or with others?

Yes  No

If **YES**, the endorsement **CANNOT** be made by the supplier.

10. Does the supplier exercise direct or indirect control over the endorsing body?

Yes  No

If **YES**, the endorsement **CANNOT** be made by the supplier.

### Criteria for endorsements

11. Does the endorsement refer to a serious disease (except in reference to the endorsing body if the serious disease is part of the name of the endorsing body)?

Yes  No

If **YES**, the endorsement **CANNOT** be made by the supplier.

12. If you are the supplier (including an importer) of the food that carries the endorsement, have you kept the required records and are you able to provide these to the relevant authority if requested?

Yes  No

If **NO**, then you do not meet the criteria for endorsements.

*If the label on, or advertisement for, an imported food makes or includes an endorsement, the supplier must keep required records for the information period.*

*'Information period', in relation to food, means the period –*

- (a) during which the food is available for sale or advertised for sale; and*
- (b) the period of 2 years after the food was last sold, or advertised or available for sale, whichever is the latest.*

*'Required records' means a document or documents that demonstrate that –*

- (a) a supplier using an endorsement has obtained the permission of the endorsing body to use the endorsement; and*
- (b) the endorsing body has a nutrition- or health-related function or purpose; and*
- (c) the endorsing body is a not-for-profit entity; and*
- (d) the endorsing body is not related to the supplier using the endorsement.*

13. Does the endorsement comply with **clause 7** of Standard 1.2.7 (claims must not be therapeutic in nature)?

Yes  No

If **NO**, the endorsement **CANNOT** be made.



## 8. Glossary

**Act** means the Act, as amended or, as the case may be, ordinance of a state, territory, external territory, Commonwealth or New Zealand, under the authority of which the Food Standards Code is enforced.

**Biologically active substance** is as defined in Standard 1.2.8.

**Biomarker** means a measurable biological parameter that is predictive of the risk of a serious disease when present at an abnormal level in the human body.

**Claim** means an expressed or implied statement, representation, design or information in relation to a food or property of food which is not mandatory in the Food Standards Code.

**Comparative claim** means a nutrition content claim that directly or indirectly compares the nutrition content of one food or brand of food with another, and includes claims using the descriptors – a) light or lite, b) increased, or c) reduced, or words of similar import. A nutrition content claim using the descriptor ‘diet’ is also a comparative claim, if it meets the conditions for making that claim by having at least 40% less energy than the same quantity of reference food.

**Endorsement** means a nutrition content claim or a health claim that is made with the permission of an endorsing body.

**Endorsing body** is a not-for-profit entity which has a nutrition or health-related purpose or function, that permits a supplier to make an endorsement.

**Food group** is referred to in the definition of reference food, for the purposes of comparative claims and means any of the following groups:

- (a) bread (both leavened and unleavened), grains, rice, pasta and noodles
- (b) fruit, vegetables, herbs, spices and fungi
- (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
- (d) meat, fish, eggs, nuts, seeds and dried legumes
- (e) fats including butter, edible oils and edible oil spreads.

**Fruit** means 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), but does not include nuts, spices, herbs, fungi, legumes and seeds.

**General level health claim** means a health claim that is not a high level health claim.

**High level health claim** means a health claim that refers to a serious disease or a biomarker of a serious disease.

**Health claim** means a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect.

**Health effect** means an effect on the human body, including an effect on one or more of the following:

- (a) a biochemical process or outcome
- (b) a physiological process or outcome
- (c) a functional process or outcome
- (d) growth and development
- (e) physical performance
- (f) mental performance
- (g) a disease, disorder or condition.

**Infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

**Information period**, in relation to food, means the period:

- (a) during which the food is available for sale or advertised for sale; and
- (b) the period of 2 years after the food was last sold, or advertised or available for sale, whichever is the latest.

**Label** means any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package.

**NPSC** means the nutrient profiling scoring criterion.

**Nutrition content claim** means a claim about –

- (a) the presence or absence of –
  - (i) a biologically active substance; or
  - (ii) dietary fibre; or
  - (iii) energy; or
  - (iv) minerals; or
  - (v) potassium; or
  - (vi) protein; or
  - (vii) carbohydrate; or
  - (viii) fat; or
  - (ix) the components of any one of protein, carbohydrate or fat; or
  - (x) salt; or
  - (xi) sodium; or
  - (xii) vitamins; or
- (b) glycaemic index or glycaemic load;

that does not refer to the presence or absence of alcohol, and is not a health claim.

**Property of food** means a component, ingredient, constituent or other feature of food.

**Reference food** means a food that is:

- (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
- (b) a dietary substitute for the food in the **same food group** as the food for which a claim is made.

**Relevant authority** means the authority responsible for the enforcement of the Food Standards Code.

**Required records** means documents regarding endorsement which demonstrate that:

- (a) a supplier using an endorsement has obtained the permission of the endorsing body to use the endorsement; and
- (b) the endorsing body has a nutrition or health-related function or purpose; and
- (c) the endorsing body is a not-for-profit entity; and
- (d) the endorsing body is not related to the supplier using the endorsement.

**Serious disease** means a disease, disorder or condition which is generally diagnosed, treated or managed in consultation with or with supervision by a health care professional.

**Small package** means a package with a surface area of less than 100 cm<sup>2</sup>.

**Supplier** means the packer, manufacturer, vendor or importer of the food in question.

**Vegetable** means 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), but excludes nuts, spices, herbs, fungi, dried legumes (including dried legumes that have been cooked or rehydrated) and seeds.

## Checklist for Nutrition Content Claims

This checklist is to assist food businesses when making nutrition content claims and is useful for documenting due diligence. It should be read in conjunction with 'Getting Your Claims Right: A Guide to Complying with the Nutrition, Health and Related Claims Standard of the Australia New Zealand Food Standards Code'.

### Claims not permitted or foods not permitted to carry claims by Standard 1.2.7.

You need to tick **all** of the following boxes to ensure that you are not making a claim prohibited by Standard 1.2.7.

- The claim is not about kava or about an infant formula product.
- The claim is not about a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about energy or carbohydrate content.
- The claim does not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition.
- The claim does not compare a food with a good that is represented in any way to be for therapeutic use; or likely to be taken for therapeutic use, whether because of the way in which the food or substance is presented or for any other reason.
- The claim does not compare the vitamin or mineral content of a food with another food, unless specifically permitted by the Food Standards Code.

### Standard 1.2.7 applies

You need to tick **all** of the following boxes to ensure that Standard 1.2.7 applies to the claim and to the food that the claim is about.

- The food the claim is made about does not require further processing, packaging, or labelling before retail sale.
- The food will not be delivered to a vulnerable person by a delivered meals organisation, or provided to a patient in a hospital or other similar institution, other than a food in a package.
- The claim is not managed by another standard of the Australia New Zealand Food Standards Code (e.g. Standard 2.9.5 – Foods for Special Medical Purposes).

- The claim does not concern risks or dangers of alcohol consumption, or concern moderating alcohol intake.
- The claim concerns the presence or absence of a biologically active substance, or dietary fibre, or energy, or minerals, or potassium, or protein, or carbohydrate, or fat, or the components of any one of protein, carbohydrate or fat, or salt, or sodium, or vitamins, or glycaemic index or glycaemic load; that does not refer to a health effect or the presence or absence of alcohol.
- The claim is not a mandatory declaration required by the Act (as defined in the Food Standards Code).

### Conditions for making nutrition content claims

You need to tick **all** the applicable boxes to ensure that your claim complies with Standard 1.2.7.

- If the nutrition content claim is based on a property of food in Column 1 of **Schedule 1**;
  - (i) the claim states the property of food as mentioned in Column 1 of **Schedule 1** of Standard 1.2.7;
  - (ii) the food meets the general claim conditions that must be met as mentioned in Column 2 of **Schedule 2** of Standard 1.2.7; and
  - (iii) the claim complies with any relevant conditions that must be met as defined in Column 4 of **Schedule 1** if using a specific descriptor (or synonym) provided in Column 3 of **Schedule 1**.
- If the claim concerns lactose or trans fatty acids, any descriptor used is mentioned in Column 3 of **Schedule 1**, corresponding with the relevant property of food (lactose or trans fatty acids), or is a synonym of one of those descriptors.
- If the claim concerns gluten, any descriptor used is mentioned in Column 3 of **Schedule 1** in conjunction with gluten, or is a synonym of one of those descriptors, or the claims states that the food contains gluten or is high in gluten.
- If the claim is made about glycaemic load (GL), it only uses a numeric descriptor, or descriptor expressed in numeric form.
- If the claim is made about glycaemic index (GI), glycaemic load (GL), or is a 'diet' claim, the food carrying the claim meets the nutrient profiling scoring criterion (NPSC).

- If the claim concerns choline, fluoride or folic acid, there is an accompanying health claim about that substance made on the same food, and the claim states only:
  - (i) the food contains choline, fluoride or folic acid; or
  - (ii) the food contains a specified amount of choline, fluoride or folic acid in a specified amount of food; or
  - (iii) a combination of the above.
- If the claim meets the conditions for using the descriptor 'diet', a descriptor that directly or indirectly refers to slimming or a synonym for slimming is not used.
- If the nutrition content claim is a comparative claim, including a 'diet' claim where the food meets the conditions for making the 'diet' claim by having at least 40% less energy than the same quantity of reference food, the identity of the reference food and the difference between the amount of the property of food in the reference food to the claimed food is provided together with the claim.
- If the nutrition content claim is not based on a property of food in Column 1 of **Schedule 1**, the claim states only:
  - (i) that the food contains or does not contain the property of food; or
  - (ii) that the food contains a specified amount of the property of food in a specific amount of that food; or
  - (iii) both of the above.
- A statement concerning the form of the food to which the claim relates is included with the nutrition content claim (unless the claim relates to the form of the food as sold).
- The nutrient or biologically active substance that is the subject of the claim has been included in the nutrition information panel (NIP) on the label of the package containing the food.
- None of the words used in the nutrition content claim alter or contradict the effect of a statement or information required by Standard 1.2.7.

## Checklist for General Level Health Claims (pre-approved)

This checklist is to assist food businesses when making general level health claims based on pre-approved food-health relationships and is useful for documenting due diligence. It should be read in conjunction with 'Getting Your Claims Right: A Guide to Complying with the Nutrition, Health and Related Claims Standard of the Australia New Zealand Food Standards Code'.

### Claims not permitted or foods not permitted to carry claims by Standard 1.2.7.

You need to tick all of the following boxes to ensure that you are not making a claim prohibited by Standard 1.2.7.

- The claim is not about kava or about an infant formula product.
- The claim is not about a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about energy or carbohydrate content.
- The claim does not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition.
- The claim does not compare a food with a good that is represented in any way to be for therapeutic use; or likely to be taken for therapeutic use, whether because of the way in which the food or substance is presented or for any other reason.
- The claim does not compare the vitamin or mineral content of a food with another food, unless specifically permitted by the Food Standards Code.

### Standard 1.2.7 applies

You need to tick all of the following boxes to ensure that Standard 1.2.7 applies to the claim and to the food that the claim is about.

- The food the claim is made about does not require further processing, packaging, or labelling before retail sale.
- The food will not be delivered to a vulnerable person by a delivered meals organisation, or provided to a patient in a hospital or other similar institution, other than a food in a package.



- The claim is not managed by another standard of the Australia New Zealand Food Standards Code (e.g. Standard 2.9.5 – Foods for Special Medical Purposes).
- The claim does not concern risks or dangers of alcohol consumption, or concern moderating alcohol intake.
- The claim is not a mandatory declaration required by the Act (as defined in the Food Standards Code).


### Conditions for making general level health claims

You need to tick **all** the following boxes to ensure that your claim complies with Standard 1.2.7.

- The words in the claim do not refer to a serious disease or a biomarker of a serious disease.
- The correct Nutrient Profiling Scoring Criterion (NPSC) category is identified for the food (**Schedule 4**), except for food standardised in part 2.9 of the Food Standards Code.
- The nutrient profiling score is calculated correctly and is below the number specified for its category in the NPSC (**Schedule 4**).
- The health claim states the food or property of food mentioned in Column 1 of **Schedule 3** of Standard 1.2.7.
- The health claim states the specific health effect mentioned in Column 2 of **Schedule 3** that is claimed for that food or property of food.
- The health claim refers to the relevant population group in Column 3 of **Schedule 3** to which the health effect relates (if any).
- A dietary context statement<sup>1</sup> is included with the health claim which:
  - (i) states that the stated health effect must be considered in the context of a healthy diet involving the consumption of a variety of food; and
  - (ii) is appropriate to the type of food or property of food that is the subject of the claim and the health effect claimed.

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<sup>1</sup> Not required on foods in a small package

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- The dietary context statement includes words to the effect of any relevant dietary context statement provided in Column 4 of **Schedule 3**.
  - The food complies with any relevant conditions in Column 5 of **Schedule 3** of Standard 1.2.7.
  - A statement concerning the form of the food to which the claim relates is included with the health claim (unless the claim relates to the form of the food as sold).
  - The nutrient or biologically active substance that is the subject of the claim has been included in the nutrition information panel (NIP) on the label of the package containing the food.
  - None of the words used in the health claim alter or contradict the effect of a statement or information required by Standard 1.2.7.

## Checklist for General Level Health Claims (systematic review)

This checklist is to assist food businesses when making general level health claims based on self-substantiated food-health relationships and is useful for documenting due diligence. It should be read in conjunction with 'Getting Your Claims Right: A Guide to Complying with the Nutrition, Health and Related Claims Standard of the Australia New Zealand Food Standards Code'.

### Claims not permitted or foods not permitted to carry claims by Standard 1.2.7.

You need to tick **all** of the following boxes to ensure that you are not making a claim prohibited by Standard 1.2.7.

- The claim is not about kava or about an infant formula product.
- The claim is not about a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about energy or carbohydrate content.
- The claim does not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition.
- The claim does not compare a food with a good that is represented in any way to be for therapeutic use; or likely to be taken for therapeutic use, whether because of the way in which the food or substance is presented or for any other reason.
- The claim does not compare the vitamin or mineral content of a food with another food, unless specifically permitted by another Standard in the Code.

### Standard 1.2.7 applies

You need to tick **all** of the following boxes to ensure that Standard 1.2.7 applies to the claim and to the food that the claim is about.

- The food the claim is made about does not require further processing, packaging, or labelling prior to retail sale.
- The food will not be delivered to a vulnerable person by a delivered meals organisation, or provided to a patient in a hospital or other similar institution, other than a food in a package.

- The claim is not managed by another standard of the Australia New Zealand Food Standards Code (e.g. Standard 2.9.5 – Foods for Special Medical Purposes).
- The claim does not concern risks or dangers of alcohol consumption, or concern moderating alcohol intake.
- The claim is not a mandatory declaration required by the Act (as defined in the Food Standards Code).

### Conditions for making general level health claims

You need to tick **all** the following boxes to ensure that your claim complies with Standard 1.2.7.

- The words in the claim do not refer to a serious disease or a biomarker of a serious disease.
- The correct Nutrient Profiling Scoring Criterion (NPSC) category is identified for the food (**Schedule 4**), except for food standardised in part 2.9 of the Food Standards Code.
- The nutrient profiling score is calculated correctly and is below the number specified for its category in the NPSC (**Schedule 4**).
- The health claim is based on the details of a relationship between a food or property of food and a health effect that has been established by a process of systematic review described in **Schedule 6** of Standard 1.2.7.
- The person responsible for making the claim has notified the CEO of FSANZ of the details of the relationship between a food or property of food and a health effect that has been established by a process of systematic review described in **Schedule 6** of Standard 1.2.7.
- The person giving notice to the CEO of the Authority has provided:
  - (i) the name of the person giving the notice and the address in Australia or New Zealand of that person;
  - (ii) consent to the publication by the Authority of information concerning the relationship that is the subject of the notice plus information in (i) above; and
  - (iii) certification that the relationship that is the subject of the notice provided in question 3 above has been established by a process of systematic review that is described in **Schedule 6**.

- The responsible person has records to demonstrate, if requested by a relevant authority,
  - (i) the systematic review was conducted in accordance with the process of systematic review described in **Schedule 6**; and
  - (ii) the notified relationship is a reasonable conclusion of the systematic review.
- A dietary context statement<sup>1</sup> is included with the health claim which:
  - (i) states that the stated health effect must be considered in the context of a healthy diet involving the consumption of a variety of food;
  - (ii) is appropriate to the type of food or the property of food that is the subject of the claim and the health effect claimed; and
  - (iii) is a reasonable conclusion of the systematic review.
- A statement concerning the form of the food to which the claim relates is included with the health claim (unless the claim relates to the form of the food as sold).
- The nutrient or biologically active substance that is the subject of the claim has been included in the nutrition information panel (NIP) of the package containing the food.
- None of the words used in the health claim alter or contradict the effect of a statement or information required by Standard 1.2.7.

### Schedule 6 components

- A statement has been made that describes the food or property of food, the health effect and the proposed relationship between the food or property of food and the health effect.
- A search strategy has been provided that describes how scientific evidence has been captured relevant to the proposed relationship, between the food or property of food and the health effect, including inclusion and exclusion criteria.
- A final list of studies has been provided, based on the inclusion and exclusion criteria, in support of the proposed relationship.
- Studies in humans have been reviewed and are included as part of the evidence provided in support of the claimed food-health relationship.

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<sup>1</sup> Not required on foods in a small package

- A table with key information from each included study has been provided as part of demonstrating compliance with **Schedule 6**. This table must include information on:
  - (a) the study reference;
  - (b) the study design;
  - (c) the objectives;
  - (d) the sample size in the study groups and loss to follow-up or non-response;
  - (e) the participant characteristics;
  - (f) method used to measure the food or property of food including amount consumed;
  - (g) confounders measured;
  - (h) the method used to measure the health effect;
  - (i) the study results, including effect size and statistical significance; and
  - (j) any adverse effects.
  
- An assessment of the quality of each included study has been undertaken that includes, as a minimum:
  - (a) a clearly stated hypothesis;
  - (b) minimisation of bias;
  - (c) adequate control for confounding;
  - (d) the study participants' background diets and other relevant lifestyle factors;
  - (e) study duration and follow-up adequate to demonstrate the health effect; and
  - (f) the statistical power to test the hypothesis.
  
- An assessment of the results of the included studies as a group has been provided, that considers whether:
  - (a) there is a consistent association between the food or property of food and the health effect across all high quality studies;
  - (b) there is a causal association between the consumption of the food or property of food and the health effect that is independent of other factors (with most weight given to well-designed experimental studies in humans);

- (c) the proposed relationship between the food or property of food and the health effect is biologically plausible; and
- (d) the amount of the food or property of food to achieve the health effect can be consumed as part of a normal diet of the Australian and New Zealand populations.

A conclusion has been provided based on the results of the studies that includes:

- (a) whether a causal relationship has been established between the food or property of food and the health effect based on the totality and weight of evidence.
- (b) where there is a causal relationship between the food or property of food and the health effect:
  - (i) the amount of the food or property of food required to achieve the health effect; and
  - (ii) whether the amount of the food or property of food to achieve the health effect is likely to be consumed in the diet of the Australian and New Zealand populations or by the target population group, where relevant.

## Checklist for High Level Health Claims

This checklist is to assist food businesses when making high level health claims and is useful for documenting due diligence. It should be read in conjunction with 'Getting Your Claims Right: A Guide to Complying with the Nutrition, Health and Related Claims Standard of the Australia New Zealand Food Standards Code'.

### Claims not permitted or foods not permitted to carry claims by Standard 1.2.7.

You need to tick **all** of the following boxes to ensure that you are not making a claim prohibited by Standard 1.2.7.

- The claim is not about kava or about an infant formula product.
- The claim is not about a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about energy or carbohydrate content.
- The claim does not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition.
- The claim does not compare a food with a good that is represented in any way to be for therapeutic use; or likely to be taken for therapeutic use, whether because of the way in which the food or substance is presented or for any other reason.
- The claim does not compare the vitamin or mineral content of a food with another food, unless specifically permitted by the Food Standards Code.

### Standard 1.2.7 applies

You need to tick **all** of the following boxes to ensure that Standard 1.2.7 applies to the claim and to the food that the claim is about.

- The food the claim is made about does not require further processing, packaging, or labelling before retail sale.
- The food will not be delivered to a vulnerable person by a delivered meals organisation, or provided to a patient in a hospital or other similar institution, other than a food in a package.
- The claim is not managed by another standard of the Australia New Zealand Food Standards Code (e.g. Standard 2.9.5 – Foods for Special Medical Purposes).



- The claim does not concern risks or dangers of alcohol consumption, or concern moderating alcohol intake.
- The claim is not a mandatory declaration required by the Act (as defined in the Food Standards Code).


### Conditions for making high level health claims

You need to tick **all** the following boxes to ensure that your claim complies with Standard 1.2.7.

- The words in the claim refer to a serious disease or a biomarker of a serious disease.
- The correct Nutrient Profiling Scoring Criterion (NPSC) category is identified for the food (**Schedule 4**), except for food standardised in part 2.9 of the Food Standards Code.
- The nutrient profiling score is calculated correctly and is below the number specified for its category in the NPSC (**Schedule 4**).
- The health claim states the food or property of food mentioned in Column 1 of **Schedule 2** of Standard 1.2.7.
- The health claim states the specific health effect mentioned in Column 2 of **Schedule 2** of Standard 1.2.7.
- The health claim refers to the relevant population group in Column 3 of **Schedule 2** to which the health effect relates (if any).
- A dietary context statement<sup>1</sup> is included with the health claim which:
  - (i) states that the stated health effect must be considered in the context of a healthy diet involving the consumption of a variety of food; and
  - (ii) is appropriate to the type of food or property of food that is the subject of the claim and the health effect claimed.
- The dietary context statement includes words to the effect of any relevant dietary context statement provided in Column 4 of **Schedule 2**.

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<sup>1</sup> Not required on foods in a small package

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- The food complies with any relevant conditions in Column 5 of **Schedule 2** of Standard 1.2.7.
  - A statement concerning the form of the food to which the claim relates is included with the health claim (unless the claim relates to the form of the food as sold).
  - The nutrient or biologically active substance that is the subject of the claim has been included in the nutrition information panel (NIP) of the package containing the food.
  - None of the words used in the health claim alter or contradict the effect of a statement or information required by Standard 1.2.7.



