ATTACHMENT 8

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

Substantiation of General Level Health Claims

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1. Overarching decision

FSANZ recommends that general level health claims must be substantiated according to the Scientific Substantiation Framework. One of the following four methods must be used to substantiate a general level health claim:

Method 1 List of nutrient function statements
Method 2 Prescribed list of pre-approved food-disease relationships for high level health claims
Method 3 Prescribed list of authoritative sources
Method 4 Systematic review

The supplier of the food carrying the general level health claim must have records that substantiate the claim and must make these available to the enforcement authority upon request.

The requirement that a general level health claim must be substantiated is prescribed in paragraph 6(1)(b) of the draft Standard. The Scientific Substantiation Framework is at Schedule 2 of the draft Standard.

2. Level of Evidence Required for General Level Health Claims and General Comments on the Scientific Substantiation Framework

2.1 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, two high level principles were described. These principles were:

- general level health claims will not be subject to pre-market assessment and approval by FSANZ because they do not reference a serious disease or a biomarker of a serious disease; and
- general level health claims will nonetheless be required to be scientifically substantiated. This requires the supplier to assess the evidence supporting the claim prior to market, holding this evidence and producing it at the request of enforcement officials.

The proposed substantiation of general level health claims was outlined in Chapter 4 of the Substantiation Framework (Attachment 8 to the Draft Assessment Report). Chapter 4 of that document presented a number of mechanisms that could be drawn on for substantiating general level claims. Briefly, these included: a pre-approved list of selected nutrient function statements; various authoritative information sources; and systematic review. The level of evidence to substantiate general level health claims was not explicitly stated in Chapter 4 but the content of the discussion indicated that the required level of evidence would be like that proposed to substantiate high level health claims (a level of evidence described at that time in the Framework as ‘convincing’).

The proposed Substantiation Framework document attracted a large number of submissions. Concerns were raised over the enforceability of the substantiation requirements of health claims and levels of evidence required for the substantiation of general level health claims.

2.2 Preliminary Final Assessment Report – approach taken and submitter comments

The Substantiation Framework was not included in the Preliminary Final Assessment Report. However, FSANZ recommended that the minimum level of evidence to support a general level health claim be established at 'probable', whereas a 'convincing' level would be required for high level health claims. At this time, FSANZ concluded that the level of evidence for the relationship between long-chain omega-3 fatty acids and cardiovascular disease was 'probable' and therefore could be used to support a general level health claim even though a high level health claim from this relationship had not been substantiated.

Several government agencies did not support a 'probable' level of evidence for general level health claims, citing lack of clarity and unenforceability as key objections. There was concern from some jurisdictions around a tiered approach to substantiation and some jurisdictions objected to a general level health claim being made based on a relationship that was found not to be 'convincing'. In addition, from further discussions held with enforcement agencies, it became apparent that the use of the descriptors 'probable' and 'convincing' was a source of confusion, the confusion being between the scientific and the legal use of these terms.

2.3 Consultation Paper (December 2007) – approach taken and submitter comments

In December 2007, FSANZ proposed to incorporate the requirements for substantiation of general level health claims as a schedule to the draft Standard, and proposed to restructure the Scientific Substantiation Framework from its earlier form for the following reasons:

- The language in the document needed to be more prescriptive in order for (i) jurisdictions to make clear decisions about whether enforcement action needs to be taken on the basis that a claim could not be substantiated and (ii) for stakeholders to follow a specific and clear process in order to substantiate the claim.

- Substantiation of nutrition content claims has been taken out of the Scientific Substantiation Framework because this type of claim is verified by analysing or calculating the value of the nutrient content of the food.

- Substantiation of food-disease relationships which form the basis of high level health claims has been removed from the Scientific Substantiation Framework because these types of claims are subject to pre-approval by FSANZ. The *Application Handbook* will detail what an applicant must provide to FSANZ in order to amend an existing high level health claim in the draft Standard or to seek pre-approval of a new food-disease relationship once the draft Standard has been gazetted.

In the explanatory material provided in the Consultation Paper (refer 3.1.1 *Summary of changes since the Draft and Preliminary Final Assessment Reports*, page 24) it was stated that 'In response to jurisdictional concerns, there is now one strength of evidence that applies to general and high level health claims'.

FSANZ proposed that there would be four methods available to substantiate a general level health claim:

Method 1 List of nutrient function statements.
Method 2 Prescribed list of pre-approved food-health relationships.
Method 3 Prescribed list of scientific source documents.
Method 4 Systematic review.

FSANZ received 65 submissions in response to the Consultation Paper. Of these submissions, all but four provided comment on substantiation. Many submitters chose not to express a clear position on the proposal to include the revised Scientific Substantiation Framework as a schedule to the draft Standard. However, of those who did express a view the majority did not support the proposal. Comments in support of putting the Framework into the draft Standard as a Schedule, included the approach being clearer and more precise. Submitters not expressing a clear view tended to support Methods 1 or 2 as proposed but expressed concern about Method 3 in particular. Supporters of Methods 1 and 2 often suggested that those methods could be incorporated into the draft Standard rather than as part of a Schedule, and that Methods 3 and 4 should be relocated to a User Guide. Submitters from all stakeholder sectors were in general support of FSANZ including a list of pre-approved statements to form a basis of general level heath claims within the draft Standard. The issues raised by stakeholders about each of the four methods are presented in more detail in the following sections.

Stakeholders from all sectors supported the necessity of substantiation of all health claims. Differences of opinion arise with regard to the proposed regulatory approach to substantiation and the level of prescription versus flexibility that is desired by the various stakeholders who will be users of the system. For enforceability, a prescriptive approach is desired. For flexibility, and perceived ease of updating information on a regular basis, approaches such as User Guides are preferred over the inclusion of detail about substantiation requirements in the draft Standard. Various stakeholders contend that including the proposed Schedule in the draft Standard will disallow sound scientific evidence being used as substantiation, and that using supporting documentation such as User Guides, rather than the Code, would aid flexibility. It was contended that it is logical, consistent and clearer to incorporate all the explanatory information about substantiation in the supplementary documentation. Some stakeholders contend that a User Guide approach would align with other regulatory systems such as that employed for complementary medicines, whilst others believe that the FSANZ proposal is consistent with requirements of the system for complementary medicines. Stakeholders who prefer to see the Framework in a User Guide, contend that it would be sufficient for the draft Standard to contain simpler requirements that all claims be truthful, scientifically substantiated, not misleading and capable of delivering the benefits (in its normal consumption occasion) in the context of a balanced diet only. Others suggested the minimal requirements in the draft Standard should be that information sources be credible, supported and up-to-date.

Some enforcement agencies submitted that the proposed approach is not yet prescriptive enough and sought to require that general level health claims be pre-approved to enable equitable enforcement action. It was submitted that it is not clear that the Framework as it stands would guarantee that some food-health relationships are ‘clear, confident and definitive’ and thus whether the same conclusions about the evidence would be reached by different manufacturers, resulting in consequences for monitoring and enforcement. The jurisdictions require that evidence for a food-health relationship be defensible in a court of law.

Enforcement agencies are concerned about the onus that will be placed on them to assess and weigh evidence to substantiate claims, contending that, being a voluntary system, the onus of responsibility to prove or not prove a claim should be on the manufacturer, not on the enforcement body. One agency argues that the proposed system creates an uneven playing field for small business with the likelihood that they will simply use the same claims as their larger competitors. Another says that having pre-approved claims and prescribed wording would eliminate the requirement for industry to prepare a dossier and hold the evidence.

Only a very small number of stakeholders provided direct comment with regard to the FSANZ position of December 2007 that 'there is now one strength of evidence that applies to general and high level health claims.' Stakeholders who did comment supported the approach, noting that 'convincing' at both levels is appropriate and helps to support the credibility of claims generally, and to ensure they are accurate and science-based, underpinned by a wealth of research. Other comments were about the importance of all claims being based on the totality of available evidence and the need for all food health relationships upon which claims are based to be proven beyond reasonable doubt. One submitter suggested alternative language to classify the required level of evidence based upon NHMRC guidelines for reviewing evidence and making clinical practice guidelines, that puts forward recommendations from a body of scientific evidence that is graded as 'good' or 'excellent'. That submitter recommended a consistent substantiation approach be adopted and the level of evidence, whether validated through either authoritative sources or from a systematic review, is required to be consistent and graded as 'consistent'. When the choice of language was addressed by other submitters, there was support from different stakeholder sectors for discontinuing use of the terms 'convincing' and 'probable' to describe levels of evidence. Stakeholders acknowledged that this would remove potential confusion with regard to the scientific and legal application of these terms. It was also stated that this would better facilitate consistent use and enforcement of the Scientific Substantiation Framework across jurisdictions due to the removal of a degree of subjectivity.

Several stakeholders indirectly opposed the proposition to raise the evidentiary requirements for general level health claims to meet those for high level health claims, through contending that FSANZ should allow a nutrient function statement about long-chain omega-3 fatty acids and heart health, as had been proposed in the Preliminary Final Assessment Report.

Other submitter comments about the proposed substantiation requirements were:

- Requests to clarify the meaning of 'clear and definitive' as used in the draft Schedule, as opposed to descriptors or legal terms such as 'consistent'.
- The suggestion to use limiting words such as 'may' or 'assists' to place perspective on the claim.
- Clarification that advertisers and not publishers should be held responsible for self-substantiating and holding the evidence for general level health claims.
- A suggestion that FSANZ provide training courses to company employees about how to analyse data and substantiate claims.
- Clarification as to whether it is the ingredient or the product formulation that is relevant.
- That the extrapolation of claims be justifiable and relevant to the nutrient level for the duration of the product's shelf life.

- The regulatory burden (cost of compliance) for small and medium enterprises remains disproportionate compared with large enterprises. Access to research and information is often costly. Substantiation requirements should not provide unfair advantage to larger organisations.
- Any regulatory requirement of the Code should not be onerous.
- There has been no estimation of the cost of enforcement.
- Query as to why the substantiation provisions do not extend to nutrition content claims, on the basis that consumers may be misled by such claims as to the composition, nutritional quality or quantity or health benefits of a food.
- FSANZ needs to ensure that companies understand the scientific substantiation rules and that issues regarding conflict of interest are avoided where possible and revealed where this is not possible.
- FSANZ needs to refer companies to independent experts who can guide them before they make claims that would be costly to retract.
- Processed food manufacturers have a greater capacity to invest in research and therefore to substantiate general level health claims compared to sellers of fresh produce.
- The draft Standard should not impose indirect costs of compliance.
- Manufactured and processed food should be required to meet a higher level of substantiation and compliance than fresh produce.
- The functionality of the draft Standard should not be driven by the ease of enforcement.

FSANZ has considered all the comments raised by submitters in response to the substantiation of general level health claims. Many of the recommended changes are reflected in Schedule 2 of the draft Standard. In this Attachment, FSANZ has commented only on those issues of major significance to the substantiation approach.

2.4 FSANZ response to submitter comments

FSANZ proposes to retain the Scientific Substantiation Framework to substantiate general level health claims as Schedule 2 of the draft Standard. This is because enforceability can be better assured through including requirements to substantiate claims as a Schedule to the draft Standard than through supporting material such as User Guides.

The four methods of substantiation have been retained in the Framework to provide food manufacturers with a range of substantiation choices of varying complexity. The scientific rigour underpinning each of the four methods ensures that the food-health relationships are 'clear, confident and definitive'.

There is generally a shared view amongst stakeholders that all health claims must be substantiated and that one level of evidence be used to substantiate both general and high level health claims. For general level health claims, the Scientific Substantiation Framework provides the guidance as to the amount and quality of evidence required to substantiate a food-health relationship. For high level health claims, the *Application Handbook* will provide the guidance as to the amount and quality of evidence required to substantiate a food-disease relationship.

3. Scientific Substantiation Framework – Method 1

3.1 Draft Assessment Report – approach taken and submitter comments

The Substantiation Framework included a list of pre-approved statements for recognised vitamins and minerals (refer pages 40-41 of Attachment 8 of the Proposal P293 Draft Assessment Report; Appendix 2 Table 1 and Table 2). The list was prepared by FSANZ taking into account the well understood and generally accepted roles of nutrients in the human body, and was intended to be indicative rather than exhaustive. It was felt that an indicative list would particularly assist those stakeholders (e.g. smaller industry) who might lack the resources necessary to substantiate general level health claims using more complex methods.

Submitter comments on Method 1 included:

- the absence of a nutrient function statement for vitamin A should be rectified;
- the suggestion that the pre-approved statements are included in the draft Standard;
- support for the list since it facilitates consistency of communication messages to consumers and eases the substantiation process for industry and enforcement agencies;
- recommendations that the list be extended to include more statements from the Joint Health Claims Initiative;
- a request for a commitment from FSANZ to continue to undertake new reviews for pre-approval of statements for general level health claims; and
- the suggestion that statements about saturated fat and sodium be included in the list.

It was commented that clarification is required with respect to the use of nutrition function statements from the Joint Health Claims Initiative list that have not been chosen for inclusion in the FSANZ list. It was questioned whether a statement that is in the Joint Health Claims Initiative list but not the FSANZ list could be used and considered substantiated subject to verification that the claim is relevant to Australian/New Zealand populations. It also questioned why some statements relating to iodine had not been included in the FSANZ list.

3.2 Consultation Paper (December 2007) – approach taken and submitter comments

In the Consultation Paper, FSANZ proposed to retain the list that had been included in the Draft Assessment Report to assist smaller suppliers in selecting a nutrient function in the knowledge that these statements were sufficiently substantiated. FSANZ proposed three changes to the indicative list that had been presented. Firstly, the nutrient function statement for docosahexaenoic acid (DHA) was removed because there are no criteria for qualifying claims about DHA in the Code on which to base a general level health claim; secondly, a vitamin A nutrient function statement was added; and thirdly, a second iodine nutrient function statement (iodine is necessary for normal brain development in the unborn child, babies and young children) was included in the revised list. The use of this indicative list as a basis for making a general level health claim was presented as Method 1 of Schedule 2 to the draft Standard.

This Method received almost unanimous support from those stakeholders who commented on Method 1.

One submitter expressed the view that the proposed nutrient function statements do not reflect current scientific evidence and that the statements do not necessarily reflect the most important function of that nutrient and in some cases are too restrictive. Several other submitters recommended that nutrient function statements about long-chain omega-3 fatty acids be added to the list: firstly, that a statement about DHA and the normal development of brain, eyes and nerves be reinserted; and secondly that a statement about long-chain omega-3 fatty acids and the relationship to heart health be added. To support these recommendations, submitters contended that criteria in clause 13 of Standard 1.2.8 - Nutrition Information Requirements could be used to support the DHA claim that had been removed, and that FSANZ assessment of the relationship between omega-3 fatty acids and cardiovascular disease in the Preliminary Final Assessment Report (where FSANZ concluded the evidence was 'probable') justified inclusion of the second statement. Some submitters went further, challenging FSANZ's assessment of the omega-3 relationship with cardiovascular disease and contended that the relationship is convincing.

Additional comments provided by submitters included:

- a suggestion to provide a mechanism with time intervals for the list of nutrient function statements to be modified or added to over time;
- a query over the use of 'food-health' when all the statements are about nutrients;
- a suggestion that wording of the statements should be prescribed; and
- a suggestion that the list be the only part of the proposed Scientific Substantiation Framework that is included in the draft Standard.

3.3 Key changes from proposed approach in the Consultation Paper

In this Final Assessment Report, FSANZ has only made minor amendments to Method 1. No nutrient function statements have been added to Table 1.

To improve clarity, the term 'food-health relationship' has been replaced with 'nutrient function statement' where appropriate under this method. Also, the words 'based on' have been deleted from clause 1.2 and replaced with 'consistent with' in response to a suggestion from a submitter.

3.4 FSANZ response to submitter comments

The list of nutrient function statements is indicative only. Comments from stakeholders indicated that this intent was not entirely clear under the Schedule as drafted in December 2007; as a result FSANZ has made minor wording changes to Method 1.

FSANZ has not included any nutrient function statements about saturated fat or sodium. The nutrient function statements generally imply that a health benefit is gained as intake of the nutrient increases and this is not considered appropriate for saturated fat and sodium. Method 2 allows general level health claims about a low intake of saturated fat or sodium to be derived from the relevant high level health claim.

A statement about omega-3 fatty acids and heart health has not been added to Table 1. Food manufacturers can use other methods in the framework to potentially substantiate this food-health relationship.

In the Draft Assessment Report, the list of pre-approved statements included a statement that 'DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves'. FSANZ removed this statement in December 2007, stating there are no criteria for claims about DHA in the Code on which to base a general level health claim. Submitters argued that conditions under clause 13 of Standard 1.2.8 could be used as a basis for the DHA statement and recommended the statement be reinserted in Table 1. Standard 1.2.8, clause 13 (which will be moved to the draft Standard) states that a nutrition claim must not be made about omega-3 fatty acid content of a food unless the food contains 200 mg alpha-linolenic acid per serving or 30 mg total eicosapentaenoic acid (EPA) and DHA per serving. Hence, this clause does not provide for claims that relate to DHA only, but provide for claims based on, amongst other things, the total EPA and DHA per serving. To include a DHA statement in Table 1, without conditions for a DHA claim, could result in use of a DHA claim on foods containing variable amounts of DHA and FSANZ believes that this could be misleading.

4. Scientific Substantiation Framework – Method 2

4.1 Draft Assessment Report – approach taken and submitter comments

The Substantiation Framework was included in the Draft Assessment Report (refer Attachment 8 to the Draft Assessment Report) however, Method 2 (refer Consultation Paper December 2007) was not proposed at that time.

4.2 Consultation Paper (December 2007) – approach taken and submitter comments

In the Consultation Paper, FSANZ introduced a mechanism for substantiating certain general level health claims and presented it as Method 2 of Schedule 2 of the draft Standard. This Method was intended to provide an alternative to those manufacturers who wish to use health claims based on pre-approved food-disease relationships but who do not wish to include mention of a disease in the claims they make (refer to the Table to clause 7 of the draft Standard). For example, instead of making a high level health claim about fruits and vegetables and coronary heart disease, Method 2 states that a manufacturer may make a claim about fruits and vegetables and heart health instead.

Of those who commented about Method 2, most viewed this method favourably and supported the approach. Some requested that FSANZ go further and pre-approve terms that would be considered appropriate alternatives to disease states, such as 'heart health' being an appropriate alternative to 'coronary heart disease' while others suggested that guidelines on what is and is not acceptable would be useful. Some requested clarification of the terminology used, and felt it was confusing to have to apply the term 'food-health' relationships to general level health claims but 'food-disease' to high level health claims. Others interpreted the method as being 'quite limited' as only five foods/nutrients are involved.

4.3 FSANZ response to submitter comments

FSANZ is retaining the approach presented in the Consultation Paper for Method 2.

In response to submitter comment, FSANZ considers that pre-approving specific terms would be overly prescriptive, however, further guidance will be provided in the User Guide. It was evident from various stakeholder comments about Method 2, that not all submitters had understood that the potential use of Method 2 would be limited only to those manufacturers wishing to use the health claims based on the pre-approved food-disease relationships (Table to clause 7 of the draft Standard) without mentioning a disease in their claims, i.e. for manufacturers who prefer to express the pre-approved substantiated relationship as a general level health claim rather than a high level health claim. FSANZ has made minor amendments to clarify this.

5. Scientific Substantiation Framework – Method 3

5.1 Draft Assessment Report – approach taken and submitter comments

The Substantiation Framework was included in the Draft Assessment (refer Attachment 8 to the Draft Assessment Report). Chapter 4 of the Substantiation Framework (pages 28-32) proposed five information sources as generally accepted information sources for manufacturers to self-substantiate (and hold the evidence for) general level health claims. These were:

1. national diet policy publications such as dietary guidelines and nutrient reference values;
2. position papers and scientific reviews published by peak authoritative organisations;
3. reviews conducted by internationally recognised scientific bodies (e.g. the Cochrane Collaboration and World Health Organization);
4. authoritative, current, science texts presently used in university dietetics courses (as listed by the Dietitians Association of Australia and the New Zealand Dietetic Association); and
5. reports of health claims assessed by overseas governments (conducted to the standards established by FSANZ for high level health claims).

In the Draft Assessment Report, the proposed information sources were presented as a relatively 'open' list of source documents. Stakeholders expressed concern that this did not provide a consistent evidence base for substantiation of general level health claims. Comments indicated that this approach was too open to interpretation and that documents of very different scientific rigour could be used. The jurisdictions viewed this approach as unable to be enforced.

In the Draft Assessment Report there was no indication as to what might constitute an 'internationally recognised scientific body'. Some jurisdictions expressed reservations of having relatively loosely defined criteria for source documents as it could permit the use of inappropriate work. It was also proposed that science texts used in dietetic courses be used for substantiating general level health claims. However, submitters commented that these texts cover a wide range of topics, some of which were not relevant to substantiating general level health claims. This approach also would have excluded appropriate textbooks that were not used in dietetics courses.

5.2 Consultation Paper (December 2007) – approach taken and submitter comments

In the Consultation Paper, amendments to the proposed list of acceptable information sources were made. These amendments were designed to address stakeholder concerns about the consistency of levels of evidence, clarity and enforceability of this approach to substantiating general level health claims. In the restructured Scientific Substantiation Framework (Schedule 2 of the draft Standard), the information sources that could be used to self-substantiate general level health claims was presented as Method 3.

Under Method 3, national diet policy publications were retained as per the Draft Assessment Report. FSANZ restricted publications by international bodies to three World Health Organization (WHO) documents and the United States Institute of Medicine Dietary Reference Intake series. These documents are highly regarded and cover a broad range of foods and nutrients. Scientific reviews were restricted to USFDA health claims that meet significant scientific agreement, the Cochrane database of systematic reviews and the UK Joint Health Claims Initiative. FSANZ requirements for assessing the totality of evidence for health claims align with the test of significant scientific agreement. Cochrane systematic reviews are recognised for their high standard in evidence-based analysis. The strength of evidence required as the basis of a general level health claim is consistent with the Cochrane systematic review process and the Joint Health Claims Initiative document that lists 'well-established' nutrient functions. FSANZ proposed to be more prescriptive in the type of textbook that could be used whilst broadening the range. Suggested textbooks were those in human nutrition whose authors are specialists in the topics covered. The approach included a requirement that the textbook is edited by a specialist or specialists in human nutrition as this level of oversight provides a degree of peer-review. Recognising that nutritional science is evolving, to maintain relevance it was suggested that the textbooks used as the basis of a general level health claim should have been published within 10 years at the time of substantiation.

To reinforce the credibility of the source documents used to self-substantiate general level claims, FSANZ proposed a requirement that a food-health relationship must be found in at least two corroborating sources.

Position papers and review articles are not always founded on a formal and transparent systematic review process. FSANZ believed that this is likely to lead to variable strengths of evidence among these reviews and for this reason proposed that position papers and review articles appearing in the general scientific literature would not be permissible as source materials on which to base general level health claims.

FSANZ received more comment against the proposed Method 3 of the Scientific Substantiation Framework than any other aspect of the revised Framework. Stakeholders expressed concern about the level of prescription versus flexibility inherent the approach. Those stakeholders placing priority on enforceability contended that the approach was not clear enough. Other stakeholders placing priority on flexibility contended that the approach lacked flexibility, would not be able to be kept up-to-date, excluded other credible sources currently in existence and did not underpin the aim of fostering an innovative globally competitive food industry. These stakeholders all expressed a preference for moving Method 3 to a User Guide and presenting the list as a list of examples of authoritative sources only, and not including a prescriptive list of authoritative sources in the draft Standard.

Many stakeholders expressed concern about the proposal to require two corroborating sources, suggesting that this idea had not been taken far enough because the same author could be behind two different sources. Suggestions were made to require the two corroborating sources to be from different types of publications. In contrast, submitters questioned the need for two corroborating sources if all sources were authoritative. It was recommended by some that steps be taken to remove the possibility of sources having been prepared by those who might have a commercial conflict of interest. It was also suggested that more effort was required to ensure that an equal amount of rigour had been applied to the independent peer-review of each of the sources included in Table 3.

Additional comments about Method 3 included:

- the list is culturally and geographically limited;
- position papers and reviews from peak medical groups, nutrition organizations etc in New Zealand and Australia could be included;
- scientific textbooks should be removed as some are based on highly dubious research or theories and may not be up-to-date;
- there should be a requirement that any source must have been subject to peer review;
- the list should be extended to include papers published in peer reviewed scientific journals as these are more up-to-date;
- European Food Safety Authority (EFSA) is a credible source and should be included in the list;
- suggest FSANZ considers the use of high quality methods for conducting systematic reviews such as QUOROM and MOOSE; and
- there should be a process for the regular review of the list in Table 3 of the Schedule.

5.3 Key changes from proposed approach in the Consultation Paper

FSANZ proposes more amendments to Method 3 than to any other part of the proposed Scientific Substantiation Framework. This reflects the balance of concern expressed by stakeholders with regard to each part of the proposed Framework.

The following sources have been removed from Table 3:

- Australian dietary guideline reports.
- New Zealand food and nutrition background papers.
- Vitamin and mineral requirements in human nutrition (WHO).
- Trace elements in human nutrition and health (WHO).
- Expert Consultation on Diet, Nutrition and the prevention of Chronic Diseases (WHO/FAO).
- Textbooks of university standard produced in the last 10 years (edited by specialist academic authors).

Health claims that meet the test of significant scientific agreement as assessed by Health Canada have been added to the list.

The prescribed list of authoritative sources now includes the following:

- Nutrient Reference Values for Australia and New Zealand.

- United States Institute of Medicine Dietary Reference Intake series.
- The UK Joint Health Claims Initiative.
- Health claims that meet significant scientific agreement (Health Canada and US FDA).
- The Cochrane database of systematic reviews.

The requirement for two corroborating sources has been removed.

The requirement that the relationship should be confirmed by comparison with current scientific literature has been removed.

5.4 FSANZ response to submitter comments

In response to submitter comments, the list of authoritative sources has been reduced and only one source is required. FSANZ considers that these sources provide sufficient rigour in relation to substantiation of food-health relationships and although the number of sources has been reduced, in combination they describe food-health relationships for a wide range of nutrients.

In the case of the Nutrient Reference Values for Australia and New Zealand, the food-health relationship must be based on a definitive statement and not rely on tentative statements such as 'x nutrient is thought to play a role in y function' or 'x nutrient has been related to a reduction in y disease'. Similarly, much of the content in the Chapter on 'Optimising diets for lowering chronic disease risk' is based largely on emerging evidence. FSANZ's requirement in Method 3 that the food-health relationship be 'confident and definitive and not rely on qualified, equivocal or unsupportive evidence' addresses the rigour required to substantiate a general level health claim derived from the Nutrient Reference Values report. The list of scientific sources which have been removed from Table 3 contain information that cannot always be guaranteed to meet this requirement.

Many submitters recommended that the EFSA is a credible source that should be added to the list. FSANZ has not added EFSA to the list, because while EFSA is expected to comment in the future on the level of evidence for a long list of food-health relationships that it has been asked to assess, documents from EFSA that would be relevant to include under Method 3 of the Scientific Substantiation Framework are not available at this time. FSANZ may, however consider including EFSA documents at a later date.

Several submitters recommended that a tool known as the QUORUM statement, relating to the quality of reporting of meta-analyses (Moher *et al.*,1999) and a proposal commonly known as MOOSE, relating to reporting of meta-analysis of observational studies in epidemiology (Stroup *et al*., 2000), should be added to the list. Submitters suggested that these sources were as authoritative as the Cochrane database. FSANZ has not added either the QUORUM tool or the MOOSE statement to the list because neither constitutes a library of authoritative one-to-one reviews of food-health relationships in the same way that the Cochrane database does. These two tools could be useful references to be included in a User Guide to support the draft Standard as they describe scientific methods. However, neither is as yet a convenient repository of review literature.

6. Scientific Substantiation Framework – Method 4

6.1 Draft Assessment Report – approach taken and submitter comments

The Substantiation Framework in the Draft Assessment Report provided extensive detail about how to undertake a systematic approach to substantiate high level health claims and to assess the strength of evidence from the totality of evidence for such claims (refer Attachment 8 to the Draft Assessment Report). It stated that 'the substantiation principles underpinning general level claims are the same as those for high level health claims' (page 32). However the strength of evidence needed to substantiate a general level health claim, whilst not explicitly defined was described in general terms only. The Substantiation Framework said 'Only a totality of evidence that is described in unequivocal terms with a significant degree of confidence with no equally strong opposing, or equivocal evidence should be relied on' (page 32). Further, it said that reports could not be taken to provide evidence to substantiate a general level health claim when the description of the evidence in support of a diet-health relationship is uncertain, yet to be confirmed, based only on animal or in vitro studies, or is speculative.

Where scientific reviews were suggested as appropriate mechanisms to substantiate general level health claims, it was stated that the reviews should be conducted in accordance with the processes generally drawn on for scientific research, and be similar to the process outlined in the Substantiation Framework for high level health claims (page 34 in the Draft Assessment Report).

The Draft Assessment Report stated that the processes used to substantiate high level health claims (either a comprehensive review or a streamlined approach based on updating an authoritative review) may also be used to substantiate a relationship for a general level health claim, in instances where alternative information sources are not appropriate. In the absence of other information sources, it was stated that this method would be expected to be appropriate for substantiating general level health claims referring to biologically active substances.

6.2 Consultation Paper (December 2007) – approach taken and submitter comments

In the revised and restructured Scientific Substantiation Framework proposed by FSANZ in the Consultation Paper (refer Schedule 2 of the draft Standard) use of the mechanism of systematic review to substantiate a general level health claim was retained (as suggested in the Draft Assessment Report) and was presented as Method 4. The Consultation Paper stated 'This method may be useful for the substantiation of relatively recent food-health relationships that have not yet been published in textbooks or undergone an independent systematic review.' FSANZ acknowledged that conducting a systematic review is complex and committed to producing supporting documentation to assist in the process.

Several stakeholders expressed concern about Method 4. This concern related mostly to the notion of substantiating relationships from evidence that is still under investigation or relates to an emerging food-health relationship. Stakeholders submitted that such evidence was insufficient and that claims based on evidence of this kind would lack the rigour expected to underpin all claims.

Concern was also expressed about the ability for the outcome of systematic reviews to be manipulated by those undertaking the review and the suggestion was made for FSANZ to state who would be appropriate and inappropriate to conduct systematic reviews. Stakeholders noted that the resource and expertise required to undertake and assess systematic reviews is considerable and submitted that the quality and transparency of reviews was a key consideration.

Additional comments made by submitters about Method 4 included:

- the suggestion that guidelines on how to conduct a systematic review with a model of a general level health claims dossier prepared by Method 4 be given in a User Guide;
- requirements for substantiation of general level health claims should be more open to new innovative nutrient functions and be different to that for high level health claims. For example, accept animal trials in place of human trials; and
- there should be a requirement for a systematic review to be peer reviewed and/or to be published.

6.3 Key changes from proposed approach in the Consultation Paper

FSANZ proposes some amendments to Method 4 of the Scientific Substantiation Framework. These are designed mostly to clarify the intent of the method and to remove the possibility of the method being interpreted as one that primarily involves assessment of emerging evidence.

FSANZ has clarified in Step 2 of Method 4 that existing systematic reviews may include reports of position papers prepared by government or non-government agencies, not just articles published in peer-reviewed scientific journals.

6.4 FSANZ response to submitter comments

A major concern expressed by stakeholders was that general level health claims should not be based on emerging evidence. FSANZ's intention is that the method of systematic review would not be used to assess emerging evidence only or to substantiate a general level health claim based on emerging evidence in the absence of other established information. It is likely that the method would be used where recently published evidence adds weight to the totality of evidence for a food-health relationship. Alternatively, the method could be used where the data set is entirely unpublished but are based on rigorous scientific studies.

FSANZ does not consider it necessary to specify who would be appropriate or inappropriate to conduct systematic reviews. The choice between four methods of substantiation should meet the varied requirements, expertise and resources of differing food manufacturers.

FSANZ will be including guidance for substantiating general level health claims in the User Guide for the draft Standard. As noted above specific requirements for Method 4 will be included in the *Application Handbook*.

References

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