29 March 2012

Project Officer Proposal P293
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

FS350-118-293

Dear Sir/Madam

Proposal P293 – Nutrition, Health and Related Claims – Consultation Paper February 2012

Thank you for the opportunity to comment on the Consultation Paper for Proposal P293.

MAF would like to acknowledge the extensive work carried out by FSANZ in developing P293 and providing the opportunity for a further round of public consultation prior to completing the First Review Report. Our comments on the consultation questions are provided in the tables below. In addition, we have made a number of additional comments that we consider important to the final outcome of the standards development process for P293.

Revised draft Standard 1.2.7

1. Does the revised drafting accurately capture the regulatory intent as provided in Attachment B? Please consider the clarity of drafting, any enforceability issues and the level of 'user-friendliness'.	
Clause 1(a)	This sub clause talks about "…a property or properties of a food", where as the definition for health claim in Clause 2 mentions "… a property of a food". Clarification is sought on the need to include the words "or properties". .
Clause 2 Interpretation	MAF notes that the definition for biomarker has been deleted as the term is no longer used in the Standard. While the term is not used in the Standard it is still relevant to health claims as part of the substantiation process for a health claim. MAF recommends that the useful work carried out to define a biomarker and identify how they are handled in the health claims system is not lost and should be included in the Application Handbook. **Definition "NPSC" -** For clarity we suggest that consideration is given to inserting the words "specified in schedule 3" after the word "criterion".

Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere
Pastoral House, 25 The Terrace, PO Box 2526, Wellington, 6140, New Zealand
Telephone: 0800 00 83 33, Web: www.maf.govt.nz

Clause 4 and associated editorial note	We question if the use of the term 'vulnerable person' in this clause is necessary as **all** clients of a delivered meals organisation are captured in the definition of vulnerable person. If the term is to remain in the clause we note that the Editorial Note directs you to Standard 3.3.1 for the definition of vulnerable person. However, Chapter 3 of the Food Standards Code (the Code) does not have legal effect in New Zealand. In order for the definition of vulnerable person to be applicable to New Zealand it would need to be incorporated (by reference) in Chapter 1 of the Code. One suggestion is that Clause 2 Interpretation (Std 1.2.7) contains the following: **Vulnerable person** has the same meaning as defined in Standard 3.3.1 The editorial note to this clause may then need to be modified.
Clause 7 Claims must not be therapeutic in nature Cl7(b)	Use of the word "good" The usual word in this context, (when being applied to material things) which is a noun, is plural – "goods". When good is used in the singular, it is normally an adjective with many meanings such as benefit, excellent, right, wholesome etc…This could cause confusion in the context of a standard for health claims where "good" could be associated with health benefits. Consideration should be given to the use of an alternative word to "good". Alternative words suggested are: merchandise; product; article. Another option would be to reconstruct the clause and use "goods".
Clause 10 Presentation of nutrition content claims	For clarity we suggest that the words '(in accordance with clause 6)" be inserted in brackets after the words "form of the food"
Clause 13 Nutrition content claims about folic acid	MAF supports the inclusion of a clause regarding nutrition content claims about folic acid. However we do not think it is necessary to require that a folic acid health claim is also made wherever a content claim for folic acid is made. MAF considers that it would be sufficient for a folic acid content claim to meet the criteria for a folic acid health claim (as Column 5 of Schedule 2) without having to make the health claim itself. Some food producers may wish to highlight the presence of folic acid in their products without making the folic acid health claim. As folic acid fortification is currently voluntary in New Zealand, it may be necessary for women of childbearing age to make conscious changes to their diet in order to achieve a greater folic acid intake, including identifying and choosing folic acid fortified foods. In addition to offering manufacturers an incentive to add folic acid to their foods through the use of claims, the MAF commissioned report entitled 'Consumer survey of women of childbearing age 2010' found that while two-thirds (68%) of respondents reported having heard of folate, in comparison, almost all (95%) had heard of folic acid. This suggests that the use of the term 'folic acid' rather than 'folate' would be preferable on folic acid fortified foods.

Clause 16 New health claims deemed to be high level health claims	MAF supports the use of the high level claims provisions in the FSANZ Act to provide for the confidential assessment of new claims submitted for pre-approval. However, we do not support all 'new' health claims being considered high level health claims. MAF considers that the Standard should provide additional substantiation mechanisms for 'general level' health claims. To this end we have reviewed our position on the approach to general level health claims set out in the Final Assessment report and 2009 Consultation Paper, and consider that a mechanism to provide for 'industry self-substantiation', such as undertaking and holding a systematic review, is desirable. Industry self-substantiation of general level claims would support innovation while maintaining the policy intent that claims will be based on a substantiated food-health relationship. For applications for pre-approval of new claims, MAF considers it essential that the substantiation framework acknowledges that different levels of claims require different levels of evidence. It is MAF's view that in the First Review Report FSANZ must clearly describe how it intends to differentiate the substantiation requirements for lower-level claims from high level claims. Definitions in the FSANZ Act are not incorporated into the Code. Therefore clause 16 needs to expressly incorporate the FSANZ Act definitions of "high level health claims variation". The editorial note to this clause may then need to be modified. Subclause 16(2) The meaning of "Schedule 2 to that schedule" is unclear. We suggest that FSANZ reword this subclause to clarify its meaning.
Potassium/mineral/electrolytes nutrition content claims.	There has been a change as to how potassium (and sodium) claims are proposed to be portrayed in Standard 1.2.7 between the March 2009 consultation paper and the February 2012 consultation paper. These changes are summarised in Attachment 1 to this submission. Standard 1.2.7 Schedule 2 - Locating sodium and potassium in 'Part 3 Other' suggests that sodium and potassium are not deemed to be minerals. MAF's view is that sodium and potassium should be acknowledged as a mineral but require different criteria/conditions to other minerals. Our suggestion is that in Schedule 2 sodium and potassium should be moved from 'Part 3 Other' to 'Part 2 Minerals.' There is currently a lack of clarity as to whether claims regarding sodium and potassium are currently permitted on foods standardised in Standard 2.6.4 Formulated Caffeinated Beverages. MAF would like to see this ambiguity clarified within the drafting of Standard 1.2.7, by expressly prohibiting sodium and potassium claims. Noting that vitamin and mineral claims in general are prohibited. Such claims put a positive spin on

	sodium/potassium content which is not appropriate when vitamin and mineral claims in general are prohibited on these foods. MAF also suggests that the use of 'electrolyte content claims' should also be prohibited on these foods. Electrolyte claims should be considered as separate claims to sodium/potassium/vitamin/mineral claims. In considering the point above it has brought to our attention that electrolyte claims have not been included in Schedule 1. We consider this is an oversight and would like to propose that FSANZ consider including criteria for electrolyte claims in Schedule 1.
Clause 18 How health claims are to be made Cl 18(2)	The hyphen at the end of the first line of this clause should be an m-dash
Clause 18(2)(c)	For clarity we suggest that the words '(in accordance with clause 6)" be inserted in brackets after the words "form of the food"
Clause 24 Labelling of food required to meet the NPSC Cl 24(5)	The cross reference to 'subclause (5)' should be to 'subclause (6)'. This subclause requires the percentage of each *element* of fvnl relied on to meet the NPSC to be declared on the label. We note that in clause 4(2) of Schedule 4 V points cannot be scored for a *constituent* of a fvnl. There could be some confusion regarding the use of the two terms *element* and *constituent* and suggest that an alternative be looked at for element.
Clause 24(6)	The wording could be made clearer by the insertion of extra words as shown below: "(6) The percentage of fvnl need not be declared for – (a) a health claim about a connection between fruits and vegetables and heart health; or (b) a health claim about a connection between fruits and vegetables and coronary heart disease."
Clause 24(7)(a)	For clarity it is suggest the wording is amended to read "a food is classified as Category 3 in Schedule 3 for the purpose of determining the food's nutrient profiling score; and".
Schedule 1 Gluten Claims	MAF appreciates that the requirements for both gluten free and low gluten claims have been moved to the new schedule, without amendment to the levels. We acknowledge that the term 'gluten-free' means free of any detectable gluten under both the Food Standard Code, and consumer protection/fair trading laws in both Australia and New Zealand. When the Code was first published, the Codex 'gluten-free' standard at that time was represented as 'low gluten' i.e 200 ppm, to enable a dual approach (i.e. persons with coeliac disease could choose 'low gluten' foods, on the advice of health professionals). However, the Code

	requirement (20 mg gluten per 100 g which equates to 200 ppm) for 'low gluten' was not updated when the Codex limit for 'gluten free' changed from 200 ppm to 20 ppm in 2008. Furthermore, the terminology used by the EU and Codex, to support a dual standards approach, is 'very low gluten' (rather than low gluten). MAF appreciates that this matter cannot be consulted on within P293, however we ask that FSANZ considers this issue under a separate process (for example, a Proposal), in due course.
Schedule 4 (3) Baseline points for Category 3 foods	The meaning of "(1) Use the information in Table 2 and the formula in sub item (2) to work out the baseline points (up to 10 for each nutrient),"…is not clear because the table has more then 10 baseline points for energy content, saturated fatty acids and sodium. It is our understanding that baseline points are not capped at 10 for these entries and should use the full values entered into the table. Removal of the text "(up to 10 for each nutrient)"would remove the potential confusion. We also suggest the same text be deleted from item 2
Consequential variation 2 Standard 1.2.8	The definitions of "health claims", "nutrition content claim" and "endorsement" (being the meanings given in Standard 1.2.7) should be included in subclause 1(1). This is needed for the purpose of the new Clause 4 in Standard 1.2.8.
Consequential variation 8, standard 2.9.3	The explanatory note that accompanies this consequential variation is '…This will provide consistency with the permissions under Standard 1.2.7 for vitamin and mineral claims on other foods.' MAF supports consistency with Standard 1.2.7. However this may not have been achieved as the entry in Standard 1.2.7 Schedule 1 is for 'vitamin or mineral (not including potassium or sodium)'. It is ambiguous if potassium or sodium content claims can be made on foods standardized under 2.9.3. This ambiguity should be clarified in the drafting. MAF's view is that potassium or sodium should be consistent between Standards 1.2.7 and standard 2.9.3.
Consequential variation 13 Transition period	MAF agrees with the intent of the transition period that during this time a food business has to comply with either Standard 1.2.7 or Standard 1.1A.2 but not a combination of both. The Editorial Note under Part 1 – Purpose and Interpretation states 'If Standard 1.1A.2 is relied on, the changes made to other Standards by this variation also have no effect'. Without a copy of the Standard in the format to be gazetted MAF is unsure how this will be presented. For example provisions currently in Standards 1.2.8 and 1.3.2 that are proposed to be moved to Standard 1.2.7 still need to be retained if industry is complying with Transitional Standard 1.1A.2. They will be unable to comply with provisions if they have been moved from Standard 1.2.8 and 1.3.2. From a compliance and enforcement perspective the Code needs to clearly identify current variations that will still be effective. Clarification is sought on the term 'date of omission' [13.1]. How does this differ to the date when a Standard is repealed.?

	It is suggested that under [13.2] "as if items [3] – [10] of this Schedule had not commenced" should read "as it items [2] – [10] of this Schedule had not commenced".
Attachment B – Explanatory Information Clause 4	The last sentence explains that the word "package" is defined in clause 2 of Standard 1.2.1. The wrong standard is being referenced. It should be Standard 1.1.1

Fat-free and % fat-free claims

2. What evidence can you provide that shows consumers are purchasing foods of lower nutritional quality because they are being misled by fat-free or % fat-free claims?	MAF is not aware of any New Zealand evidence on this matter.
3. Do you support option 1 (status quo), option 2 (voluntary action through a code of practice, or option 3 (regulate with additional regulatory requirements for fat-free and % fat-free claims)?	MAF supports option 1 (status quo). New Zealand is unaware of evidence that consumers are misled by 'fat free' or '% fat free' claims on foods high in sugar. In the absence of such evidence and in the interests of minimum effective regulation, option 1 Status Quo is adequate to regulate such claims.
4. Please comment on the possible options for additional regulatory requirements for fat-free and % fat-free claims)(option 3) as follows: (a). Which option do you support and why?	New Zealand supports option 1 and does not believe there is any need for additional regulatory requirements. If evidence of a problem is presented New Zealand would be able to comment on potential options for additional provisions at that point.
(b). What is an appropriate sugar concentration for options 3(b) and 3(d)	New Zealand supports option 1
(c). Are there other suitable options for additional regulatory requirements for fat-free and %fat -free claims?	

Additional comments

Assessments of new food-health relationships

The Standard's role in creating a regulatory environment that is supportive of innovation is a priority for New Zealand.

While MAF is comfortable with claims being deemed 'high-level health claims' for the purposes of pre-approval, we consider that additional mechanisms should be provided for the substantiation of general level health claims.

As the agency responsible for enforcement of food standards in New Zealand, MAF has reviewed its position on the general level health claims proposals in the Final Assessment Report for P293, and considers that providing for 'self-substantiation' of general level claims would significantly reduce the regulatory impact of the Standard and increase the net benefit to New Zealand.

MAF therefore considers that provisions for self-substantiation for general level health claims should be included in the Standard alongside provisions for the pre-approval of both general and high level claims.

We are also conscious that the process used to assess new food-health relationships will have a profound impact on the success of the Standard in supporting innovation and the economic development of the Australian and New Zealand food industries.

MAF notes that the Forum on Food Regulation's Policy Guideline on Nutrition, Health and Related Claims asks that any standard regulating this area 'contain a process of substantiation which aligns levels of scientific evidence with the level of claims along the theoretical continuum of claims, and at minimum costs to the community.' It is essential that the substantiation framework acknowledges that different levels of claims require different levels of evidence.

Revising the regulatory impact statement for P293

MAF notes that FSANZ will be preparing a revised regulatory impact statement (RIS) that takes account of the changes to the draft Standard since the first RIS was prepared in 2008. It is crucial that the revised RIS take account of the impact that pre-assessment of all health claims—both 'general level' and 'high level'—will have over the self-substantiation approach for 'general level' claims which was proposed when the original RIS was prepared.

Mitigating the regulatory impact of the Standard

As noted above, MAF considers that provisions should be included in the Standard to allow self-substantiation for general-level health claims. This would significantly reduce the regulatory impact of the Standard. However, if the inclusion of self-substantiation provisions is not supported, other ways need to be explored for limiting the regulatory impact.

MAF is aware of a number of products currently on the market that indicate a food-health relationship through qualified phrases like 'x food *may support* y health effect'. As long as these claims do not contravene the existing provisions of the Food Standards Code or the Fair Trading Act 1986 they can be made on food products in New Zealand. However, under the Standard these claims would be effectively prohibited if the food-health relationships are not listed in the Standard.

In the 2009 Consultation Paper, FSANZ noted that implementation of the then preferred option (which involved the pre-approval of general level health claims) should include 'consideration of GLHC [general level health claim] relationships that underpin GLHCs in the market, and how these should be assessed during the transition period for Standard 1.2.7.'[1] The current consultation paper

[1] P293 Consultation Paper for First Review, 2009, p. 12

does not comment on how existing claims that make reference to food-health relationships that are not listed in the Standard should be assessed during the transition period.

The regulatory impact of the Standard is predominantly focused on label changes to products carrying such claims. MAF considers that there is scope to mitigate this regulatory impact by providing a process to consider these claims during the transition period.

To do this MAF recommends that FSANZ raises a proposal to consider *en masse* food-health relationships underpinning claims currently on the market. A food-health relationship would only be considered under this proposal if:

(a). it was referenced in health claims on products on the market on the date the Standard is gazetted; and

(b). the health claims that make reference to the food-health relationship complied with:
   i the Food Standards Code prior to gazettal of Standard 1.2.7; and
   ii relevant consumer protection legislation (e.g. the Fair Trading Act in New Zealand); and

(c). FSANZ is notified of the food-health relationship and health claim, and evidence that it meets conditions (a) and (b) above, by a date three to four months after the Standard is gazetted.

As the objective of this process would be to minimize the regulatory impact, the cost of the assessments should not be recovered from food businesses. However, FSANZ should be able to seek substantiation evidence and data from food businesses if necessary to the assessment. As above, assessment process for these existing health claims should draw on a substantiation framework that recognizes different levels of claims.

MAF considers this proposal should be separate from and in addition to the proposal that FSANZ intends to raise to integrate food-health relationships approved by the European Union (EU) into Standard 1.2.7.

EU claims – process and timelines for adoption in FSC

The executive summary to the proposal states that further food-health relationships will be able to be added through FSANZ periodically translating appropriate food-health relationships that are the basis for health claims permitted in the EU. This principle does not appear to be embedded anywhere in the standard and should be included, if this is the intent. This is an important mechanism for keeping the standard up to date in a timely fashion and will allow resources to focus on applications for variation to health claims not already approved in the EU.

Yours sincerely

Manager (Food Science and Risk Assessment), Science and Risk Assessment

Attachment 1

Drafting of Standard 1.2.7 wrt potassium and vitamin / mineral claims

	March 2009 consultation paper	February 2012 consultation paper
Definition of nutrition content claim		Includes the term minerals, potassium and sodium
Nutrition Content Claims Schedule 1	Schedule 1 entitled specific conditions for nutrition content claims Food standardised in Std 2.6.4 unable to make vitamin or mineral claim Sodium and potassium separate entries to vitamin or mineral	Schedule 1 entitled conditions for nutrition content claims Food standardised in Std 2.6.4 unable to make vitamin or mineral (not including potassium or sodium) claim Sodium and potassium separate entries to vitamin or mineral (not including potassium or sodium)
Permitted General Level Health Claims Schedule 2 Part 2 - Minerals	Entries for sodium and potassium listed in Part 2 - Minerals	Entries for sodium and potassium listed in Part3 - Other