Ministry for Primary Industries
Manatū Ahu Matua

The New Zealand Food (Supplemented Food) Standard 2013: Summary of submissions and MPI analysis

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Growing and Protecting New Zealand

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1 The proposal and submissions received

On 25 July 2013, the Ministry for Primary Industries (MPI) released a discussion paper: *Proposed Amendment to the New Zealand Food (Supplemented Food) Standard 2010.* The paper sought submissions on a proposal to:

- incorporate Standard 1.2.7 – Nutrition, Health and Related Claims of the Australia New Zealand Food Standards Code (the Food Standards Code), by reference, into the New Zealand Food (Supplemented Food) Standard 2010 (SFS);
- clarify the application of the SFS to foods containing added caffeine; and
- make several minor technical amendments.

The paper did not seek to revisit decisions made in relation to Standard 1.2.7 as the Standard was agreed to by the Legislative and Governance Forum on Food Regulation (the FoFR)[1]. It did not seek to review the caffeine regulation in New Zealand as a separate review of the trans-Tasman Policy Guideline on the Addition of Caffeine to Foods is currently being conducted by the FoFR. It did not seek to review the SFS in its entirety either. MPI is aware of other issues related to the SFS that have become apparent since its introduction in 2010 and will conduct a broader review in the near future.

Seven submissions were received in response to the discussion paper. Five of them were from food industry stakeholders and two were from food industry consultants.

2 Health Claims

2.1 INCORPORATING STANDARD 1.2.7 INTO THE SFS

Standard 1.2.7 – Nutrition, Health and Related Claims of the Food Standards Code was gazetted on 9 April 2013. Standard 1.2.7 permits and regulates nutrition and health claims on foods.

2.1.1 Submitter comments

Six submitters commented on MPI's proposal to incorporate Standard 1.2.7, by reference, into the SFS. All six submitters supported the changes. The following reasons were provided:

- it supports the alignment of the SFS with the Food Standards Code;
- it enables supplemented foods to carry nutrition and health claims;
- health claims support new science and future innovation, particularly with respect to functional ingredients;
- health claims will help support collaboration between crown research organisations, universities and the food industry;
- consumers will benefit as they will have fresh ideas to enhance their lifestyles.

Only two submitters provided information on the impact that incorporation of Standard 1.2.7 would have on their businesses. One submitter, who markets a single product under the SFS, stated that no labelling change was required. The other submitter, who sold a number of supplemented foods, said that the last label change was in 2010 when the SFS was introduced.

[1] The FoFR is the Ministerial committee that oversees the joint Australia New Zealand food standards system.

2.1.2 MPI evaluation

MPI confirms that Standard 1.2.7 should be incorporated, by reference, into the SFS for the reasons provided by the submitters above and as outlined in MPI's discussion paper.

2.2 CLAUSE 10 AND 11 OF THE SFS

Clause 10 of the SFS restricts advertising and labelling on supplemented food by preventing claims of a therapeutic nature. Clause 11 regulates claims in relation to the presence of a vitamin or mineral in a supplemented food (for example, 'contains x' or 'good source of x').

2.2.1 Submitter comments

Clause 10 of the SFS

Four submitters commented on and generally supported MPI's proposal to delete clause 10 of the SFS. It was noted by one of the submitters that no sub-clauses should remain as clauses 7 and 14 of Standard 1.2.7 and the definitions of "health claim" and "health effect" will restrict supplemented foods from carrying therapeutic claims.

A submitter also noted that an amendment was being made to regulations under the Medicines Act 1981 so that foods carrying compliant health claims were excluded from regulation under the Medicines Act. The submitter pointed out that this exclusion should be extended to supplemented foods.

Clause 11 of the SFS

Two submitters supported the proposal to delete clause 11 of the SFS as vitamin and mineral content claims are contained in Standard 1.2.7. In contrast, one submitter thought it prudent to keep clause 11 on the basis that the 2006 Australia New Zealand National Health and Medical Research Council Nutrient Reference Values (2006 NRVs) have values for nutrients that are not in Standard 1.1.1.

2.2.2 MPI evaluation

Clause 10 of the SFS

MPI confirms that clause 10 should be deleted from the SFS as the incorporation of Standard 1.2.7 into the SFS prohibits therapeutic claims but allows for health claims. As this is the intention, clause 10 of the SFS is no longer relevant.

On 26 August 2013 regulations under the Medicines Act[2] were amended so that foods carrying certain compliant health claims under Standard 1.2.7 are not also regulated under the Medicines Act 1981. The regulations also include a clause that will revoke, at the end of 17 January 2016, the current exclusion for foods carrying a health claim that relates folate to a reduced risk of neural tube defects (NTDs). The health claim is not listed in Schedule 2 of Standard 1.2.7. Instead a health claim that relates folic acid (the synthetic form of folate) to a reduced risk of NTDs is permitted in Schedule 2 as this reflects the current scientific evidence.

Supplemented foods carrying health claims that are compliant with Standard 1.2.7 will therefore not be regulated under the Medicines Act.

[2] Medicines (Related Products (Exempted Foods)) Amendment Regulations 2013.

Clause 11 of the SFS

MPI confirms that clause 11 should be deleted from the SFS as vitamin and mineral content claims are provided in Standard 1.2.7.

Clause 11 of the SFS only permits content claims for vitamins and minerals that are listed in column 1 of the Schedule to Standard 1.1.1. Retaining clause 11 will not, therefore, allow for content claims that describe a property of the food (for example, 'source of x' and 'contains x') when related to vitamins and minerals not listed in Standard 1.1.1. In order to continue aligning the SFS as closely as possible with the Food Standard Code, MPI confirms that this policy should continue.

Although choline, fluoride and folic acid are not listed in Standard 1.1.1, content claims for these nutrients are covered in clause 13 of Standard 1.2.7. As per clause 13, claims that the food contains choline, fluoride or folic acid are permitted only when a corresponding general level health claim is made. However, nutrition content claims that describe the content of folate (for example, 'source of folate' and 'good source of folate') are permitted as folate is listed in column 1 of the Schedule to Standard 1.1.1.

On 30 August 2013 an amendment to regulations under the Medicines Act was introduced. The amendment excluded foods carrying certain health claims that comply with Standard 1.2.7 from being regulated under the Medicines Act. Incorporating Standard 1.2.7 into the SFS therefore extends the exclusion to supplemented foods.

2.3 COMPARATIVE VITAMIN AND MINERAL CONTENT CLAIMS

Comparative claims are nutrition content claims that directly or indirectly compare the nutrient or energy content of a food or brand of food with a reference food (see clause 15 of Standard 1.2.7). Clause 8 of Standard 1.2.7 does not permit comparative claims that are made in relation to a vitamin or mineral unless the claim is permitted by another standard in the Food Standards Code.

2.3.1 Submitter comments

Four submitters commented on MPI's proposal to prohibit comparative claims that relate to vitamins and minerals (for example, 'x% higher in vitamin C compared to our regular product').

Three submitters noted that the SFS is for products that are typically fortified with vitamins and minerals. Permitting comparative claims would therefore clarify to consumers the level of fortification with other foods, without having to read the Nutrition Information Panel. One submitter specifically opposed the prohibition while another stated that there is no basis for supplemented food to exclusively make comparative claims about vitamin and minerals.

Two submitters stated that they do not sell products with comparative vitamin and mineral content claims.

2.3.2 MPI evaluation

MPI confirms that supplemented food should not be able to carry claims that directly or indirectly compare the vitamin or mineral content of a food with another food. This is because:

- prohibition will align the SFS with Standard 1.2.7 and will therefore assist with transitioning supplemented foods in the Food Standards Code once appropriate permissions become available;
- no other food, including fortified food, can make comparative claims for vitamins and minerals;
- information is available in the Nutrition Information Panel so consumers can compare the vitamin and mineral content between products;
- supplemented foods are not intended to be a replacement for basic, nutrient-rich foods as their purpose is to supplement the diet.

2.4 NOTIFICATION OF SELF-SUBSTANTIATED HEALTH CLAIMS

Standard 1.2.7 requires the person who is responsible for making a self-substantiated general level health claim to notify the Chief Executive Officer of Food Standards Australia New Zealand (FSANZ) of the details of the relationship between their food or property of food and the health effect.

2.4.1 Submitter comment

Only one submitter commented on MPI's proposal for the notification of self-substantiated claims to be made to the Director-General of MPI rather than the Chief Executive Officer of FSANZ. The submitter supported the proposal given that no Australian agency administers the SFS.

2.4.2 MPI evaluation

MPI confirms that notification of a self-substantiated general level health claim should be directed to the Director-General of MPI as MPI administers the SFS and is therefore the appropriate agency for notification. The following clauses in Standard 1.2.7 need to be amended for the purpose of the SFS:

- clause 17(4)(b) – notification of a self-substantiated health claim is to the Director-General of MPI;
- clause 18(a) - the person making the self-substantiated claim can only provide a New Zealand address;
- clause 18(b) - consent to publication of the information required in 17(4)(b) and 18(a) must be given to the Director-General of MPI as opposed to the authority.

A small cost-recovered fee may be incurred when listing a self-substantiated general level health claim.

2.5 REFERENCE TO RECOMMENDED DIETARY INTAKE

Standard 1.2.7 makes use of regulatory Nutrient Reference Values (rNRVs) for vitamins and minerals based on the 1991 Recommended Dietary Intakes (RDI)[3] and, where values were unavailable, the 1989 United States Estimated Safe and Adequate Daily Dietary Intakes (ESADDI). In contrast the SFS refers to the 2006 NRVs.

[3] RDI is the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97–98 per cent) healthy individuals in a particular life stage and gender group.

2.5.1 Submitter comments

Two submitters supported MPI's proposal to replace references to the rNRVs in Standard 1.2.7 with the 2006 NRVs for supplemented foods.

Two submitters noted, however, that inconsistencies occur with use of the 2006 NRVs on supplemented foods and rNRVs on similar foods regulated under the Food Standards Code. For example, for vitamin D, the 2006 NRV AI[4] for men aged 19-50 years is 5 mcg per day whereas the rNRV is 10 mcg per day. One of the submitters encouraged MPI to make representations to Food Standards Australia New Zealand (FSANZ) to amend the rNRVs. The other submitter suggested retaining clause 11 of the SFS until FSANZ reviews the rNRVs in order to maintain consistency between the clauses of the SFS.

A submitter also noted that the 2006 NRVs encompass more reference values than just the RDI and AI. The submitter pointed out that it would be inappropriate to use the EAR or UL[5] to determine the conditions for nutrition content claims.

2.5.2 MPI evaluation

Clause 5(3) of the SFS refers to the 2006 NRVs. MPI therefore confirms that the rNRVs (RDI and ESADDI) referred to in Standard 1.2.7 should be replaced with the new 2006 NRVs (RDI and AI) for the purpose of making nutrition content claims on supplemented food. FSANZ acknowledges that the rNRVs are out of date and it is therefore not appropriate to use the rNRVs for supplemented food.

The inconsistencies that occur between the 2006 NRVs referred to in the SFS and the rNRVs used in the Food Standards Code must therefore remain until the Food Standards Code is updated. This issue has existed for nutrition content claims since the introduction of the SFS, so the status quo will remain.

MPI agrees with the submitter who noted that it would be inappropriate to use the EAR or UL to determine the conditions for nutrition content claims and therefore confirms that the drafting should be changed to reflect that only the 2006 NRVs (RDI or AI) can be used.

2.6 AGE AND GENDER APPROPRIATE NUTRIENT REFERENCE VALUES (NRV)

The User Guide to the SFS currently states that where a supplemented food has not been formulated for a specific population age/sex group, then the RDI or AI (from the 2006 NRVs) for adult males can be used for determining a vitamin or mineral content claim.

2.6.1 Submitter comments

Two submitters considered that clarity would be improved if the RDI or AI (from the 2006 NRVs) for adult males were stated in the SFS rather than the User Guide. The submitters suggested the following drafting under clause 6(3): "Where no specific age and/or gender is

[4] AI is Adequate Intake (used when an RDI cannot be determined) (that is, the average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.

[5] EAR is the Estimated Average Requirement (that is, the daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group); UL is Upper Level of Intake (that is, the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population).

clearly identified, the NRV's to be used are those for Adult Males 31-50 years of age" or similar wording.

2.6.2 MPI evaluation

MPI has reconsidered the recommendation outlined in the User Guide to the SFS to use the RDI or AI (from the 2006 NRVs) for adult males when determining conditions for a vitamin or mineral content claim. Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) recommend that NRVs for the general population older than 36 months should be used for labelling purposes. The NRVs – Requirements (NRVs-R) derived by Codex Alimentarius Commission (Codex) are based on the widest applicable age range for each of adult males and females; pregnant and lactating women excluded.

Where a product is intended for the general population, MPI considers it more appropriate that the mean RDI or AI for adult men and women be used for determining a vitamin or mineral content claim. It is not clear as to why the adult male was originally chosen. MPI therefore confirms that, in the absence of more justified reasoning, it should align with the Codex recommendation. Using the Codex approach, micronutrients with RDI or AI values that are higher for women compared to men (for example, iron) will therefore better reflect the needs of women than if the RDI or AI was only used for adult men.

As MPI did not consult on the age/gender appropriate NRVs for determining conditions for nutrition content claims, the change will be made to the User Guide only. When MPI next conducts a wider review of the SFS, it will seek comment on whether to include the amendments in the SFS.

2.7 REFERENCE TO STANDARD 2.9.4

Nearly all health claims must meet the conditions for the relevant nutrition content claim in Standard 1.2.7. Standard 1.2.7 does not allow nutrition content claims for a vitamin or mineral to be applied to foods regulated by Standard 2.9.4 - Formulated Supplementary Sports Food of the Food Standards Code. This means that with few exceptions, food regulated under Standard 2.9.4 cannot carry health claims in relation to a vitamin or mineral.

The SFS does not refer to Standard 2.9.4, although many supplemented foods are sports foods with similar properties to foods regulated under Standard 2.9.4.

2.7.1 Submitter comments

Two submitters commented on and agreed that supplemented foods that are marketed for the purposes of sports performance should be able to make nutrition content and health claims when they relate to a vitamin or mineral.

One submitter pointed out that the permitted forms of nutrients in the SFS may need to be changed. It was noted that the SFS regulates the forms of nutrients by reference to column 2 of the Schedule to Standard 1.1.1 and that fewer forms are permitted compared to those listed in the Schedule to Standard 2.9.4. It was also suggested that if changes were made then paragraph (d) in column 2 of Schedule 1 in Standard 1.2.7 for a vitamin or mineral (not including potassium or sodium) should be removed.

The submitter also noted an inconsistency between the conditions that apply to certain general level health claims under Standard 1.2.7 and the conditions that apply to the equivalent

nutrition content claims under Standard 2.9.4. For example, a high carbohydrate supplement regulated under Standard 2.9.4 must have no less than 90% of the energy yield of the product derived from carbohydrate whereas a general level health claim about carbohydrate only requires 55% of its energy to be derived from carbohydrate (column 5 of Schedule 3 for carbohydrate in Standard 1.2.7).

Finally the submitter noted that if it is necessary for supplemented foods marketed for the purpose of sports performance to meet the NPSC, then clarification is needed on how clause 17(5) of Standard 1.2.7 applies. Clause 17(5) states that a food standardised in Part 2.9 of the Food Standards Code does not need to meet the nutrient profiling scoring criterion (NPSC).

2.7.2 MPI evaluation

MPI confirms that supplemented foods that are marketed for the purposes of sports performance should be able to make nutrition content and health claims when they relate to a vitamin or mineral provided all the requirements in Standard 1.2.7 are met. This is regardless of the specific provisions outlined in Standard 2.9.4. Standard 2.9.4 is not referenced in the SFS as one that specifically applies to supplemented foods.

MPI also confirms it appropriate for supplemented foods that are formulated and marketed to enhance sports performance, to be able to make health claims given that general-purpose foods can make the same claims if they meet the conditions that apply.

The claims permitted for certain products regulated under Standard 2.9.4 are specific to their sports related use. For example, high carbohydrate supplements permit the use of claims related specifically to their use in situations of sustained and strenuous exercise. Since the general level claim permitted under Standard 1.2.7 for carbohydrate is different to that permitted for high carbohydrate supplements under Standard 2.9.4, MPI does not consider there to be a conflict between the standards. Furthermore, the SFS does not refer to Standard 2.9.4 and therefore the claims under this standard do not apply to the SFS.

Because the SFS does not refer to Standard 2.9.4 there is also no need to change:

- the permitted forms for vitamins and minerals as described to in Schedule 1.1.1;
- any of the conditions that apply to health claims in Schedule 3 of Standard 1.2.7 (for example general level health claims that relate to carbohydrate, protein or energy);
- clause 17(5) of Standard 1.2.7. It can simply be ignored when reading it as part of the SFS.

2.8 GENERAL LEVEL HEALTH CLAIMS THAT RELATE TO FLUORIDE AND CHOLINE

There are no rNRVs for fluoride and choline in Standard 1.1.1 of the Food Standards Code. Conditions for general level health claims that relate to these two nutrients are specified in Standard 1.2.7 as specific amounts. In contrast, the SFS references the 2006 NRVs which include AIs for both fluoride and choline.

2.8.1 Submitter comments

Fluoride

Two submitters supported MPI's recommendation for a general level health claim about fluoride to contain no less than 0.6 mg per litre (as prescribed in Standard 1.2.7) but two other submitters queried the conditions for the claim.

One submitter stated that the proposed level of 0.6 mg per litre appears to be conservative for children from four years of age and adults. The submitter noted that fluoridated water only equates to approximately 25% of fluoride intake in the New Zealand diet and some communities are choosing not to have fluoride added to their water supply. They also noted that other food sources of fluoride may not be well absorbed.

Another submitter queried whether the claim "contributes to the maintenance of tooth mineralisation" should be permitted on a reduced sugar acidic drink that is based on reconstitution with fluoridated water. The submitter suggested that the conditions relating to fermentable sugars for general health claims about sugar(s) (column 5 of Schedule 3 for sugar or sugars) should apply.

The submitter also noted that in the database of medicine classifications, fluoride for general sale has no lower limit. The submitter queried, on the basis that all fluorides are therefore captured as medicines, whether there is a permission to fortify food with fluoride, other than through fluoridated water or food products containing it naturally.

Choline

One submitter supported the proposed approach to use the 2006 NRV AI for adult males as the basis for determining conditions for general level health claims that relate to choline. Another submitter supported either the approach used in Standard 1.2.7 (2006 NRV mean AI for adult men and women) or in the SFS (2006 NRV AI for adult males).

A submitter noted that if clause 11 of the SFS is retained, then there is a conflict with clause 13 of Standard 1.2.7. Clause 13 does not permit descriptor claims in relation to choline such as 'source' and 'good source'.

2.8.2 MPI evaluation

Fluoride

In the consultation phase, MPI asked submitters whether the level of 0.6mg /L was appropriate to use. MPI confirms that the conditions for a general level health claim that relates to fluoride in Standard 1.2.7 are appropriate for supplemented food, and there is no sufficient reason to use a different level than proposed in Standard 1.2.7.

MPI considers that a general level health claim "contributes to the maintenance of tooth mineralisation" made on a reduced sugar acidic drink that is based on reconstitution with fluoridated water, is an issue not unique to the SFS. It is however more likely that this type of issue may fall under the Fair Trading Act. The Fair Trading Act requires that information provided to consumers is not misleading.

Fluoride is permitted for general sale at a certain level according to the Medsafe Classification of Medicines Schedule. For food, fluoride can only be added to packaged water (as specified in Standard 2.6.2 of the Food Standards Code). It may also occur naturally in food. There is no other permission to add fluoride to food under the Food Standards Code.

Choline

Section 2.5.2 above concluded that vitamin and mineral content claims should be based on the mean RDI or AI (in the 2006 NRVs) for adult men and women. This means that the condition for a general level health claim that relates to choline, as set out in column 5 of Schedule 3 in Standard 1.2.7 (the food must contain no less than 50 mg choline per serve), is appropriate.

Clause 11 will not be retained for the reasons provided in section 2.2.2 above, and therefore no conflict will exist between Clause 13 and Clause 11.

2.9 OTHER COMMENTS

2.9.1 Submitter comments

Submitters made several other comments. One submitter supported the proposed transition period until 18 January 2016 and also supported the current action to finalise regulations under the Medicines Act to exclude foods that carry certain compliant health claims from being related products.

Another submitter believed that regulation around health claims and advisory statements provide consumers with greater confidence around food label information.

2.9.2 MPI evaluation

No submitter objected to the proposed transition period. Because the period aligns with the end of the transition period for nutrition and health claims, MPI confirms that all supplemented food must comply with Standard 1.2.7, as presented in the amended SFS, by 18 January 2018. No stock-in-trade provisions apply.

Amendments to regulations under the Medicines Act have been finalised as discussed in section 2.2.2.

No submitter provided evidence to suggest that consumers might be confused by a product carrying an advisory statement as well as a health claim. MPI is not aware of any research that suggests consumers might be confused. Also if an issue exists, then it is not specific to supplemented foods as it would affect all food products carrying permitted health claims. No change is therefore recommended.

3 Caffeine

3.1.1 Submitter comments and MPI evaluation

Two submitters supported the clarification around the use of caffeine in the SFS. One submitter also stated that they supported the review of the caffeine policy and that they wished to be kept informed if supplemented food containing caffeine should be moved into the Food Standards Code as a result of policy changes.

Given a lack of opposition, MPI confirms that an additional clause should be added to the SFS to clarify that products meeting the definition of supplemented food can contain added caffeine for a purpose other than as a food additive. This clarification will maintain the status quo for the regulation of caffeine in New Zealand.

4 Minor technical amendments

4.1.1 Submitter comments and MPI evaluation

One submitter supported the technical amendments as proposed concerning deletion of references to clauses in certain standards and the correct reference to the Dietary Supplements Regulations 1985. Given the lack of any contrary arguments, MPI confirms that reference to clause 6 in Standard 2.5.1 and clause 2(1)(h) in Standard 2.4.2 should be removed from the SFS as the Food Standards Code no longer refers to either of these clauses. Reference to the Dietary Supplement Regulations 1985 in clause 6(2)(a) of the SFS should also be amended to provide the correct title of the regulation.