



20 October 2004

Project Manager – Proposal P293
Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
Australia

Re Proposal P293 – Nutrition, Health and Related Claims

Thank you for providing the National Heart Foundation of New Zealand with the opportunity to comment on Proposal P293 – Nutrition, Health and Related Claims.

The Heart Foundation is the charity that leads the fight against cardiovascular disease (heart, stroke and blood vessel disease). We are committed to promoting heart health and reducing the suffering and early loss of life from heart disease through heart research, heart health promotion and rehabilitation.

The Heart Foundation aims to influence the food industry to produce, promote and signpost healthier food choices to consumers that are consistent with the Ministry of Health's Food and Nutrition Guidelines.

The accompanying document is a submission from the Heart Foundation that addresses the questions posed within the assessment report.

Tony Duncan
Executive Director
National Heart Foundation of New Zealand

Submission

Proposal P293 – Nutrition, Health and Related Claims Initial Assessment Report

National Heart Foundation of New Zealand

20 October 2004

To:

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SUBMITTER RESPONSE

From the National Heart Foundation of New Zealand – Part 2 of Submission.

PROPOSAL P293

NUTRITION, HEALTH AND RELATED CLAIMS

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IMPORTANT

Instructions on how to use this Booklet are provided on page 2.

FSANZ has proposed three options for the regulation of nutrition, health and related claims in the Initial Assessment Report (IAR) for Proposal P293. The options, described in more detail in section 9 of the [P293 - IAR](#) and summarised in the Executive Summary are:

- Option 1** Maintain the status quo;
- Option 2** Develop a new Standard and Guideline(s) for nutrition, health and related claims (with criteria and conditions for general level claims in a Guideline; high level claims in a Standard); and
- Option 3** Develop a new Standard for nutrition, health and related claims (with criteria and conditions for both general level claims and high level claims in the Standard).

**** What do you think are the advantages and disadvantages of Option 1?**

Answer:

**** What do you think are the advantages and disadvantages of Option 2?**

Answer:

**** What do you think are the advantages and disadvantages of Option 3?**

Answer:

**** What is your preferred regulatory option and why? (go to Question 106, p97 of [P293 - IAR](#))**

Answer:
See Part 1 of the Heart Foundation's submission.

Potential risks to public health and safety

To what extent does the level of compliance and non-compliance with the Code of Practice on Nutrient Claims in Food Labels and Advertising (CoPoNC) impose costs on industry and consumers? How significant are these costs? (go to **Question 1 at p18 of [P293 - IAR](#)**)

Answer:

FSANZ has pointed out the CoPoNC is voluntary and that government enforcement agencies are unable to enforce compliance. This situation would seem to jeopardise one of FSANZ's key objectives – the protection of public health and safety.

The Heart Foundation cannot comment on the level of enforcement and compliance that the AFGC is able to achieve under CoPoNC.

An unpublished survey carried out by the Heart Foundation of NZ in 2003 showed a large number of products to be making fat claims less than 97% minimum required by the CoPoNC. For example in one category 19/36 (53%) products carrying fat free claims had claims between 92% - 96% fat free.

The cost to consumers of non-compliance with CoPoNC is misleading information - with the potential for consumers making poorer dietary choices and therefore reduced potential for public health improvements. The cost to industry and government is a lack of trust in food labelling.

What are the likely impacts on consumption patterns arising from a permission to make claims relating to nutrition and health? If there is a consequential risk to public health and safety, how significant do you consider this risk to be? Please provide any evidence you have to support your response to the extent of these risks. (go to **Question 2 at p18 of [P293 - IAR](#)**)

Answer:

Provided nutrition and health claims are well-enforced, well-substantiated and have a comprehensive education strategy around them, the consumer public health and safety risks will be minimised.

The use of well-regulated claims relating to nutrition and health can encourage improvements in food formulation, improve access to healthier food choices and ultimately improve the food supply.

Would consumers in general (or specific consumer groups) benefit from a broader range of nutrition, health and related claims? If so, which claims? (go to **Question 3 at p19 of [P293 - IAR](#)**)

Answer:

The Heart Foundation believes that nutrition, health and related claims have the potential to extend the reach of nutrition messages. Furthermore they may improve the food supply by creating competition between manufacturers to produce healthier food products.

What opportunities could industry take up in terms of product development and placement? Provide examples or data to show how significant the opportunities are to industry at present. (**go to Question 4 at p19 of [P293 - IAR](#)**)

Answer:

Industry could support public health strategies by formulating products to meet criteria for carrying public health messages, and assist public health agencies in communicating the benefits of healthier dietary patterns for improved nutrition/public health.

Providing benchmarks for food manufacturers has been demonstrate to provide an incentive for industry to improve the formulation of its products. For example within the Tick Program over half of the products involved in the program have been formulated or reformulated to meet the Guidelines for Tick Approval.

The benefit of the Tick, not only extends to products within the program but to products without the Tick, as some manufacturers use the guidelines to improve the nutrition profile of non-Tick products. See - Williams P et al, Health Promotion International, 18:51-56, 2003 (attached to our hard copy of submission).

Recent research found that in a one-year period, the Tick Program in New Zealand worked with food companies to exclude 33 tonnes of salt from the food supply. This was achieved through the reformulation of 23 products in just three categories - breakfast cereals, breads and margarines. See – Young L et al. Health Promotion International, 17:13-19, 2002 (attached to our hard copy of submission).

FSANZ claim descriptors

General level claim

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

** Do you think the working definition of a ‘general level claim’ captures all the possible types of claims which would not reference a biomarker or a serious disease or condition? (go to **Question 5 at p29 of P293 - IAR**. You may also wish to refer to subsection 5.4.5, p33 of [P293 - IAR](#) for the proposed working definition of a serious disease).

Answer:
 Yes. Recommend removal of brackets around ‘includes’ and ‘content’.
 Definition should have consistency with the glossary.

High level claim

Term	<i>Proposed FSANZ Working Definition</i>
high level claim	is a claim which references a biomarker or a serious disease or condition and [includes] biomarker maintenance claims, biomarker enhancement claims and risk reduction claims which reference a serious disease or condition.

** Do you think the working definition of a ‘high level claim’ captures all the possible types of claims which would reference a biomarker or a serious disease or condition? (go to **Question 6 at p30 of P293 - IAR**. You may also wish to refer to subsection 5.4.5, p33 of the [P293 - IAR](#)) for the proposed working definition of a serious disease).

Answer:
 Recommend removal of brackets around ‘includes’.

Therapeutic claim

Term	<i>Proposed FSANZ Working Definition</i>
therapeutic claim	is a claim [outside the context of the total diet] which refers to the prevention, treatment, alleviation or cure of a disease, ailment, defect or injury.

For example, ‘This food is high in iron for the treatment and prevention of anaemia.’

** Are there any circumstances not adequately captured by the proposed wording of FSANZ’s working definition of a ‘therapeutic claim’? (go to **Question 7 at p31 of P293 - IAR**)

Answer:
 Recommend removal of [outside the context of the total diet]. Claims to the effect that a food will prevent, treat, alleviate or cure of a disease, ailment, defect or injury, should be considered therapeutic whether expressed within the context of the total diet or not

The Heart Foundation is concerned that the terms ‘may’ and ‘could’ prevent, treat etc will be used by manufacturers to avoid the classification of the claim as ‘therapeutic’ and therefore the definition should include words such as ‘that a food will, or possibly will, prevent...’.

Should the definition of a therapeutic claim explicitly include claims that can be interpreted as medical advice or is this already implied in the definition? Or should such claims be treated separately? (go to **Question 8 at p31 of [P293 - IAR](#)**)

Answer:

Does the terminology of ‘disease, ailment, defect or injury’ in the definition of a therapeutic claim, in contrast to the high level claim definition which centres on disease, conditions or biomarkers, cause any specific problems? (go to **Question 9 at p32 of [P293 - IAR](#)**)

Answer:

Serious disease

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

** Should a reference to ‘disorders, conditions or defects’ be included in the definition of serious disease? (go to **Question 10 at p33 of [P293 - IAR](#)**)

Answer:

The Heart Foundation believes that the definition of serious disease should include the concept of a condition that is of public health significance – so that it would include obesity. ‘Public health significance’ may be able to be defined in terms of the proportion of population affected, or a condition that has been identified by government as a key health priority for the population. In addition, ‘suitably qualified health care professional’ should be amended to read ‘suitably qualified medical practitioner’.

Would it be useful to include a list of serious diseases/conditions in a guideline document? Do you have any suggestions about the proposed list of serious diseases/conditions? (go to **Question 11 at p33 of [P293 - IAR](#)**)

Answer:

The Heart Foundation notes that making the distinction between a serious disease and non-serious disease is difficult and that clear guidelines need to be created. For example, does FSANZ consider dehydration a serious condition - it can require diagnosis by a doctor, and can be fatal.

The Heart Foundation considers that a list of serious and non-serious conditions should be provided in the standard and that obesity and possibly overweight should be considered serious diseases.

Should claims in relation to cancer be permitted in food regulation? (go to **Question 12 at p33 of [P293 - IAR](#)**)

Answer:

Non-serious disease

Is there a need to define 'non-serious disease' in the Standard for nutrition, health and related claims? (go to **Question 13 at p33 of [P293 - IAR](#)**)

Answer:

Non-serious diseases or conditions should be defined by FSANZ and a list of such conditions provided in the standard.

Can you provide examples of what may constitute a non-serious disease or condition. (go to **Question 14 at p33 of [P293 - IAR](#)**)

Answer:

Examples of non serious conditions may include fatigue (e.g. muscle fatigue), constipation, vomiting, colds, flu, dental caries.

Biomarker

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

Do you prefer the term 'biomarker' to that of 'surrogate outcome'? (go to **Question 15 at p34 of [P293 - IAR](#)**)

Answer:

The term biomarker is preferred to surrogate outcome, as it is a simpler term and easier to understand. However, it should not really matter which term is used if it is appropriately defined in the standard.

**** What practical implications do you see from the proposed definition? (go to **Question 16 at p34 of [P293 - IAR](#)**)**

Answer:

As it is very difficult to determine when a higher level of claim is 'implied' by the wording used in a general level claim, the Heart Foundation believes that a list of approved function claims, enhanced function claims and risk reduction claims for non-serious diseases are listed in the standard – that is, that general level claims are pre-approved by FSANZ, just as high level ones are. This then removes the need for industry and enforcement agencies to have to determine what a 'biomarker' is or what a 'serious disease is'. This will also reduce the potential for misleading and confusing claims, which will ultimately undermine consumer confidence in FSANZ and food labelling.

What practical implications do you see from the proposed criteria for use of biomarkers in substantiation? (go to **Question 17 at p34 of [P293 - IAR](#)**)

Answer:

These criteria may need to be more explicit or objectively expressed - eg what does 'highly predictive' mean?

Other related claim descriptors

Content claim

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

**** Should the descriptor for a 'content claim' refer to biologically active substances or other substances in addition to nutrients and energy? (go to **Question 18 at p36 of [P293 - IAR](#)**)**

(Please refer to [Attachment 6](#) for a discussion of issues related to the regulation of biologically active substances and other substances in food.)

Answer:

Recommend removal of brackets around 'explicitly or implicitly' from the content claim definition, in order to capture content claims that have an implication of nutritional content e.g. no added sugars.

The Heart Foundation believes that biologically active substances should be included within content claims. FSANZ should develop a list of biologically active substances that can be claimed – however it is noted that there are often no generally agreed recommended intakes and this will produce difficulties in determining minimum levels (criteria) suitable for making content claims.

Health claim

Term	<i>Related Claim Descriptor</i>
health claim	a claim, other than a therapeutic claim, that describes or indicates [explicitly or implicitly] that a relationship exists between the consumption of a food, a category of food or one of its constituents and health.

**** Do you agree that in accordance with the FSANZ Claims Classification Framework all claims other than content claims are health claims? (go to Question 19 at p37 of [P293 - IAR](#))**

Answer:

Yes. However, the terminology is not as important as giving explicit direction to industry and enforcement agencies on appropriate claims (both function claims and diet/health relationships) - hence the Heart Foundation's recommendation that general level claims are also pre-approved.

Function claims

Term	<i>Related Claim Descriptor</i>
function claim	a general level claim which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in [normal] growth, development, maintenance and other like functions of the body.
For example, 'Linoleic acid, one of the family of Omega-6 fatty acids is essential for healthy skin' or 'Calcium aids in the development of strong bones and teeth'.	
enhanced function claim	a general level claim which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] beyond [normal] growth, development, maintenance and other like functions of the body.

For example, ‘A high fibre diet may help to improve bowel function’.

**** Should claims other than content claims (that is, health claims) be made in relation to biologically active substances? (go to Question 20 at p38 of [P293 - IAR](#))**

Answer:

The Heart Foundation believes that, in principle, health claims should be able to be made about biologically active substances provided they have been through the substantiation process.

Do you agree with the descriptors for a function claim and an enhanced function claim? (go to Question 21 at p38 of [P293 - IAR](#))

Answer:

It is recommended that the definition of enhanced function claim adds ‘e.g. improvements in physiological processes and functions’.

Risk reduction claim in relation to a non-serious disease or condition

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

Should the descriptor for a risk reduction claim include the word ‘significantly’? (go to Question 22 at p39 of [P293 - IAR](#))

Answer:

Whether a food or energy or a nutrient [or a biologically active substance] reduces the risk of developing a non-serious disease or condition will be determined by the substantiation framework, which takes into account the statistical significance of the relationship. The word ‘significantly’ therefore does not need to be listed within the definition of a risk reduction claim.

Are there likely to be claims which reference a non-serious disease or condition which would not be expressed as ‘risk reduction claims’? If so, is there a need to identify another sub-category of claim in the Claims Classification Framework? (go to Question 23 at p39 of [P293 - IAR](#))

Answer:

There is no need to identify another sub-category of claim in the Claims Classification Framework.

Biomarker claims

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

Should the descriptor for a biomarker maintenance claim and biomarker enhancement claim include the phrase 'recognised biomarker'?
(go to Question 24 at p40 of [P293 - IAR](#))

Answer:

If all approved claims are listed in the standard, then it is irrelevant if a biomarker is 'recognised' or not. The substantiation process should be robust enough that it prevents misleading claims involving unrecognised biomarkers.

Risk reduction claim in relation to a serious disease or condition

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

Should the descriptor for a risk reduction claim in relation to a serious disease or condition include the word 'significantly'? **(go to Question 25 at p42 of [P293 - IAR](#))**

Answer:

As with a non-serious disease or condition, whether a food or energy or a nutrient [or a biologically active substance] reduces the risk of developing a serious disease or condition will be determined by the substantiation framework, which takes into account the statistical significance of the relationship. The word 'significantly' therefore does not need to be listed within the definition of a risk reduction claim.

Are there likely to be claims that reference a serious disease or condition, which will not be expressed as 'risk reduction claims'. (go to **Question 26 at p42 of [P293 - IAR](#)**)

Answer:

Possible examples are those that don't explicitly include the term 'risk' e.g. "....reducing LDL-cholesterol is important for heart disease", and "....improving bone density is important for osteoporosis."

Issues Arising from the Claims Classification Framework

'Whole-of-diet' claims

Do you think the examples of whole-of-diet claims provided in the Policy Guideline are claims made in the context of the appropriate total diet; and do you think the way the claimed benefit is expressed determines where the claim is positioned in the Claims Classification Framework? (go to **Question 27 at p43 of [P293 - IAR](#)**)

Answer:

The Heart Foundation believes 'whole of diet' claims are potentially health claims, but the degree to which they are health claims will depend on the degree to which dietary patterns are linked to specific health aspects. They would more likely be considered 'health claim' if they mention the dietary pattern or food, and draw a link with health in a specific way. On the other hand, they would more likely be considered 'dietary advice' if they mention the dietary pattern or food, and draw no link with health in a specific way (i.e. they don't say will reduce 'overweight' or 'risk of disease' etc – e.g. 'the Dietary Guidelines recommend people eat five serves of fruit and vegetables every day').

The Heart Foundation believes criteria for 'whole of diet' claims should, where possible, reflect the nutrient of emphasis within the claim. For example the following claim 'a healthy, balanced diet that includes dietary fibre from a number of sources is one that can help reduce your risk of constipation' could only be permitted on foods that are at least a 'good source' of dietary fibre.

**** Should whole of diet claims always be coupled with a claimed benefit (for example, those illustrated in the Policy Guideline are linked to a risk reduction claim), or should whole-of-diet claims purely represent either the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guideline? If the latter, do you consider the claim to be dietary advice which would fall outside the scope of the regulatory framework for nutrition, health and related claims? (go to Question 28 at p43 of [P293 - IAR](#))**

Answer:

Both types of claims should potentially be able to be made, provided they are used appropriately and do not mislead consumers about the nature of the food on whose label or promotional material the claim appears.

For claims that emphasise a particular nutrient, the criteria for carrying that claim should relate to that nutrient, and may include additional criteria depending on the nature of the claim.

Performance and wellbeing claims

**** Given the general requirement that claims express a specific, rather than broad health benefit/outcome, do you think that general wellbeing claims or general performance claims that do not reference a specific benefit should be prohibited? (go to Question 29 at p44 of [P293 - IAR](#))**

Answer:

General wellbeing claims or general performance claims should be prohibited as the terminology is confusing and ill-defined, giving the impression of a benefit that is unlikely to be able to be substantiated.

Life stage claims

**** Are there any unintended impacts of regulating claims that refer to normal lifestages as general level claims? (go to Question 30 at p45 of [P293 - IAR](#))**

Answer:

Slimming claims

**** How do you think 'slimming claims' should be regulated? Please provide your rationale and supporting evidence. (go to Question 31 at p45 of [P293 - IAR](#))**

Answer:

Slimming claims should be regulated as high level claims, or prohibited on the basis that no one food can assist people to 'slim'. There is a high potential for misleading consumers with slimming-related claims, particularly in the current environment of celebrity diets and supposed 'quick fixes'.

The Heart Foundation suggests FSANZ develop and list a generic claim about energy balance and overweight/obesity.

Endorsements

**** What are the impacts on industry, enforcement agencies and consumers in regulating endorsements as nutrition, health and related claims? (go to Question 32 at p46 of [P293 - IAR](#))**

Answer:

See Part 1 of the Heart Foundation's submission.

Who should be responsible for substantiating an endorsement that is considered a general level claim and hold the evidence to support the claim? (go to Question 33 at p46 of [P293 - IAR](#))

Answer:

See Part 1 of the Heart Foundation's submission.

**** Can you provide examples of endorsements currently in the market place that may constitute a general level claim or a high level claim? (go to Question 34 at p46 of [P293 - IAR](#))**

Answer:

See Part 1 of the Heart Foundation's submission.

Can you provide any evidence that indicates how consumers interpret endorsement statements? (go to Question 35 at p46 of [P293 - IAR](#))

Answer:

See Part 1 of the Heart Foundation's submission.

Cause-related marketing

**** What are the impacts on consumers, public health professionals and industry of permitting cause-related marketing statements? (go to Question**

**36 at p47 of
[P293 - IAR](#)**

Answer:

Is there any evidence to indicate how consumers interpret cause-related marketing statements? (**go to Question 37 at p47 of [P293 - IAR](#)**)

Answer:

What words could be used in a disclaiming statement to ensure that cause-related marketing is not interpreted as a nutrition, health or related claim? (**go to Question 38 at p47 of [P293 - IAR](#)**)

Answer:

Implied claims

Are you able to provide any evidence that indicates how consumers may interpret various types of representations of claims? (**go to Question 39 at p47 of [P293 - IAR](#)**)

Answer:

See Part 1 of the Heart Foundation's submission for evidence that the majority of consumers correctly interpret the meaning of the Heart Foundation's 'Tick'.

**** Does FSANZ need to establish criteria to enable industry and enforcement agencies to determine whether the representation of a claim conveys a greater perceived health benefit to the consumer? If so, what might these criteria be? (**go to Question 40 at p47 of [P293 - IAR](#)**)**

Answer:

This would not be necessary for word claims if the standard lists all approved general level and high level claims. However it may be necessary for visual images which may imply nutrition, health or related claims. Enforcement agencies should request and consider any research undertaken by the food manufacturer relating to consumer interpretation of artwork which may represent a nutrition or health claim.

Setting criteria and conditions for claims

**** Can the criteria and conditions that apply to content claims establish the minimum criteria and conditions for other general level claims? (go to Question 41 at p55 of [P293 - IAR](#))**

Answer:

Potentially yes – that is, criteria for certain claims could potentially be based on definitions of ‘low’, ‘reduced’, ‘increased’ etc.

However, an exception for this would be for Certification Trade Mark endorsement programs such as the Tick Program in which the criteria consider a range of nutrients together, and the feasibility of the combination of nutritional criteria based on the current food supply – this approach represents a more comprehensive assessment of a product’s suitability to carry the Tick, and the claim of ‘healthier choice within a food category’ that it represents. **See Part 1 of the Heart Foundation’s submission.**

In addition, do these criteria and conditions need to be taken into account in pre-market assessment and approval of high level claims? (go to Question 42 at p55 of [P293 - IAR](#))

Answer:

No – the rigorous substantiation process for high level claims should set the most appropriate criteria for these claims.

**** What factors need to be taken into account when establishing criteria which apply to general level claims that describe a relationship between a whole food and a specific health benefit? For instance, claims in relation to the whole food could only be made where that food is a primary food (i.e. fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish) otherwise the claim would need to specify the component within the food (i.e. nutrient, energy or biologically active substance) that is linked to the claim benefit. (go to Question 43 at p55 of [P293 - IAR](#))**

Answer:

‘Whole food’ claims should be permitted on foods that are consistent with the recommendations of national dietary guidelines in Australia and/or New Zealand (provided these are regularly reviewed) – these could be both primary foods and processed foods that meet criteria reflecting that they are ‘healthier choices’.

However these claims need to be used appropriately and not mislead consumers about the nature of the food on whose label or promotional material the claim appears.

Substantiation

** Does the Substantiation Framework clearly establish the processes FSANZ will use to assess high level claims? (go to Question 44 at p56 of [P293 - IAR](#))

Answer:

Yes. However, it does not clearly describe how the information should be presented to FSANZ. There are tools and templates available to guide this process i.e. evidence tables, critical appraisal tools (refer www.epiq.co.nz) which may assist manufacturers. FSANZ may wish to give guidance on the presentation of the information.

Have the different study types and evidence sources been described accurately and adequately for the purposes of the Substantiation Framework? (go to Question 45 at p56 of [P293 - IAR](#))

Answer:

No, the Heart Foundation does not agree with the categorisation of primary and secondary sources. It is unclear whether FSANZ places greater weighting on primary or secondary sources.

The Heart Foundation does not agree that systematic reviews and meta-analysis be described as secondary sources as they potentially provide a more unbiased and informative view of the literature than single 'pivotal studies'.

The Heart Foundation would support further consideration of potential conflicts of interest when describing information sources that have not undergone a peer-review process.

Under 'Language and other requirements for applications' the final sentence should read "*abstracts or summaries of articles are **never** sufficient to allow detailed evaluation.*"

The Heart Foundation does not agree that 'pivotal studies' can be objectively determined for the purposes of substantiation and sees the introduction of bias into the substantiation process if manufacturers were allowed to self-select these studies from a systematic process.

The Heart Foundation would like to see quantification of the phrase "*substantial number of human studies*" under 'convincing evidence' to remove uncertainty in definition.

Do you agree with the proposed evidence requirements for substantiating high level claims? (go to Question 46 at p56 of [P293 - IAR](#))

Answer:

Yes, the Heart Foundation agrees with the proposed evidence requirements for substantiating high level claims with the above amendments. However, the Heart Foundation supports the approval of high level claims based on convincing evidence only. As such, the final sentence under 'classifying the likelihood that the proposed claim is substantiated' should read "...*approval of such claims **will require** convincing scientific evidence so as to offer reasonable certainty...*".

** Does the Substantiation Framework clearly establish the processes manufacturers should use to assess general level claims? (**go to Question 47 at p56 of [P293 - IAR](#)**)

Answer:

Generally – except there should be a list of texts and authoritative sources. This list should include the evidence-based policy documents of the National Heart Foundation of Australia and the National Heart Foundation of New Zealand.

What practical issues do you envisage will arise when attempting to follow the Substantiation Framework to substantiate a general level claim? (**go to Question 48 at p56 of [P293 - IAR](#)**)

Answer:

Defining "other relevant national, diet-related policy documents released by authoritative bodies" could prove to be problematic.

Are there authoritative evidence sources that could be included in the appropriate evidence sources for general level claims? (**go to Question 49 at p57 of [P293 - IAR](#)**)

Answer:

Text currently in use by dietetic training programmes is probably sufficient at this time.

Would you support FSANZ producing an indicative list of acceptable authoritative evidence sources? (**go to Question 50 at p57 of [P293 - IAR](#)**)

Answer: Yes, refer Question 47.

Do you support FSANZ developing a list of model general level claims and associated qualifying/disqualifying criteria, to help manufacturers/suppliers streamline the substantiation of claims? These model general level claims may be included in interpretive user guides. (**go to Question 51 at p57 of [P293 - IAR](#)**)

Answer:

Yes. The Heart Foundation supports the development of a **comprehensive** list of general level claims to assist manufacturers but primarily to ensure consistency of messages to the public. These should be included in the standard. New claims should be submitted to FSANZ for approval. With public health frameworks describing a need to improve communications in food and nutrition, this action would go some way to aligning health and nutrient claims to that communications goal.

Issues regarding high level claims

Consultation on the priority list for pre-approved high level claims

A list of 23 diet-disease relationships that form the basis of health claims approved in other countries is provided in [Attachment 7](#) to the IAR.

** Which of the health claims in [Attachment 7](#) to the IAR do you believe would have the most public health impact? (go to **Question 52 at p63 of [P293 - IAR](#)**)

Answer:

Health claims may have public health impact if they lead to improvements in the food supply via strict criteria for their use, and through widespread reach of substantiated health messages.

If health claims are approved then those claims that impact on the chronic disease burden of Australia and New Zealand are likely to be preferred by public health interest groups, but also need to be attractive to, and used by, manufacturers.

The factors influencing appeal to, and use by, manufacturers include: ease of communication; relevance/interest to consumers; simple relationships that can be acted on. Therefore these industry-appeal criteria should be considered alongside the public health criteria of: condition represents a substantial disease burden (personal, social and economic perspectives), condition is strongly influenced by diet (quality of evidence and strength of effect); encourages food reformulations and therefore changes in the food supply.

Foods carrying health claims should not be priced out of the reach of nutritionally vulnerable groups such as Aboriginal, Maori, Pacific Islands people and those in lower socioeconomic groups.

Which of the health claims approved overseas would industry wish to make? (go to Question 53 at p63 of [P293 - IAR](#))

Answer:

Cannot comment on behalf of industry, but refer FSANZ to a recent study on nutrition label claims in the US – LeGault L et al, J Am Diet Assoc, 2004, 104:952-958.

What factors do you consider in prioritising the list of health claims in terms of scientific validation? (go to Question 54 at p63 of [P293 - IAR](#))

Answer:

Agree with points 1-6 in attachment 7 (page 273) as key factors, but with emphasis on those groups that display a greater relative prevalence of the disease burden, specifically Aboriginals, Maori, Pacific Islands people and those in lower socioeconomic groups.

Are there any other health claims that you believe should be considered for pre-market assessment? (go to Question 55 at p63 of [P293 - IAR](#))

Answer:

In both Australia and New Zealand, saturated fat intakes are approximately twice that recommended, fruit and vegetable intake is low, and there is no clear definition of 'whole grain' food products.

There are strong relationships of diet with heart disease, and many of the possible pre-approved claims concerning heart disease would satisfy the criteria mentioned in our response to question 52.

The Heart Foundation recommends that priority pre-approved claims would be: saturated/trans fat and heart disease; fruit, vegetables, whole-grains and heart disease; sodium/potassium and blood pressure; omega-3 fats and heart disease; energy balance and obesity.

Review of pre-approved high level claims

What do you consider would be an appropriate process to undertake a regular review of approved claims? (go to Question 56 at p64 of [P293 - IAR](#))

Answer:

Proactively, FSANZ could convene a technical committee of key independent academics and those with knowledge of the scientific research to meet annually or biannually to consider relevant changes in nutrition research, dietary surveys or consumer food trends and how these might impact on existing or proposed claims. There should also be a process whereby anyone can reactively challenge existing claims and this process should be open and transparent. The Heart Foundation supports FSANZ's accepting applications to change the claims listed in the standard on a case-by-case basis.

The Heart Foundation does support the revision of approved claims linking with dietary guidelines revisions, however it is mindful that dietary guidelines in New Zealand have not been reviewed for more than 10 years. This time period would seem unacceptable for review of approved claims.

What risks would there be in maintaining a watching brief on new or contrary evidence as opposed to conducting a regular review? (go to **Question 57 at p64 of [P293 - IAR](#)**)

Answer:

There is always the potential to miss information from key data sources. It does not take into account information that may be presented outside of the literature, such as conference presentation of new and emerging research. A watching brief is an unsystematic approach to what FSANZ has established as a very systematic process i.e. substantiation of high level claims.

Implications of the claim-by-claim approach to pre-market assessment

Given the claim-by-claim approach to pre-assessing claims, can you foresee any circumstance where a manufacturer can gain an exclusive right to a claim? (go to **Question 58 at p64 of [P293 - IAR](#)**)

Answer:

If so, does this present a problem in the context of the broader regulatory framework for nutrition, health and related claims? (go to **Question 59 at p64 of [P293 - IAR](#)**)

Answer:

Consumer research

Are you aware of any additional consumer research on nutrition, health and related claims? (go to **Question 60 at p71 of [P293 - IAR](#)**)

Answer:

See Part 1 of the Heart Foundation submission for research related to the Tick Program.

Education

What do you consider to be the essential components of an education strategy for nutrition and health claims? (go to **Question 61 at p73 of [P293 - IAR](#)**)

Answer:

Support the five suggestions for promotion of health claims as recorded on page 72. The Heart Foundation encourages FSANZ to ensure that these strategies are appropriate for nutritionally vulnerable groups such as Maori, Pacific Islands people and those in lower socioeconomic groups and integrated into any broader social marketing approach to nutrition that may be developed in either country.

Who should be responsible for undertaking such education activities? (**go to Question 62 at p73 of [P293 - IAR](#)**)

Answer:

FSANZ, NZFSA, NGO's, and the food industry.

How can stakeholders work together to develop and implement an education strategy for industry, health professionals and consumers in relation to the proposed regulatory framework for nutrition health and related claims? (**go to Question 63 at p73 of [P293 - IAR](#)**)

Answer:

The Heart Foundation encourages facilitation and investment by FSANZ into a robust implementation strategy that is inclusive of all relevant stakeholders and grounded in appropriate educational and learning theory.

Compliance and enforcement

Would it be more appropriate for the 'manufacturer' or the 'supplier' to hold and produce evidence in relation to a general level claim? (**go to Question 64 at p75 of [P293 - IAR](#)**)

Answer:

This would not be necessary if general level claims were pre-approved and listed in the standard.

What are the legal and/or practical difficulties for an enforcement agency when requesting and assessing evidence in relation to general level claims? (go to Question 65 at p75 of [P293 - IAR](#))

Answer:

If general level claim substantiation were left up to industry, there would be considerable difficulties imposed on enforcement agencies. Such agencies would need to be resourced with staff with a high level of knowledge in relation to assessing substantiation. In essence they would need to be replicating the process of assessing the quality, strength, totality, bias etc of the evidence (while not needing to collect it).

If however, FSANZ were to pre-approve general claims and list them in the standard, as the Heart Foundation recommends, this would not be necessary – enforcement agencies would just need to ensure that claims reflected the requirements of the standard.

Under existing food legislation, are the current powers of enforcement agencies to 'call on' evidence in support of general level claims, adequate? (go to **Question 66 at p75 of [P293 - IAR](#)**)

Answer:

From the point of view of industry, consumers, public health professionals and enforcement agencies, what are the benefits of including certain criteria and conditions relating to general level claims in a Guideline instead of a Standard? (go to **Question 67 at p75 of [P293 - IAR](#)**)

Answer:

From the point of view of industry, consumers, public health professionals and enforcement agencies, what are the costs of including certain criteria and conditions relating to general level claims in a Guideline instead of a Standard? (go to **Question 68 at p75 of [P293 - IAR](#)**)

Answer:

If criteria and conditions are listed in a non-enforceable guideline, this creates greater potential for non-compliance and therefore, for misleading information that ultimately may be of detriment to public health.

From the point of view of industry, consumers, public health professionals and enforcement agencies, which interpretive guides should be given priority during the Standard development process? (go to **Question 69 at p76 of [P293 - IAR](#)**)

Therapeutic goods and foods

From the point of view of food and medicine enforcement agencies and food and medicine manufacturers, can the proposed FSANZ Conceptual Framework for the Regulation of Nutrition, Health and Related Claims ensure a clear boundary at the food-medicine interface for foods carrying health related claims? (go to **Question 70 at p80 of [P293 - IAR](#)**)

Answer:

From the view point of food and medicine enforcement agencies and food and medicine manufacturers, would the proposed FSANZ Conceptual Framework for the Regulation of Nutrition, Health and Related Claims and proposed Substantiation Framework promote equality between the regulation of foods and medicines? (go to **Question 71 at p81 of [P293 - IAR](#)**)

Answer:

Fair trading legislation

With the exception of unqualified 'free' claims, are there any areas where the regulation of nutrition, health and related claims and fair trading provisions might be inconsistent or in conflict? (go to **Question 72 at p82 of [P293 - IAR](#)**)

Answer:

It is important that the food standard recognises that Certification trade marks have been assessed under fair trading laws. The standard development should ensure that there is no duplication or inconsistency with the processes already undertaken for approval of Certification trade marks.

Monitoring and evaluation

Can the jurisdictions provide enforcement data on food categories where the use of nutrition, health and related claims may be a problem? (go to **Question 73 at p84 of [P293 - IAR](#)**)

Answer:

Can the food industry provide data on the types of food categories currently carrying content or function claims, a folate/neural tube defect health claim or endorsements? (go to **Question 74 at p84 of [P293 - IAR](#)**)

Answer:

Impact analysis - consumers and the community

Regulatory Option 1 – Status quo

Are consumers currently being presented with consistent messages regarding the role of individual foods in improving or maintaining health? (go to **Question 75 at p87 of [P293 - IAR](#)**)

Answer:

If not, what is the extent of any inconsistency and what is the impact on consumers? (go to **Question 76 at p87 of [P293 - IAR](#)**)

Answer:

What is the impact of the general prohibition on health claims on the ability of consumers to make informed choices about foods? (go to **Question 77 at p87 of [P293 - IAR](#)**)

Answer:

Are consumers' choices being distorted towards purchasing dietary supplements in preference to food not carrying health claims? Is so, to what extent is this occurring? (go to **Question 78 at p87 of [P293 - IAR](#)**)

Answer:

What, if any, are the impacts on consumers of choosing to purchase dietary supplements over food? (go to **Question 79 at p87 of [P293 - IAR](#)**)

Answer:

Are consumers in Australia confused or misled by current nutrition content claims? If so, to what extent is this occurring? (go to **Question 80 at p88 of [P293 - IAR](#)**)

Answer:

Are consumers in New Zealand confused or misled by the absence of specified criteria for making content claims? If so, to what extent is this occurring? (go to **Question 81 at p88 of [P293 - IAR](#)**)

Answer:

To what extent has CoPoNC been effective in providing a framework to facilitate informed consumer choice? (go to **Question 82 at p88 of [P293 - IAR](#)**)

Answer:

Regulatory Option 2 – Standard and Guideline

In what circumstances would consumers be prepared to pay higher prices for foods carrying claims? (go to **Question 83 at p88 of [P293 - IAR](#)**)

Answer:

Under Option 2, is there a risk of consumers losing a whole of diet perspective when choosing food? (go to **Question 84 at p89 of [P293 - IAR](#)**)

Answer:

To what extent could this risk be addressed through education and the efforts of health professionals? (go to **Question 85 at p89 of [P293 - IAR](#)**)

Answer:

Under Option 2, what would be the impacts on consumers of including a greater range of claims in a Guideline, which is not legally enforceable? (go to **Question 86 at p89 of [P293 - IAR](#)**)

Answer:

To what extent would consumers use additional information presented in health claims and in what circumstances would this be of benefit to them? (**go to Question 87 at p89 of [P293 - IAR](#)**)

Answer:

Regulatory Option 3 - Standard

Under what circumstances would consumers be prepared to pay higher prices for foods carrying claims? (**go to Question 88 at p90 of [P293 - IAR](#)**)

Answer:

Under Option 3, is there a risk of consumers losing a whole of diet perspective when choosing food? (**go to Question 89 at p90 of [P293 - IAR](#)**)

Answer:

To what extent can this risk be addressed through education and the efforts of health professionals? (**go to Question 90 at p90 of [P293 - IAR](#)**)

Answer:

Does Option 3 provide greater benefits to consumers than Option 2 in relation to the reliability and validity of general level claims? If so, why? (**go to Question 91 at p90 of [P293 - IAR](#)**)

Answer:

Impact analysis - industry

To what extent, if any, has your business been disadvantaged by the current ambiguities regarding the prohibition on health claims? (**go to Question 92 at p90 of [P293 - IAR](#)**)

Answer:

To what extent does the current prohibition on health claims prevent real marketing opportunities for your products or limit innovation? (go to **Question 93 at p91 of [P293 - IAR](#)**)

Answer:

To what extent, if any, is the Australian food industry disadvantaged by being unable to make health claims on products that compete with imports? (go to **Question 94 at p91 of [P293 - IAR](#)**)

Answer:

In Australia, how effective is [CoPoNC](#) in providing guidance to industry on content claims and does the fact that it is not legally enforceable create compliance problems? (go to **Question 95 at p91 of [P293 - IAR](#)**)

Answer:

In New Zealand, are there any costs to industry from a general reliance on fair trading provisions to manage content claims? If so, please identify these costs. (go to Question 96 at p91 of [P293 - IAR](#))

Answer:

How effective is CoPoNC in providing guidance to industry in marketing current products and developing new products? (go to **Question 97 at p91 of [P293 - IAR](#)**)

Answer:

Regulatory Option 2 - Standard and Guideline

Can industry indicate the nature and extent of compliance costs that could be incurred under Option 2? (go to **Question 98 at p92 of [P293 - IAR](#)**)

Answer:

Can industry indicate the probable cost of complying with the need to develop systems to compile and assess evidence to substantiate general level claims? (go to Question 99 at p92 of [P293 - IAR](#))

Answer:

What would be the impact on your business arising from a permission to use high level claims? In your response consider marketing opportunities and potential sales revenue. (go to Question 100 at p93 of [P293 - IAR](#))

Answer:

What would be the impact on your business arising from permission to use a greater range of general level claims? In your response, consider marketing opportunities and potential sales revenue. (go to Question 101 at p93 of [P293 - IAR](#))

Answer:

10.2.3 Regulatory Option 3 - Standard

To what extent, does Option 3 provide greater benefits to your business than Option 2 in relation to general level claims? (go to Question 102 at p93 of [P293 - IAR](#))

Answer:

Impact analysis - government

Regulatory Option 1 – Status quo

What are the impacts of the current regulatory arrangements on enforcement agencies? Please provide evidence of the level of resources involved. (go to Question 103 at p95 of [P293 - IAR](#))

Answer:

Regulatory Option 3 - Standard

To what extent would Options 2 and 3, that permit a wider range of claims, require additional resources to enforce? (go to **Question 104 at p95 of [P293 - IAR](#)**)

Answer:

Are there any additional benefits for government in proceeding with Option 3? If so, please identify. (go to **Question 105 at p95 of [P293 - IAR](#)**)

Answer:

Transitional issues

** Are there any reasons why the proposed transitional arrangements should be shortened, lengthened or otherwise changed? (go to **Question 99 at p192 of [P293 - IAR](#)**)

Answer:

Review

While the Policy Guideline points to an assessment of the effectiveness of the 'watchdog' body, what aspects of the system for regulating nutrition, health and related claims should be a priority for review within two years of the implementation of the Standard? (go to **Question 108 at p100 of [P293 - IAR](#)**)

Answer:

Noting that the focus of the review is on implementation, compliance and enforcement under the health, nutrition and related claims system, who should be involved in conducting such a review and how might this be undertaken? (go to **Question 109 at p100 of [P293 - IAR](#)**)

Answer:

Criteria and Conditions for Content Claims
([Attachment 6](#) of Initial Assessment Report)

Placement of content claims

What is the best approach for the placement of generic content claims? Please provide a rationale to support your preferred approach. (go to **Question 1 at p201 of [Attachment 6](#) of P293 - IAR**)

Answer:

The Heart Foundations preferred approach is the placement of the generic content claims within a legally enforceable standard. This will ensure that all of industry is on an equal playing field and reduce the likelihood of misleading, non-compliant claims.

Eligibility of food

Should any foods be prohibited from making content claims, other than those standards already stipulated in the Code? Please provide evidence and a cohesive rationale to support your answer. (go to **Question 2 at p201 of [Attachment 6](#) of P293 - IAR**)

Answer:

Methods of analysis

Do you think that there should be provisions that stipulate analytical methods for content claims? If yes, what is the appropriate approach or what are the appropriate methods? (go to **Question 3 at p202 of [Attachment 6](#) of P293 - IAR**)

Answer:

The Heart Foundation supports FSANZ's approach not to prescribe individual analytical methods for content claims.

The Heart Foundation acknowledges that it would be ideal if all manufacturers used IANZ or NATA accredited laboratories for testing of nutrient levels for claims but this would be a significant cost to industry and is not likely to be able to be easily monitored or enforced.

Synonyms

Are each of the synonyms listed in section 2.3 in Attachment 6 similar in meaning? Should the list be considered 'exhaustive' and therefore stipulated in a standard in the Code or 'illustrative' and therefore provided in a guideline document as examples for manufacturers to use. (go to **Question 4 at p204 of [Attachment 6](#) of P293 - IAR**)

Answer:

The Heart Foundation believes that synonyms should be listed within the standard and other claims prohibited.

Where a definition of 'very high' is not provided in the standard, it should be made clear that the terms like 'very high' or 'excellent' cannot be used for contents greater than the definition of 'high'. On the other hand, if a product meets the definition of, say, 'very high', then it should also be clear that the label can also use terms that indicate lesser amounts, eg 'high', 'provides', or 'source'.

Conditions regarding food for consumption

Do you agree with CoPoNC's conditions regarding food for consumption? If not, please provide a rationale for why they are not appropriate. (go to **Question 5 at p205 of [Attachment 6](#) of P293 - IAR**)

Answer:

The Heart Foundation agrees that the claim criteria should be relevant to the food 'as prepared for consumption' according to the directions on the pack. If there are several ways that the food can be prepared for consumption, then it should be clear for which preparation method the claim is correct.

Foods naturally or intrinsically high or low in a nutrient

Do you agree with CoPoNC and NZFR conditions for foods naturally or intrinsically high or low in a nutrient? If not, please explain why you think they are not appropriate. (go to **Question 6 at p204 of [Attachment 6](#) of P293 - IAR**)

Answer:

The Heart Foundation agrees with the current CoPoNC and NZFR provisions. However guidelines should be created to assist with identifying whether certain foods should claim whether or not the food is required to refer to the food being naturally or intrinsically high or low in a nutrient or not. The example used by FSANZ is bread being naturally low in fat, however there are some higher fat grainy breads containing around 8g/100g of fat.

Normal counterpart or reference foods

Do you agree with CoPoNC requirements for 'normal counterpart' or 'reference foods'? If not, please explain why you think they are not appropriate. (go to **Question 7 at p207 of [Attachment 6](#) of P293 - IAR**)

Answer:

- The Heart Foundation agrees that the reference food should be of the same food type.

- Determining ‘average’ or ‘weighted averages’ of nutritional values across the market is difficult, but the Heart Foundation suggests the provisions remain as they are given the complexities and the ever-changing market.
- To facilitate accuracy, it would be useful if the proposed User Guide specifies appropriate food composition tables to use, and where they can be accessed.
- In addition, FSANZ’s food composition tables should be regularly updated to reflect the changing marketplace.

Comparative claims

FSANZ’s preferred criteria for comparative claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
‘reduced’, ‘increased’ ‘less than’	With the exception of micronutrients, the comparison should be based on a relative difference of at least 25% in the energy value or relevant nutrient content. The identity of the reference food and the percent, fraction or amount of difference in energy value or nutrient content should be indicated adjacent to the comparative claim. Comparative claims should only be made between foods of the same food group or foods that may substitute for one another in the diet.

Should these comparative claims be permitted? Briefly explain. (go to **Question 8** at p206 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation agrees that comparative claims of ‘reduced’ (and synonyms) and ‘increased’ (and synonyms) should be permitted – with the exception of reduced cholesterol claims.

If permitted, do you agree with FSANZ’s preferred criteria? (go to **Question 9** at p206 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation agrees with FSANZ’s preferred criteria for ‘increased’ claims.

However, the Heart Foundation recommends that claims for ‘reduced (or less than) fat’ and ‘reduced (or less than) sugar(s)’ should have an additional criterion that they are at least 25% reduced in kilojoules/energy.

** Should there be an additional criterion that relates to energy when ‘reduced’ and ‘less than’ claims are made in relation to total fat and sugar? If so, what criteria should apply and what evidence supports such an approach? (go to **Question 10** at p206 of [Attachment 6](#) of P293 - IAR)

Answer:

Comparative claims for fat and sugar should be permitted, with the additional criterion that they are at least 25% reduced in kilojoules, as consumers may perceive these claims to mean a reduction in energy density when this might not be the case.

A survey conducted by the Heart Foundation of NZ in 2003 showed evidence that some products claiming reduced in fat only had a small reduction in energy. Within a certain category five products carried reduced fat or lite/light claims of 25% - 50% less fat, however the reduction in energy for these products was on average only 13%.

'Free' claims

FSANZ's preferred criteria for 'free':

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
'Free'	No provisions.

Should 'free' claims be permitted? Briefly explain. (go to **Question 11 at p208 of [Attachment 6](#) of P293 - IAR**)

Answer:

The Heart Foundation believes 'free' claims should be permitted but understands the difficulty of potential inconsistency with fair trading laws. It is suggested that attention is drawn to the requirements of fair trading laws within the standard.

If permitted, do you agree with FSANZ's preferred criteria? (go to **Question 12 at p208 of [Attachment 6](#) of P293 - IAR**)

Answer:

It is suggested that to reduce potential for confusion, the proposed criterion of 'no provisions' is replaced with something like 'none present (needs to comply with fair trading legislation)'.

In addition, the Heart Foundation recommends FSANZ consider defining additional requirements for a term such as 'negligible', to give industry some flexibility for products with extremely low, or virtually zero, contents of nutrients.

Energy

FSANZ's preferred criteria for energy claims:

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Low calorie, low joule, low energy</i> (as per Std 1.2.8 Clause 14)	The average energy content of the food is no more than 80 kJ per 100 ml of beverages or other liquid foods and no more than 170 kJ per 100 g of solid or semi-solid foods. For claims relating to 'calories', the energy declaration in the NIP must be expressed as calories as well as kilojoules.
<i>Reduced calorie, reduced joule, reduced energy</i>	The comparison should be based on a relative difference of at least 25% in the energy value. The identity of the reference food and the percent, fraction or amount of difference in energy value should be indicated adjacent to the comparative claim. For claims relating to 'calories', the energy declaration in the NIP must be expressed as calories as well as kilojoules.
<i>Calorie free</i>	No provisions.

Should these energy claims be permitted? Briefly explain. (go to Question 13 at p210 of [Attachment 6](#) of P293 - IAR)

Answer:

These should be permitted. These claims have the ability to help consumers identify lower energy options which may assist in weight loss and/or management.

If so, do you agree with FSANZ's preferred criteria? (go to Question 14 at p210 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation supports FSANZ's preferred criteria.

Protein

FSANZ's preferred criteria for protein claims:

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>'source of protein'</i>	≥ 5 grams of protein per serving and ≥ 12% of energy value of the food must be provided by protein
<i>'good source/ high in protein'</i>	≥ 10 grams of protein per serving and ≥ 20% of energy value of the food must be provided by protein

Should these protein claims be permitted? Briefly explain. (go to Question 15 at p213 of [Attachment 6](#) of P293 - IAR)

Answer:
Yes.

If so, do you agree with FSANZ's preferred criteria? (go to Question 16 at p213 of [Attachment 6](#) of P293 - IAR)

Answer:
The Heart Foundation agrees with the proposed criteria. Consideration should be given to a disclosure statement indicating the energy content of the food.

Fats

FSANZ's preferred criteria for fat claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Low (in) fat</i>	$\leq 3\text{g per }100\text{g}; \leq 1.5\text{ ml per }100\text{ ml liquid food.}$
<i>Reduced (in) fat</i>	The comparison should be based on a relative difference of at least 25% in the fat content. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim.
<i>Fat free</i>	No provisions.
<i>% fat free</i>	The food must meet the requirements specified for the 'low fat' claim.

Should these fat claims be permitted? Briefly explain. (go to Question 17 at p215 of [Attachment 6](#) of P293 - IAR)

Answer:
These claims should be permitted.

However, a survey conducted by the Heart Foundation of NZ in 2003 showed common use of '% fat free' claims on high sugar, high energy products containing very little nutritional value. For example 21/68 (31%) of non chocolate confectionary products reviewed contained claims of 97%, 98%, 99% or 100% fat free. Such claims have the potential to mislead consumers that the products would be a healthier choice.

If so, do you agree with FSANZ's preferred criteria? (go to Question 18 at p215 of [Attachment 6](#) of P293 - IAR)

Answer: The Heart Foundation proposes that a disclosure statement about energy content is required to accompany '% fat free' claims.

In addition, there should be an additional criterion for 'reduced fat' claims of 25% reduction in energy.

The Heart Foundation questions the manner in which a 'liquid food' can be determined e.g. yoghurts, ice-cream, chunky soups – there needs to be more clarity as to which criterion to use for these types of products.

Should there be an additional criterion that relates to energy for 'reduced fat' claims? If so, what criteria should apply and what evidence supports such an approach? (go to **Question 19** at p216 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation recommends that FSANZ include a minimum reduction of 25% energy for all reduced fat, reduced sugar and light (lite) claims.

A survey conducted by the Heart Foundation of NZ in 2003 showed evidence that some products claiming reduced in fat only had a small reduction in energy. Within a specific food category, five products carried reduced fat (25% - 50% less fat) or lite/light claims. The average reduction in energy for these products was only 13%.

As with other comparative claims, there should be a statement of comparison with the normal counterpart.

Saturated and trans fat

FSANZ's preferred criteria for saturated and trans fat claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Low (in) saturated fat/ Low in saturated and trans fat</i>	<p>≤ 1.5 g in total of saturated and trans fatty acids per 100g of solids; ≤ 0.75 g in total of saturated and trans fatty acids per 100 ml of liquids. The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).</p>
<i>Reduced (in) saturated fat/ Reduced in saturated and trans fat</i>	<p>The comparison should be based on a relative difference of at least 25% in the saturated and trans fatty acid intake. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim. The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).</p>
<i>Saturated fat free</i>	No provisions.

Should these saturated and trans fat claims be permitted? Briefly explain. (go to Question 20 at p219 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation recommends people choose foods that are low in saturated and trans-unsaturated fats. The permitting of low saturated and trans-unsaturated claims is a positive way that the food industry can assist consumers in identifying foods low in saturated and trans-unsaturated fats.

In addition, provisions should be made for 'low in trans fat' or 'reduced in trans fat' claims, as these are likely to be used by the food industry.

If so, do you agree with FSANZ's preferred criteria? (go to Question 21 at p219 of [Attachment 6](#) of P293 - IAR)

Answer:

All these claims should require the combination of saturated plus trans fats to be addressed in their criteria, not saturated fat alone, or trans fat alone. This is because trans fats act similarly to saturated fats in increasing LDL cholesterol levels (on an equal weight basis).

The Heart Foundation recommends that the criteria for 'low in saturated fat' and 'low in trans fat' claims (or any combination of these eg 'low in saturated and trans fat') be the same. There should be two alternative definitions (manufacturer to choose), based on an 'absolute' low level or a 'relatively' low level. The recommended definitions are: saturated + trans fat of 1.5g/100g or less in a solid food (0.75g/100g or less in a liquid food) **or** saturated + trans fat of 20% of total fats or less. This latter option allows oils and high oil foods such as nuts and mayonnaise to make the claim and supports the notion that the ratio of saturated to unsaturated fatty acids is more important than a reduction in saturated fatty acids alone.

'Reduced' claims related to saturated and/or trans fat should be based on a relative difference of at least 25% in the saturated + trans fat content, with the other requirements as proposed by FSANZ. In addition, there should be a disqualifier that there is no increase in trans fat levels (this is because the science demonstrates that gram for gram, trans fats are potentially more harmful than saturated fats).

The Heart Foundation supports the requirement of listing all four fatty acids in the panel for any claims related to any fatty acids or cholesterol.

Is there merit in a disqualifier for 'low in saturated fat/low in saturated and trans fat'? A possible option is that saturated fat must not provide more than 10% of energy. (go to Question 22 at p219 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation further recommends that all 'low' or 'reduced' fatty acid claims require a disclosure statement about energy content (eg 'see NIP for energy content').

Is there justification in considering a new criterion for 'low in saturated fat/low in saturated and trans fat' claims, such that the total of saturated fatty acids and trans fatty acids comprises no more than 28% of the total fatty acid content of the food? What advantages and disadvantages would such a criterion provide in comparison to FSANZ's preferred option? (go to Question 23 at p219 of [Attachment 6](#) of P293 - IAR)

Answer:

Yes – see answer to 21.

Is there merit in a disqualifier for 'reduced in saturated fat/reduced in saturated and trans fat', such that there should be no increase in trans fatty acids? (go to **Question 24 at p219 of [Attachment 6](#) of P293 - IAR**)

Answer:

Yes – see answer to 21.

Polyunsaturated, monounsaturated and omega fatty acids

FSANZ's preferred criteria for polyunsaturated, monounsaturated and omega fatty acid claims.

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Polyunsaturated or monounsaturated fatty acid content of a food</i>	See Standard 1.2.8, clause 12 of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).
<i>In relation to omega-3 fatty acids</i>	See Standard 1.2.8, sub-clauses 13 (1), (2) and (3) of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the source of omega-3 fatty acids in accordance with sub-clause 13(5) and the editorial note following sub-clause 13(6).
<i>Good source of omega-3 fatty acids</i>	See Standard 1.2.8, sub-clause 13(4) of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the source of omega-3 fatty acids in accordance with sub-clause 13(5) and the editorial note following sub-clause 13(6).
<i>In relation to</i>	See Standard 1.2.8, sub-clause 13(6) of the Code.

<i>omega-6 or omega-9 fatty acids</i>	The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the editorial note following sub clause 13(6).
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Should these polyunsaturated, monounsaturated and omega fatty acid claims be permitted? Briefly explain. (go to **Question 25 at p222 of [Attachment 6](#) of P293 - IAR**)

Answer:
 The Heart Foundation recommends people to eat moderate amounts of monounsaturated and polyunsaturated fats and for these fats to replace saturated and trans-unsaturated fats in the diet. The Heart Foundation supports the labelling of foods that are sources of monounsaturated, polyunsaturated and omega fatty acids, but only on foods that are also low in saturated and trans-unsaturated fat.

Permitting claims for unsaturated fats is a positive way for the food industry to can assist consumers choosing better fats.

If so, do you agree with FSANZ's preferred criteria? (go to **Question 26 at p222 of [Attachment 6](#) of P293 - IAR**)

Answer:
 The Heart Foundation supports FSANZ's preferred criteria.

Should the Code be clarified in relation to polyunsaturated and monounsaturated fat claims? Two possible options are that:

- (a) the provisions should only relate to 'source of' claims in order to ensure consistency with omega-6 and omega-9 claims; or
- (b) there should be provisions for 'source', 'good source' and 'increased' claims to ensure consistency with other content claims.

(go to **Question 27 at p222 of [Attachment 6](#) of P293 - IAR**)

Answer:
 There should be provisions for 'source', 'good source' claims to ensure consistency with omega 3 claims.

Cholesterol

FSANZ's preferred criteria for cholesterol claims:

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Low (in) cholesterol</i>	PROHIBITED.
<i>Reduced (in) cholesterol,</i>	PROHIBITED.
<i>Cholesterol free</i>	PROHIBITED.

Should these cholesterol claims be permitted? Briefly explain. (go to **Question 28 at p224 of [Attachment 6](#) of P293 - IAR**)

Answer:
The Heart Foundation agrees with prohibiting claims related to cholesterol content.

If so, do you agree with FSANZ's preferred criteria? (Hgo to **Question 29 at p224 of [Attachment 6](#) of P293 - IAR**)

Answer:
The Heart Foundation agrees with FSANZ's preferred criteria.

Carbohydrate

FSANZ's preferred approach for carbohydrate claims

**** Is there merit in including provisions for making 'carbohydrate claims'?**
Please provide evidence to support any criteria for preferred 'carbohydrate claims', and suggest, with the support of evidence, where disqualifying criteria such as maximum sugar levels or minimum fibre levels would be required for foods to carry such carbohydrate claims. (go to **Question 30 at p227 of [Attachment 6](#) of P293 - IAR**)

Answer:
The Heart Foundation believes there should be no provisions for 'high', 'low', 'increased' or 'reduced' carbohydrate claims, as it is extremely difficult to determine 'normal' levels, due to the widely varying needs of people. In addition, the consumer interest in low carbohydrate diets for weight loss may encourage an excessive use of 'low carbohydrate' claims, which could add to consumer confusion about balanced healthy diets.

If high carbohydrate claims are ultimately allowed, it would be inappropriate to have a disqualifier related to sugars content, as sugars are carbohydrates, so the claim would be accurate and non-misleading.

**** Are Glycaemic Index and Glycaemic Load content claims? If so, what criteria should apply and what provisions should be made in relation to declaring the quantity for GI? (go to Question 31 at p227 of [Attachment 6 of P293 - IAR](#))**

Answer:

Glycaemic Index and Glycaemic Load should have criteria specified in the Code, because these claims are being used and will likely continue to be used. The Heart Foundation would support the definitions of Glycaemic Index as recommended by Professor Jennie Brand Miller, as she is a world recognised expert in this area.

Because GI concerns the effect of the food's carbohydrate on the body, and requires a minimum carbohydrate content in order to be measured, there should be a provision that GI claims only be on foods with a specified minimum carbohydrate content eg 10g per serve.

As GL claims are based on GI values, they should also be prohibited on foods that don't meet a minimum carbohydrate content.

GI and GL claims refer to the normal physiological impact of a food, so are probably best classified as nutrition function claims.

Sugar

FSANZ's preferred criteria for sugar claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Low (in) sugar(s)</i>	<p>≤ 5 g total sugars per 100g of food ≤ 2.5 g total sugars per 100 mL of liquid food. The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with sub-clauses (5) and (7) of clause 5 of Standard 1.2.8 of the Code.</p>
<i>Reduced (in) sugar(s)</i>	<p>The comparison should be based on a relative difference of at least 25% in the sugar content. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim. The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with sub-clauses (5) and (7) of clause 5 of Standard 1.2.8 of the Code.</p>

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>No added sugar/sugars</i>	<p>The claims cannot be made unless the food contains no added:</p> <ul style="list-style-type: none"> (i) hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or (ii) starch hydrolysate; or (iii) glucose syrups, maltodextrin and similar products; or (iv) products derived at a sugar refinery, including brown

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>(No added sugar/sugars Cont.)</i>	sugar and molasses; or (v) icing sugar; or (vi) invert sugar; or (vii) fruit sugar syrup; (viii) malt or malt extracts; or (ix) honey; or (x) concentrated and/or deionised fruit juice where it does not constitute the essential character of the food; and (xi) a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food.
<i>Unsweetened</i>	The claims cannot be made unless the food contains no added: (i) hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or (ii) starch hydrolysate; or (iii) glucose syrups, maltodextrin and similar products; or (iv) products derived at a sugar refinery, including brown sugar and molasses; or (v) icing sugar; or (vi) invert sugar; or (vii) fruit sugar syrup; (viii) malt or malt extracts; or (ix) honey; or (x) concentrated and/or deionised fruit juice where it does not constitute the essential character of the food; and no (xi) intense sweeteners; or (xii) sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol; and (xiii) a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food.
<i>Sugar free</i>	No provisions.

Should these sugar claims be permitted? Briefly explain. (go to Question 32 at p231 of [Attachment 6](#) of P293 - IAR)

Answer:
Yes.

If so, do you agree with FSANZ's preferred criteria? (go to Question 33 at p231 of [Attachment 6](#) of P293 - IAR)

Answer:
The Heart Foundation agrees with the recommendations by FSANZ. However 'No added sugar (s)' claims should have a disclosure statement referring to the natural sugars content of the food.

Should there be an additional criterion that relates to energy for 'reduced sugar' claims? If so, what criteria should apply and what evidence supports such an approach? (go to Question 34 at p231 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation recommends that FSANZ include a minimum reduction of 25% energy for all reduced sugar claims. Products carrying reduced sugar claims should include a statement of comparison with the normal counterpart.

Fibre

FSANZ's approach to fibre claims

** Is there merit in including disqualifying criteria for fibre claims? If so, what nutrients should be considered and what specific criteria should be applied? (go to Question 35 at p236 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation recommends a disclosure statement relating to kilojoule/energy content for 'high fibre' claims, to alert consumers to the energy density of the food.

On what basis should criteria be set for fibre claims? (go to Question 36 at p236 of [Attachment 6](#) of P293 - IAR)

Answer:

What qualifying criteria should apply to fibre claims? (go to Question 37 at p236 of [Attachment 6](#) of P293 - IAR)

Answer:

Is a 'very high fibre' claim necessary, given that there are no claims for 'very high' for any other nutrient? (go to Question 38 at p236 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation believes that 'very high fibre' or 'excellent source' claims are not needed and should be prohibited.

Should there be specific provisions for main dishes and meal type products? If so, what criteria should apply? (go to Question 39 at p236 of [Attachment 6](#) of P293 - IAR)

Answer:

Salt

FSANZ's Preferred Approach for Salt/Sodium Claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Low salt/sodium</i>	≤ 120 mg sodium per 100 g food.
<i>Very low salt/sodium</i>	No provisions.
<i>Reduced salt/sodium</i>	The comparison should be based on a relative difference of at least 25% in the sodium value. The identity of the reference food and the percent, fraction or amount of difference in sodium value should be indicated adjacent to the comparative claim.
<i>No added salt/sodium</i>	The food and the ingredients of that food contain no added sodium compound, no added salt or, as the case may be, are unsalted.
<i>Salt free</i>	No provisions.

Should these salt/sodium claims be permitted? Briefly explain. (go to **Question 40 at p239 of [Attachment 6](#) of P203 - IAR**)

Answer:
 Yes.
 High sodium consumption has proven links with high blood pressure, a key risk factor for cardiovascular disease.
 The manufacture and labelling of foods that are lower in sodium is a positive way that the food industry can assist consumers identifying lower sodium choices and lowering their sodium intakes.

If so, do you agree with FSANZ's preferred criteria? (go to **Question 41 at p239 of [Attachment 6](#) of P293 - IAR**)

Answer:
 The Heart Foundation agrees with FSANZ's preferred approach for salt/sodium claims.

Should there be additional criteria for 'no added salt/sodium' claims to address the issue of manufacturers making the claim on products that are not low in sodium? Please comment on the usefulness of the following two criteria:

- (a) The label or advertisement must include a statement adjacent to the claim drawing attention to the sodium content of the product as outlined in the nutrition information panel (for example, ‘See nutrition information panel for sodium content’); or
- (b) The food must be ‘low in salt’.

(go to **Question 42 at p239 of [Attachment 6](#) of P293 - IAR**)

Answer:
 The Heart Foundation supports a disclosure statement alerting consumers to the natural sodium present in a food as it will be useful in preventing consumer confusion related to ‘no added salt’ and ‘unsalted’ claims.

Gluten and lactose

FSANZ’s preferred approach for gluten and lactose claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>gluten free</i>	To be defined after the Ministerial review
<i>‘low’ gluten</i>	To be defined after the Ministerial review
<i>lactose free#</i>	no detectable lactose
<i>‘low’ lactose#</i>	≤ 0.3g of lactose per 100 g of the food
<i>Lactose reduced#</i>	The comparison should be based on a relative difference of at least 25% of the nutrient content. The identity of the reference food and the percent, fraction or amount of difference in energy value or nutrient content should be indicated adjacent to the comparative claim.

Where a claim is made in relation to the lactose content of a food, particulars of the lactose and galactose content of the food must be provided in the nutrition information panel.

Should these gluten and lactose claims be permitted? Briefly explain. (go to **Question 43 at p241 of [Attachment 6](#) of P293 - IAR**)

Answer:

If so, do you agree with FSANZ’s preferred criteria? (go to **Question 44 at p241 of [Attachment 6](#) of P293 - IAR**)

Answer:

Diet

FSANZ’s Preferred Approach for ‘Diet’ Claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Diet</i>	The food must meet the conditions for ‘low joule’ claims.

	The average energy content of the food is no more than 80 kJ per 100 mL of beverages or other liquid foods and no more than 170 kJ per 100 g of solid or semi-solid foods.
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Should this diet claim be permitted? Briefly explain. (go to **Question 45** at p243 of [Attachment 6](#) of IAR)

Answer:

If so, do you agree with FSANZ’s preferred criteria? (go to **Question 46** at p243 of [Attachment 6](#) of P293 - IAR)

Answer:

Light/lite

FSANZ’s Preferred Approach for ‘Light/Lite’ Claims

CLAIM	PREFERRED CRITERIA (AND CONDITIONS)
<i>Light or Lite</i>	The characteristic that makes the food ‘light/lite’ must be stated adjacent to the claim, regardless of whether the term applies to energy, a nutrient or a non-nutritional characteristic of the food. If the claim relates to a nutrient or energy, then the food must comply with the conditions for the corresponding ‘low’ or ‘reduced’.

Should these light/lite claims be permitted? Briefly explain. (go to **Question 47** at p244 of [Attachment 6](#) of P293 - IAR)

Answer:
 The Heart Foundation supports light/lite claims, provided they relate to nutrients or energy and not aesthetic characteristics of the food e.g. light in colour or flavour.

If so, do you agree with FSANZ’s preferred criteria? (go to **Question 48** at p244 of [Attachment 6](#) of P293 - IAR)

Answer:
 The Heart Foundation supports light/lite claims, provided they relate to nutrients or energy and not aesthetic characteristics of the food e.g. light in colour or flavour.

The Heart Foundation recommends that FSANZ include a minimum reduction of 25% energy for all light/lite claims except light/lite claims referring to a reduction in salt (sodium). Therefore for light/lite claims that relate to a reduction of 25% less sugar or 25% less fat there should also be a reduction of at least 25% of energy compared with the reference food.

All light/lite foods should contain a statement of comparison with the normal counterpart.

Biologically active substances

What are the most common claims in relation to biologically active substances? What criteria have been applied and what evidence is there to support them? (go to Question 49 at p244 of [Attachment 6](#) of P293 - IAR)

Answer:

**** Should criteria be set for certain claims and if so, what types of claims should be made and what criteria should apply? Please provide evidence and a cohesive argument to support your views. (go to Question 50 at p244 of [Attachment 6](#) of P293 - IAR)**

Answer:

The Heart Foundation supports the development of criteria for claims on biologically active substances, however there are difficulties because there are no officially recognised health reference standards for most of these.

Implied claims

Should 'lean' and 'extra lean' claims be defined? If so, what criteria should apply? (go to Question 51 at p245 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation proposes that 'lean' claims should require that the food is reduced or low in fat.

Should FSANZ develop a definition for implied content claims? If so, why? (go to Question 52 at p245 of [Attachment 6](#) of P293 - IAR)

Answer:

The Heart Foundation believes that implied claims should be treated on a case by case basis as with food regulation in other countries. However the need for this will be minimised if general level claims are pre-approved and listed in the standard.