Ministry for Primary Industries
Manatū Ahu Matua

Proposed Amendment to the New Zealand Food (Supplemented Food) Standard 2010

MPI Discussion Paper No: 2013/16

ISBN No: 978-0-478-41409-7 (online)
ISSN No: 2253-3907(online)

25 July 2013

New Zealand Government

Growing and Protecting New Zealand

Disclaimer

Every effort has been made to ensure the information in this document is accurate.

MPI does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

Requests for further copies should be directed to:

Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

This publication is also available on the Ministry for Primary Industries website at
http://www.mpi.govt.nz/news-resources/publications.aspx

Contents

Page

1 Executive Summary

Supplemented food contains substances that provide for more than just basic nutritional needs. Supplemented food may include the addition of vitamins and minerals in amounts that are higher than those permitted under the Australia New Zealand Food Standards Code (the Food Standards Code) and/or substances that are not otherwise permitted in food. Examples include fruit juices with Echinacea, fruit drinks with added vitamin B3, B6 and B12, and sports protein powders with extra vitamin D and iodine. Supplemented foods must be safe and must meet the same requirements for, among other things, labelling, and food additives, processing aids, toxicants and contaminants that apply to all food.

Supplemented foods are regulated under the New Zealand Food (Supplemented Food) Standard 2010 (SFS). The SFS is made under the Food Act 1981 and is an interim standard until such time as appropriate provisions are developed in reviews of standards in the Food Standards Code. The intention is to maintain consistency with the Food Standards Code so that supplemented foods can easily move when required. The SFS is not part of the Food Standards Code.

This discussion paper seeks comment from members of the public on a proposal to review the SFS to:

- incorporate by reference the new Standard 1.2.7 – Nutrition, Health and Related Claims of the Food Standards Code (which will allow supplemented foods to make health claims in accordance with Standard 1.2.7); and
- to clarify how the SFS applies to caffeine and to attend to several technical matters.

The Ministry for Primary Industries (MPI) proposes the following amendments to the SFS in order to incorporate Standard 1.2.7 into the SFS:

- incorporation of Standard 1.2.7 of the Food Standards Code by reference into clause 7 of the SFS;
- notification of self-substantiated health claims to the Director General of MPI rather than the Chief Executive Officer of Food Standards Australia New Zealand (FSANZ);
- provision of a New Zealand-only address by the business making the claim;
- replacement of references to Recommended Dietary Intake (RDI) in Standard 1.2.7 with references to the 2006 National Health and Medical Research Council Australia New Zealand Nutrient Reference Values (NRVs);
- clarification that standards from the Food Standards Code that are referenced in Standard 1.2.7 will not apply to supplemented food unless the standards are already incorporated by reference into the SFS;
- removal of clauses 10 and 11 from the SFS;
- a prohibition on content claims that compare a vitamin or mineral content of one food with another (for example, “higher in vitamin C compared with X”);
- replacement of the specified amount of choline that is required to make the relevant general level health claims with 10 percent of the Adequate Intake (AI) for adult males in the 2006 NRVs; and
- a transition period that allows businesses to have until 18 January 2016 to comply with the amendments in line with the transition period for Standard 1.2.7.

MPI also proposes that:

- the application of the SFS to foods containing caffeine is clarified by providing that supplemented food products can contain added caffeine for a purpose other than as a food additive (for example, as an ingredient);
- Part 2 of the SFS, which provides the original transition provisions, be replaced with new transition provisions; and
- clauses that are referred to in the SFS that no longer apply in the Food Standards Code should be deleted.

Submissions close at 5pm on **29 August 2013.**

2 Introduction

The purpose of this discussion paper is to seek public 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); and
- clarify the application of the SFS to foods containing added caffeine to maintain the status quo for caffeine regulation in New Zealand.

In addition to these matters, there are several technical matters that require minor amendments. These relate to:

- revocation of Part 2 of the SFS which ceased to apply from the 31 March 2012;
- incorrect naming of the Dietary Supplements Regulations 1985 in clause 6 of the SFS; and
- clauses that have been deleted in the Food Standards Code still being referenced in the SFS.

This paper will not revisit decisions made in relation to the introduction of Standard 1.2.7, as the Standard was agreed to by the Legislative and Governance Forum on Food Regulation (the FoFR).[1] Standard 1.2.7 was gazetted on 11 April 2013 in New Zealand.

This paper is not intended as a review of caffeine regulation in New Zealand. A separate review of trans-Tasman caffeine policy is currently being conducted by the FoFR.[2]

Furthermore, this paper is not a full review of the SFS. 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 of the SFS in the near future.

[1] The FoFR is the Ministerial committee that oversees the joint Australia New Zealand food standards system.
[2] For information about the review see http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policy-guidelines#1

3 Consultation

Written submissions on the issues raised and options presented in this consultation paper are invited from all interested parties. MPI is particularly interested in receiving feedback on the feasibility of the preferred option in section 8.

The closing date for submissions is 5pm **29 August 2013**.

Submissions should be sent to:

Vicky Scott, Food Policy
Biosecurity, Food & Animal Welfare Policy
Ministry for Primary Industries
PO Box 2526
Wellington 6104
New Zealand

Delivery address: Pastoral House, 25 The Terrace, Wellington

Email: foodpolicy@mpi.govt.nz

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title, the name of the organisation and the extent of internal consultation undertaken in preparing the submission.

Please make sure your comments can be clearly read, as a number of copies may be made of your submission. Please also state the number(s) of the section(s) commented on, beside each comment.

Submissions backed by evidence and argument will carry more weight than statements of opinion.

3.1 Official Information Act

Under the Official Information Act 1982 (OIA), information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information, such as names or contact details, to be withheld. MPI will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

3.2 Process after submissions

Once the consultation period has closed, MPI will analyse submissions and make recommendations to the Minister for Food Safety who is responsible for issuing food standards under the Food Act 1981. A summary of submissions and analysis will be sent to all submitters and posted on the MPI website.

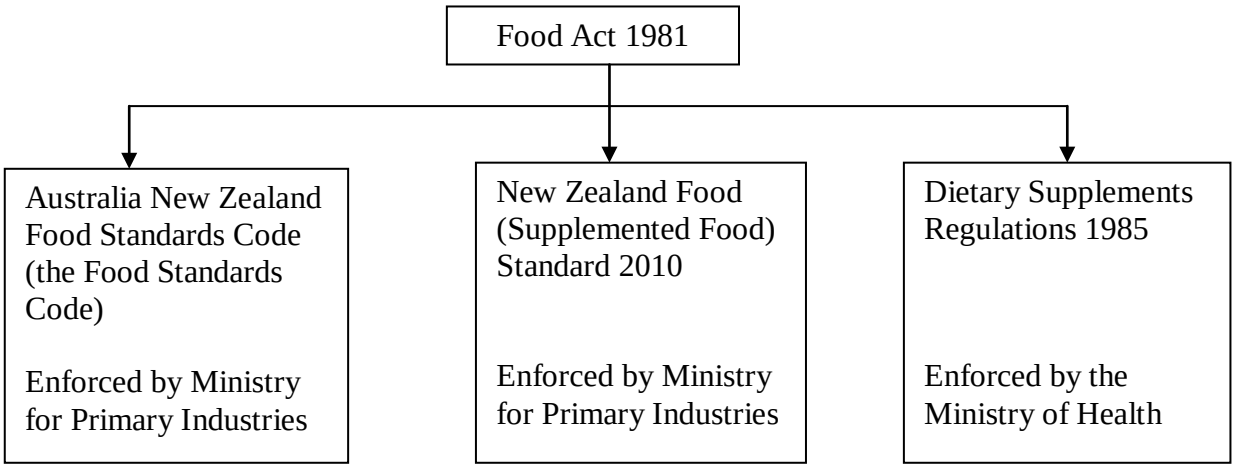
4 Background

Most food sold in New Zealand is regulated under the Food Standards Code, which is a set of common food standards shared by Australia and New Zealand.

Supplemented foods, however, sit outside the Food Standards Code and are regulated by a New Zealand standard under the Food Act 1981 which MPI administers (Figure 1). This standard is the SFS (see Figure 1). The SFS continues arrangements for food-type dietary supplements agreed with Australia when the Food Standards Code came into force in 2002.

Supplemented foods contain substances that provide for more than just basic nutritional needs. Supplemented food may include the addition of vitamins and minerals in amounts that are higher than those permitted under the Food Standards Code and/or substances that are not otherwise permitted in food. Examples include fruit juices with Echinacea; fruit drinks with added vitamin B3, B6 and B12; and sports protein powders with extra vitamin D and iodine.

Figure 1. Food regulation in New Zealand



The SFS is an interim standard as the intention is to move products into the Food Standards Code when there are appropriate provisions developed through future reviews of standards in the Food Standards Code. The SFS therefore needs to be consistent with the Food Standards Code to allow for an easy transition. To this end, the SFS incorporates by reference the majority of the standards in the Food Standards Code.

Therapeutic-type dietary supplements (products sold in controlled dosage form, including, for example, pills, capsules and tablets) are not supplemented foods. They are regulated under the Dietary Supplements Regulations 1985 and administered by the Ministry of Health.

4.1 The Supplemented Food Standard

The objectives of the SFS[3] are to:

- provide adequate regulatory coverage for supplemented food in order to:
  - protect public health and safety while maintaining consumer choice;

[3] The objectives are set out in NZFSA (2008). *Proposed Standard for Supplemented Food: NZFSA Public Discussion Paper, no. 05/08.* http://www.foodsafety.govt.nz/elibrary/industry/supplemented-food-draft-standard/ Accessed 14 June 2013

  - support economic growth; and
  - maintain an existing right for New Zealand consumers, manufacturers, importers and exporters to access and supply supplemented food.
- align supplemented food with the requirements of the Food Standards Code to the maximum extent possible pending the development of appropriate permissions in the Food Standards Code. This is consistent with the objectives of the Single Economic Market and Trans-Tasman Mutual Recognition Arrangement;
- facilitate the transfer of products to regulation under the Food Standards Code when appropriate permissions are developed; and
- prevent the addition of substances to food that have a function and/or have a purpose of intoxication.

Provisions within the SFS include:

- the definition of supplemented food;
- aspects of the Food Standards Code that apply;
- a prohibition on supplemented food for infants and young children under four years of age;
- a prohibition on the addition of certain substances;
- a list of substances that may be added subject to restrictions;
- identification requirements;
- safe daily consumption statements.
- restrictions on:
  - advertising and labelling;
  - content claims of vitamins and minerals;
  - intoxicating substances; and
  - the addition of vitamins and minerals.

A two-year transitional period was included in the SFS. The transition period ended on 30 March 2012.

Question

If your company sells product lines and/or stock keeping units that are regulated under the SFS, what sort of products are they?

How many product lines and/or stock keeping units does your company sell under the SFS? How often do you re-label these product lines and/or stock keeping units and when was the last time you re-labelled them?

5 The Problem

5.1 Incorporating Standard 1.2.7 by reference into the SFS

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

As the SFS is intended to align supplemented foods as closely as possible to the standards applying under the Food Standards Code, it is now necessary to incorporate by reference Standard 1.2.7 into the SFS. The incorporation by reference of Standard 1.2.7 was signalled during public consultation processes during the development of the SFS.[4]

5.2 Clarifying the application of the SFS to foods containing added caffeine

When the SFS was introduced, one of the objectives was to maintain existing rights for New Zealanders in relation to supplemented food.[5] This included a number of food supplement products on the market that contained caffeine. However, as noted by the High Court in a recent judgment,[6] there is a lack of clarity in the SFS in how it applies to supplemented foods that contain caffeine.

5.3 Replacing Part 2 of the SFS

The SFS contains Part 1 – *Supplemented Food Requirements* and Part 2 – *Temporary Option for Supplemented Food*. Part 2 is the original transitional provisions and expired on 30 March 2012 (as provided for in clause 4(3)) and is therefore no longer necessary.

If this review results in amendments, appropriate transitional provisions for those amendments would be included in a new Part 2 of the SFS.

5.4 Amendments of a minor or technical nature

5.4.1 Clause 7 and references to the Food Standards Code

Clause 7 of the SFS excludes:

- clause 6 in Standard 2.5.1 – *Milk*; and
- clause 2(1)(h) in Standard 2.4.2 – *Edible Oil Spreads*.

These clauses were removed from the Food Standards Code after the SFS was introduced. It is therefore necessary to remove the references to these clauses from the SFS.

[4] See http://www.foodsafety.govt.nz/elibrary/industry/supplemented-food-draft-standard/
[5] NZFSA (2008). *Proposed Standard for Supplemented Food: NZFSA Public Discussion Paper; no.05/08.* http://www.foodsafety.govt.nz/elibrary/industry/supplemented-food-draft-standard/ Accessed 14 June 2013.
[6] *Sanson v The Attorney-General* HC WN CIV-2011-485-2386 [9 October 2012]

5.4.2 Reference to 'Dietary Supplements Regulations' in the SFS

Clause 6(2)(a) states that a product is not a supplemented food if it is "a dietary supplement (as defined in the Dietary Supplement Regulations 1985)". The correct name for the Regulations is the "Dietary Supplements Regulation 1985". It is therefore necessary to amend the reference to the regulations in the SFS.

6 Proposal

6.1 Incorporating Standard 1.2.7 into the SFS

6.1.1 Standard 1.2.7 – Nutrition, Health and Related Claims

Standard 1.2.7 of the Food Standards Code, which was gazetted on 11 April 2013, regulates the voluntary use of nutrition content claims, health claims and endorsements. The Standard supports industry innovation and provides consumers with scientifically based information that can assist in informed decision making.

A "nutrition content claim" is a claim about the presence or absence of energy, a nutrient or a biologically active substance in food. Examples include, "low in fat" or "good source of calcium". In order to make such claims, certain conditions apply. For example, a food that is described as "low fat" must contain no more fat than 3 grams per 100 grams for solid food.

A 'health claim' is a claim that a food or a property of food has or may have a health effect. There are two types of health claims:

1. "high level health claims" refer to the presence of a nutrient or substance in a food and its relationship to a serious disease or a biomarker of a disease (for example, "diets high in calcium may reduce the risk of osteoporosis"). All high level health claims must be pre-approved by Food Standards Australia New Zealand (FSANZ). Standard 1.2.7 currently lists 13 pre-approved high level claims;
2. "general level health claims" refer to the presence of a nutrient or substance in a food and its relationship to a health or physiological function (for example, "calcium is good for healthy bones and teeth"). Food businesses wishing to make general level health claims can base their claims on either:
   - Food–health relationships that have been pre-approved by FSANZ and listed in Standard 1.2.7 (of which there are currently 212); or
   - self-substantiated food–health relationships established in accordance with criteria set out in Standard 1.2.7. The criteria includes a requirement to hold evidence to support the claimed food – health relationship, and a requirement to notify FSANZ of an intention to market a product with a claim based on a self-substantiated food – health relationship.

All health claims are required to be supported by scientific evidence and are only permitted on foods that meet specific eligibility criteria, including the nutrient profiling scoring criteria (NPSC). The NPSC restricts the use of health claims on products considered to be of "lower nutritional quality". For example, health claims will not be allowed on foods high in saturated fat, sugar or salt. Standard 1.2.7 aims to ensure that consumers can have confidence that health claims are scientifically based.

Food businesses have three years to meet the requirements of Standard 1.2.7 from 18 January

2013, with no additional stock-in-trade[7] period. That means that food businesses will be able to choose to comply with either Standard 1.2.7 (including the consequential variations) or the existing provisions for nutrition and health claims currently in the Food Standards Code (such as Standards 1.1A.2, 1.2.8 and 1.3.2).

During the transition, FSANZ plans to undertake further work with industry, public health organisations and consumers on a range of issues including refining the NPSC and developing and implementing a process to maintain the scientific currency of pre-approved food – health relationships.

6.1.2 Rationale for incorporating Standard 1.2.7 into the SFS

The incorporation of Standard 1.2.7 into the SFS would maintain consistency with the Food Standards Code, in line with the policy intent to move supplemented foods into regulation under the Food Standards Code as appropriate permissions become available in the future (as per clause 3 in the current SFS). The incorporation by reference of Standard 1.2.7 into the SFS would allow supplemented foods to make health claims if they meet the requirements of Standard 1.2.7.

Without the amendment, supplemented food can carry nutrition content claims but the criteria that apply to them may be inconsistent. Consumers may therefore be misled.

The intention to incorporate Standard 1.2.7 into the SFS was signalled in a 2008 consultation paper.[8] Six of the forty-two submitters who responded to the paper made comments about nutrition content and health claims but because Standard 1.2.7 was still under development, nearly all of the comments related to aspects of it. These comments are therefore largely outdated. Overall though, submitters implied support for a regime that permits nutrition and health claims on supplemented foods.

Now that Standard 1.2.7 has been gazetted, MPI proposes to amend the SFS to incorporate by reference Standard 1.2.7.

Question

Do any of the product lines and/or stock keeping units your company sells under the SFS currently have health claims? How many?

Will any of these product lines and/or stock keeping units require labelling changes? How much do you estimate that the label changes will cost (given the length of the transition period)?

6.1.3 Mechanism for incorporating Standard 1.2.7 in to the SFS

Standard 1.2.7 can be incorporated into the SFS via clause 7 of the SFS, which lists aspects of the Food Standards Code that apply to supplemented foods. However, certain clauses from Standard 1.2.7 will need to be excluded or modified where they conflict with the intent of the SFS. Similarly, certain clauses from the SFS need to be removed in order to ensure consistency with Standard 1.2.7. The relevant adjustments are discussed in the following sections.

[7] Stock-in-trade refers to all supplemented food products kept on hand and used in carrying on a business
[8] NZFSA (2008). *Proposed Standard for Supplemented Food: NZFSA Public Discussion Paper; no.05/08.* http://www.foodsafety.govt.nz/elibrary/industry/supplemented-food-draft-standard/ Accessed 14 June 2013.

6.1.4 Changes to the SFS to enable the incorporation by reference of Standard 1.2.7

Clause 10: Restrictions on advertising and labelling

Clause 10 restricts advertising and labelling on supplemented food by preventing claims of a therapeutic nature. It does this by applying the relevant subclauses of the definition of "therapeutic purpose" from the Medicines Act 1981 and replicating subclauses 3(b) and 3(c) of the transitional standard for health claims in the Food Standards Code (Standard 1.1A.2 – Transitional Standard – Health Claims).

Incorporating Standard 1.2.7 by reference into the SFS means that clause 10 in the SFS can be deleted. Clauses 7 and 14 of Standard 1.2.7 and the definitions of "health claim" and "health effect" will restrict therapeutic claims.

Questions

Should clause 10 be removed from the SFS?

Are there any subclauses within clause 10 of the SFS that need to remain in order to retain the intent of not permitting claims of a therapeutic nature, unless permitted under Standard 1.2.7?

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 as provided in clause 15 of Standard 1.2.7 of the Food Standards Code. Examples of comparative claims are those using the terms "reduced", "increased", and "less than", "light" and "lite".

Clause 8 of Standard 1.2.7 does not permit comparative claims that are made in relation to vitamins and minerals unless the claim is permitted by another standard in the Food Standards Code. This provision previously existed in Standard 1.3.2 of the Food Standards Code.

The SFS does not reference Standard 1.3.2 and so comparative claims for vitamins and minerals are not prohibited on supplemented foods. However, by incorporating Standard 1.2.7 into the SFS, supplemented foods will no longer be able to make such claims. Given the need for consistency between the SFS and the Food Standards Code, MPI proposes that such claims should not be permitted under the SFS.

Questions

Does your company currently sell product lines and/or stock keeping units with comparative vitamin and mineral content claims? What sort of products are they? How many product lines and/or stock keeping units does your company sell?

What impact will the removal of permission to make comparative claims about vitamins and minerals have on your product lines and/or stock keeping units?

Is there any basis for supplemented food to exclusively make comparative claims about vitamins and minerals?

Clause 11 of the SFS

Clause 11 of the SFS restricts nutrition content claims for vitamins and minerals. It regulates claims about the presence of a vitamin or mineral as well as claims that are a "good source" of a vitamin or mineral.

Incorporating Standard 1.2.7 into the SFS means that clause 11 can be deleted. Vitamin and mineral content claims are contained in Schedule 1 of Standard 1.2.7.

Question

Is there any need to retain part or all of clause 11 of the SFS?

6.1.5 Aligning provisions in Standard 1.2.7 with the SFS

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 FSANZ of the details of the relationship between their food or property of food and the health effect (subclause 17(4)(b)). This notification is not applicable to the SFS, because FSANZ does not have a role in administering the SFS.

MPI therefore proposes that subclause 17(4)(b) of Standard 1.2.7 should be replaced when applied to supplemented food so that notification is to the Director-General of MPI.

A consequence of the above is that the following clauses from Standard 1.2.7 also need to be replaced when applied to the SFS.

Subclause in Standard 1.2.7	**Proposed variation when incorporated into the SFS**	**Reason**
18(a)	Removal of the requirement to provide an address in Australia	The SFS applies to foods made in and imported into New Zealand and therefore all addresses must be in New Zealand
18(b)	Replacement of the word "Authority" with "Ministry for Primary Industries"	The word "Authority" refers to FSANZ under the FSANZ Act 1991. MPI administers supplemented food.

Reference to Recommended Dietary Intake

When the SFS was developed, the 2006 National Health and Medical Research Council Australia New Zealand Nutrient Reference Values (NRVs) were adopted. The 2006 NRVs provided the most up to date published Recommended Dietary Intakes (RDIs) and adequate intakes (AIs) for certain nutrients for specific population sub-groups in Australia and New Zealand at the time.

Standard 1.2.7 refers to older NRVs[9] for the conditions that must be met in order to make a vitamin or mineral content claim.[10]

[9] The Food Standards Code makes use of regulatory NRVs (rNRVs) for vitamins, minerals[9] and protein based on the 1991 Recommended Dietary Intakes and, where values were unavailable, the 1989 United States Estimated Safe and Adequate Daily Dietary Intakes. The rNRVs for macronutrients and their components were drawn from other government recommendations.

MPI considers that any reference to the regulatory NRVs (rNRVs) within Standard 1.2.7 should be replaced by the 2006 NRVs in the SFS. As the SFS already uses the updated NRVs, MPI does not consider it is appropriate to use the rNRVs that are now well out of date, even though a number of the rNRVs for vitamins and minerals are lower than the 2006 NRVs for certain age groups. Nor is it appropriate to provide manufacturers of supplemented food with the choice of using either the rNRVs or the 2006 NRVs as this is likely to result in all manufacturers of supplemented food using the rNRVs (that is, a nutrition content claim could be made with a lesser quantity of a vitamin or mineral in the product).

It is important to note that the discrepancy between the rNRVs in the Food Standards Code and the 2006 NRVs has existed for nutrition content claims since the introduction of the SFS. Although this paper addresses the NRVs in relation to the introduction of Standard 1.2.7, the purpose of this review is not to address the ongoing discrepancy between the Food Standards Code and the SFS. Furthermore, FSANZ has recognised the need to incorporate the 2006 NRVs in the Food Standards Code, and has publicly consulted on the matter in the past few years.[11] This is not likely to be addressed in the near future as it is currently not listed on the FSANZ work plan.[12]

Reference to Standard 1.3.2 – Vitamins and Minerals

Standard 1.3.2 – Vitamins and Minerals of the Food Standards Code does not apply to supplemented food as per clause 7 of the current SFS. This is because Standard 1.3.2 has restrictions around the levels of vitamins and minerals, which are not relevant to supplemented food. The SFS has its own restrictions on the addition of vitamins and minerals as per clause 16.

Column 2 states that in order to make a claim for a vitamin or mineral (other than potassium or sodium):

> (c) a claim is not for more of the particular vitamin or mineral than the maximum claimable amount as prescribed by clause 4 or clause 5 of Standard 1.3.2.

Condition (c) for vitamins and minerals in column 2 of Schedule 1 in Standard 1.2.7 will therefore not apply to supplemented food.

Reference to Standard 2.9.4

Standard 2.9.4 – Formulated Supplementary Sports Foods does not apply to supplemented food. This means that foods are not prohibited from being marketed under the SFS for sports purposes if they contain higher levels of vitamins and minerals than permitted in Standard 2.9.4.

Because Standard 2.9.4 is not incorporated by reference into the SFS, any references to it in Standard 1.2.7 would not apply to supplemented food.

Why health claims made under Standard 1.2.7 cannot be applied to Standard 2.9.4

During the development of Standard 1.2.7, the focus was on a standard for nutrition, health and related claims that would apply to general–purpose foods rather than on claims for product-specific standards. This was partly because product-specific standards, including

[10] See (b) in column 2 and column 4 of Schedule 1 for "Vitamin or Mineral (not including potassium or sodium)" in Standard 1.2.7 of the Food Standards Code

[11] Food Standards Australia New Zealand .*Nutrient Reference values in the Australia New Zealand Food Standards Code – Potential Revision*. http://www.foodstandards.gov.au/scienceandeducation/mediacentre/webseminars/nutrientreferenceval4824.cfm. Accessed on 14 June 2013.

[12] Food Standards Australia New Zealand *Work plan* http://www.foodstandards.gov.au/foodstandards/changingthecode/standardsworkplan.cfm. Accessed 14 June 2013.

Standard 2.9.4, contained allowable claims. It was also because foods relating to standards such as Standard 2.9.4 were on FSANZ's work programme for review and it seemed appropriate that permission for nutrition and health claims would be better addressed during the review of those standards.

Clause 6 of Standard 2.9.4 outlines a general prohibition on health claims unless expressly permitted elsewhere within the Standard. A review of sports food is on the FSANZ work plan and still on hold pending completion of related work.

Vitamin and mineral content claims

Column 2 of Schedule 1 in Standard 1.2.7 of the Food Standards Code states that, in order to make a nutrition content claim for a vitamin or mineral (except potassium or sodium) the food:

(d) is not a food standardised by Standard 2.9.4.

Almost all health claims must meet the conditions for the relevant nutrition content claim in Standard 1.2.7. The effect of condition (d) then, is that foods regulated under Standard 2.9.4 cannot carry health claims about a vitamin or mineral unless expressly permitted within Standard 2.9.4 (except for high level health claims that relate to calcium and general level health claims that relate to fluoride and choline). In contrast, health claims can be made on general-purpose foods provided they meet the requirements in Standard 1.2.7.

For supplemented foods, there are no product specific categories. MPI therefore considers that supplemented foods that are marketed for the purposes of sports performance should be able to make nutrition content claims and health claims about vitamins and minerals, provided they meet all the requirements in Standard 1.2.7, including the NPSC.

Reference to Standard 2.6.4, 2.9.2 and 2.9.3

Clause 6 in the SFS prohibits a supplemented food from being a formulated meal replacement or a formulated supplementary food (as defined in Standard 2.9.3 of the Food Standards Code) or a formulated caffeinated beverage (as defined in Standard 2.6.4 of the Food Standards Code). Clause 8 also prohibits supplemented food for infants or young children under the age of four years.

Standard 1.2.7 makes references to the above standards. Therefore, these references should not apply to supplemented food.

General level health claims that relate to fluoride and choline

There are no rNRVs for fluoride and choline in the Food Standards Code. Conditions for general level health claims that relate to these two nutrients therefore specify amounts in Standard 1.2.7. The SFS, however, references the 2006 NRVs (clause 5(3) of the SFS), which include NRVs for fluoride and choline. MPI considers that the 2006 NRVs should be used for supplemented food wherever possible.

For a general level health claim that relates fluoride to the maintenance of tooth mineralisation, the food must contain no less than 0.6 milligrams of fluoride per litre (column 5 of Schedule 3 in Standard 1.2.7). The specified amount is based on the minimum amount of fluoride in fluoridated water. The provision that the food must contain no less than 0.6 milligrams of fluoride per litre in order to make the health claim seems appropriate to adopt in the SFS. This is because fluoride that is consumed as part of a beverage is more likely to come in contact with the teeth and aid in the maintenance of tooth mineralisation.

For choline, the 2006 NRVs seem appropriate as the basis for determining the conditions for the three general level health claims that are listed in Standard 1.2.7. The User Guide for the SFS recommends that where a supplemented food has not been formulated for a specific population, the RDI or AI for adult males can be used (that is, 550 milligrams of choline per day). If the "10 percent of the AI" rule is applied to choline, the supplemented food should therefore contain no less than 55 milligrams per serve in order to make one of the three approved general level health claims (as compared with 50 milligrams of choline per serve in Standard 1.2.7, which is based on approximately 10 percent of a midpoint value for the NRV AI for men (550 milligrams per day) and women (425 milligrams per day)).[13]

Question

Should the condition for a general level health claim that relates fluoride to the maintenance of tooth mineralisation be based on 0.6 milligrams of fluoride per litre? Are there more valid reasons to base it on the 2006 NRVs? Please provide reasons for your answer.

6.1.6 Consequential changes to regulations under the Medicines Act 1981 to permit health claims on food

Foods carrying certain health claims that comply with Standard 1.2.7, particularly those carrying high level health claims, are "related products" under the Medicines Act 1981. This means that case-by-case approval is required from the Minister of Health, which is costly and time consuming for food businesses and government agencies and offers no additional benefits.

Regulations can be made under the Medicines Act to exclude a food from being a "related product". This has already occurred for foods carrying a health claim about increased maternal folate consumption prior to and in early pregnancy and a reduction in the risk of foetal neural tube defects (for example, spina bifida).

MPI and Medsafe (the regulatory arm of the Ministry of Health responsible for the regulation of medicines) are currently developing regulations under the Medicines Act to exclude foods that carry certain compliant health claims from being related products.

Supplemented foods that make health claims must meet the requirements in Standard 1.2.7 and will therefore be excluded from being related products when the necessary regulations are made under the Medicines Act.

6.1.7 Transition period

Although the incorporation of Standard 1.2.7 into the SFS provides for voluntary nutrition content and health claims, many food businesses will need time to minimise losses from stock-in-trade (especially for products carrying comparative vitamin or mineral claims) and to ensure that the labelling of existing products can be assessed and updated.

Until Standard 1.2.7 becomes fully effective in the Food Standards Code on 18 January 2016, Standard 1.1A.2 provides the transitional standard that operates concurrently with Standard 1.2.7. MPI therefore proposes that the transition period for the proposed amendment to the SFS operates until 18 January 2016 to align with the Food Standards Code, with no stock-in-trade period after this date.

[13] Personal communication with FSANZ, 28 February 2013.

6.2 Clarifying the application of the SFS to supplemented foods containing added caffeine

MPI proposes the inclusion of an additional clause in the SFS to clarify that products that meet the definition of supplemented food can contain added caffeine for a purpose other than as a food additive (for example, as an ingredient). That is, caffeine can be added at levels that are above the amounts currently permitted as a food additive (145 milligrams per litre). This clarification will maintain the status quo for the regulation of caffeine in New Zealand. Products that meet the definition of "formulated caffeinated beverage" in the Food Standards Code[14] will remain excluded from the scope of the SFS.

The existing provisions in the SFS in relation to labelling and advisory statements for caffeine in supplemented foods will continue to apply. In addition, the general provisions of the Food Act 1981 in relation to the safety and suitability of food apply to supplemented food. As such, levels of caffeine in supplemented food must be safe and suitable for their intended purpose.

6.2.1 Trans-Tasman review of caffeine policy

The FoFR has initiated a review of caffeine policy in the joint Australia–New Zealand food standards system. One of the aims is to explore the harmonisation of caffeine regulation in both countries. It is intended that the review will provide guidance for FSANZ in the future development of standards relating to caffeine in the Food Standards Code. This may provide a platform for transitioning supplemented foods containing caffeine into regulation under the Food Standards Code in the future.

6.3 Replacing Part 2 of the SFS

The SFS contains Part 1 – *Supplemented Food Requirements* and Part 2 – *Temporary Option for Supplemented Food*. Part 2 expired on 30 March 2012 (as provided for in clause 4(3)) and is therefore no longer necessary.

MPI's proposal to incorporate Standard 1.2.7 by reference into the SFS includes a recommendation that allows a transition period until 18 January 2016. MPI therefore proposes that Part 2 of the SFS be replaced with the current Part 1 and that it include a subclause that clarifies how the SFS applies to caffeine as well as the minor technical amendments, as these changes maintain the status quo. This will mean that people can refer back to the current SFS, if they choose to comply with that version, until 18 January 2016.

6.4 Technical amendments to the SFS

6.4.1 Clause 7 and the reference to: clause 6 in Standard 2.5.1 – Milk; and clause 2(1)(h) in Standard 2.4.2 – Edible Oil Spreads

Clause 7 of the SFS excludes:

- clause 6 in Standard 2.5.1 – Milk; and
- clause 2(1)(h) in Standard 2.4.2 – Edible Oil Spreads.

[14] "formulated caffeinated beverage" means a non-alcoholic water-based flavoured beverage that contains caffeine and may contain carbohydrates, amino acids, vitamins and other substances, including other foods, for the purpose of enhancing mental performance.

As the Food Standards Code no longer refers to either of these clauses, MPI proposes that they be deleted from applying to the SFS.

6.4.2 Renaming "Dietary Supplement Regulations"

Clause 6(2)(a) states that a product is not a supplemented food if it is "a dietary supplement (as defined in the Dietary Supplement Regulations 1985)". MPI proposes that "Dietary Supplement Regulations 1985" be changed to "Dietary Supplements Regulations 1985" in order to provide the correct title of the regulation.

7 Options

The options considered are as follows:

Option 1: Do not proceed with the proposal (status quo)

Option 2: Proceed with the proposal as outlined (that is, amend the SFS to incorporate Standard 1.2.7 of the Food Standards Code, to clarify the application of the SFS to supplemented foods containing added caffeine and to make minor technical amendments).

7.1 Analysis of options

The benefits and costs of each of the options are summarised in the table below.

<table>
<tr><td colspan="2">Option 1: Do not proceed with proposal (status quo)</td></tr>
<tr><td>Benefits</td><td>Costs</td></tr>
<tr><td>In relation to incorporating Standard 1.2.7 into the SFS:
• continued familiarity with existing provisions;
• no re-labelling costs as product labels do not need to be reviewed or re-labelled.
In relation to caffeine:
• continued familiarity with existing provisions.
In relation to technical matters:
• continued familiarity with existing provisions.</td><td>In relation to incorporating Standard 1.2.7 into the SFS:
• the SFS would not be aligned as closely with the Food Standards Code, making it costly and difficult to transition supplemented foods into the Food Standards Code in the future;
• supplemented foods would not be able to make health claims, reducing scope for marketing and innovation;
• foods regulated by the SFS would be disadvantaged compared with foods under the Food Standards Code – this would potentially result in the loss of business;
• consumers may continue to be misled by nutrition content claims as there are no specific criteria for them;
• consumers would not be provided with scientifically based information to assist in decision making;
• enforcement would need to enforce two regimes for health claims (that is, Standard 1.2.7 which permits health claims and the SFS which prohibits them).
In relation to caffeine:
• ongoing uncertainty as to whether caffeine can be added for purposes other than as a food additive and the potential for litigation.
In relation to technical matters:</td></tr>
</table>

	• existing redundancies would remain in legislation contrary to good legislative drafting practice; • references to clauses in the Food Standards Code that do not exist or have expired may continue to cause confusion.
Option 2: Proceed with proposal as outlined	
Benefits	**Costs**
In relation to incorporating Standard 1.2.7 into the SFS: • the SFS is aligned as closely as possible with the Food Standards Code, which supports an easy transition of supplemented food to the Food Standards Code when the appropriate permissions become available; • supplemented foods can carry health claims, providing scope for product innovation; • there is a regulatory framework for health claims on exported foods that are formulated to meet importing market requirements (other than Australia) (and therefore would not necessarily comply with the compositional requirements of the Food Standards Code); • small and medium enterprises can draw from pre-approved health claims while large enterprises investing in innovation have the flexibility to go to market with self-substantiated health claims at a time they determine; • nutrition content and health claims are based on risk analysis using the best available scientific evidence - consumers can therefore have confidence in such claims; • consumers seeking supplemented foods with specific health benefits will have substantiated information to help them make informed purchasing decisions; • misleading and deceptive behaviour is likely to be minimal as firms would be required to follow a consistent approach that is scientifically substantiated; • there are many similarities with food regulations in the European Union, United States of America and Canada; • incorporating Standard 1.2.7 into the	*In relation to incorporating Standard 1.2.7 into the SFS:* • supplemented foods would no longer be able to make comparative claims about vitamins and mineral content. A very limited search by MPI found only one supplemented food carrying a comparative claim in relation to a vitamin or mineral, so the impact of a prohibition may be small; • supplemented foods carrying claims that are not compliant with Standard 1.2.7 will have to be re-labelled. The impact may be small given that businesses will have until 18 January 2016 to make any necessary changes; • some manufacturers may re-position products that are currently under Standard 2.9.4 as supplemented foods. This may, however, be mitigated by other manufacturers reformulating and repositioning products as general purpose foods in order to make health claims under Standard 1.2.7 • the cost of re-labelling products may be handed on to consumers, though any cost is likely to be minimal, especially with a transition period of more than two years; • consumers may be confused if a product carries an advisory statement and also a health claim. *In relation to caffeine:* • there are no costs, as the intent and existing status quo is maintained. *In relation to technical matters:* • there are no costs, as the intent and existing status quo is maintained.

SFS provides uniformity for the industry and enforcement agencies. *In relation to caffeine:* • the original intent of the SFS is maintained; • there is certainty that caffeine can be added to supplemented food for purposes other than as a food additive. *In relation to technical matters:* • the SFS is tidier.	

8 Preferred Option

MPI's preferred option is to proceed with the proposal (Option 2) as outlined in this paper. The proposal would implement previously agreed policies, clarify existing provisions and make minor and technical changes to tidy up the drafting of the SFS.

While the costs and benefits of the proposal cannot be quantified, based on previous analysis prepared by FSANZ during the development of Standard 1.2.7, MPI considers that the proposal would deliver a net benefit to New Zealand, and that costs of the proposal are minimal.

Questions

What impact would the proposed changes have on you? Can you be specific in terms of economic costs and benefits?

What other impacts will the proposed changes have on businesses selling supplemented food and on consumers?

Are other groups affected by this amendment and, if so, in what way?

Is there any evidence to show that consumers are confused by products carrying both health claims and advisory statements?

9 Implementation

9.1 Implementation workshop

MPI considers there may be a need to conduct a workshop to assist with implementation of the SFS, if it is amended. This workshop would be on a needs basis and include background and details of any changes as well as content of particular interest to attendees.

Questions

Would you or your staff attend an implementation workshop for the SFS if it is amended?

What would you want the workshop to cover?

9.2 The New Zealand Supplemented Food Standard User Guide

The SFS User Guide located on the MPI website http://www.foodsafety.govt.nz/elibrary/industry/zealand-supplemented-foods-standard-user-guide/index.htm, will be updated if the standard is amended.

10 Enforcement

The SFS is issued under the Food Act 1981. The enforcement provisions of that Act therefore apply to those importing, manufacturing and selling supplemented food products. These provisions:

- ensure that people take responsibility for the safe and suitable manufacture and sale of supplemented food;
- encourage maximum compliance;
- ensure the enforcement action is commensurate with the degree of seriousness; and
- are applied consistently across all food sectors.

Attachments

A. Variation to the *New Zealand Food (Supplemented Food) Standard 2010*

Attachment A – Draft Variation to the *New Zealand Food (Supplemented Food) Standard 2010*

Pursuant to section 11C of the Food Act 1981, the Minister for Food Safety issues the following food standard.

Issued at Wellington this day of 2013

Signed

(signed)

Hon Nikki Kaye
Minister for Food Safety

Certified in order for signature

(signed)

Solicitor

/ /2013

Published by the Ministry for Primary Industries, PO BOX 2526, Wellington 6140

Contents

1 Title

This standard is the New Zealand Food (Supplemented Food) Standard 2013.

2 Commencement

This standard comes into force on XX 2013.

3 Revocation

This standard revokes the New Zealand Food (Supplemented Food) Standard 2010.

4 Purpose

The purpose of this standard is to, ─

(1) provide an interim regulatory arrangement for supplemented food until there are appropriate permissions in the Code; and

(2) regulate "food-type" dietary supplements that were formerly regulated under the Dietary Supplements Regulations 1985.

5 Application

(1) This standard applies to a person manufacturing, selling, or preparing for sale supplemented food.

(2) A person manufacturing, selling, or preparing for sale supplemented food must elect to comply with either:

(a) Part 1; or

(b) Part 2.

(3) From 18 January 2016 a person manufacturing, selling, or preparing for sale supplemented food must comply with Part 1.

Part 1
Supplemented Food Requirements

6 Interpretation for Part 1

(1) In this standard, unless the context otherwise requires─

Act means the Food Act 1981

Code means the Australia New Zealand Food Standards Code

warning statement has the same meaning as provided in the Code in addition to a statement to be expressed in the text as so prescribed in this standard, in ─

(a) clause 13 Table 1; and

(b) clause 15(3) Table 4.

(2) Any words or expressions defined in the Act or the Code and used but not defined in this standard have the same meaning as in the Act or in the Code.

(3) References to adequate intake (AI) and recommended dietary intake (RDI) mean the age-appropriate figures published by the National Health and Medical Research Council of Australia and the New Zealand Ministry of Health "Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes (2006)" (NRV (2006)).

7 Meaning of supplemented food

(1) A supplemented food is a product that is represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement.

(2) A product is not a supplemented food if it is─

(a) a dietary supplement (as defined in the Dietary Supplements Regulations 1985); or

(b) a medicine (as defined in the Medicines Act 1981); or

(c) a controlled drug or restricted substance (as defined in the Misuse of Drugs Act 1975); or

(d) a formulated meal replacement or a formulated supplementary food (as defined in standard 2.9.3 of the Code); or

(e) a formulated caffeinated beverage (as defined in standard 2.6.4 of the Code).

(3) For the avoidance of doubt subclause (2) does not contain an exhaustive list of products that are not supplemented food.

8 Certain aspects of the Code apply

The following standards in the Code apply, with all necessary modifications, to supplemented food manufactured, sold, or prepared for sale in New Zealand, or imported into New Zealand for sale:

Clauses 1(2), 6, 7, 8, 11 and columns 1 and 2 of the schedule of **Standard 1.1.1** Preliminary provisions – application, interpretation and general prohibitions

Standard 1.2.1 Application of labelling and other information requirements (excluding any references to Standard 1.2.2)

Standard 1.2.3 Mandatory warning and advisory statements and declarations

Standard 1.2.4 Labelling of ingredients (excluding clause 2(b), and clause 6(3))

Standard 1.2.5 Date marking of food

Standard 1.2.6 Directions for use and storage

Standard 1.2.7 Nutrition, Health and Related Claims (substituting the "Chief Executive Officer of the Authority" with the "Director-General of the Ministry for Primary Industries" in clause 17(4)(b); excluding the words "Australia or" in clause 18(a); substituting the word "Authority" in 18(b) with the words "Ministry for Primary Industries"; substituting the words "RDI" or "ESADDI" in Schedule 1 with the word "NRV (2006)"; excluding condition (c) in Column 2 of Schedule 1 in relation to a 'Vitamin or mineral (not including potassium or sodium)'; and substituting "The food must contain no less than 50 mg of choline per serve" with "A serving of the food must contain at least 10% of the NRV (2006)" in Column 5 of Schedule 3" in relation to Choline.

Standard 1.2.8 Nutrition information requirements (excluding clause 3(b), (o), (p), and (q))

Standard 1.2.9 Legibility requirements

Standard 1.2.10 Characterising ingredients and components of food (excluding clause 2(4)(g), (i) and (j))

Standard 1.3.1 Food additives (excluding clauses 13.1, 13.2, 13.3, 14.2, 14.3 in Schedule 1 of that standard)

Standard 1.3.3 Processing aids

Standard 1.3.4 Identity and purity

Standard 1.4.1 Contaminants and natural toxicants

Standard 1.4.3 Articles and materials in contact with food

Standard 1.4.4 Prohibited and restricted plants and fungi (excluding references to Hypericum perforatum, St John's wort, or Hypericine)

Clause 3 of **Standard 1.5.1** Novel Foods

Standard 1.5.2 Food produced using gene technology

Standard 1.5.3 Irradiation of food

Standard 1.6.1 Microbiological limits for food

Standard 2.1.1 Cereals and cereal products

Standard 2.2.1 Meat and meat products

Standard 2.2.2 Egg and egg products

Standard 2.2.3 Fish and fish products

Standard 2.3.2 Jam

Standard 2.4.1 Edible oils

Standard 2.4.2 Edible oil spreads (excluding clause 2 (1) (g))

Standard 2.5.1 Milk (excluding clause 5)

Standard 2.5.2 Cream

Standard 2.5.3 Fermented milk products (excluding clause 4)

Standard 2.5.4 Cheese

Standard 2.5.5 Butter

Standard 2.5.6 Ice cream

Standard 2.5.7 Dried milks, evaporated milks and condensed milks

Standard 2.6.1 Fruit juice and vegetable juice

Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks

Standard 2.8.1 Sugars

Standard 2.8.2 Honey

Standard 2.10.1 Vinegar and related products

Standard 2.10.2 Salt and salt products

9 Prohibition on supplemented food for infants or young children under four years of age

Supplemented food must not be specifically formulated or marketed for the purpose of sale for consumption by infants or young children under the age of four years.

10 Identification requirements

(1) The words “supplemented food” must be placed in a prominent position on the label of a package of supplemented food.

(2) The words “supplemented food” must be placed in a prominent position on any material advertising supplemented food.

(3) The label on a package of supplemented food must include a name or a description of the food sufficient to indicate the true nature of the food.

(4) The label on a package of supplemented food must include its lot identification, unless the supplemented food is in small packages, and the bulk packages and the bulk container in which the supplemented food is stored or displayed for sale includes its lot identification.

(5) The label on a package of supplemented food must include the name and business address in New Zealand of the supplier of the supplemented food.

11 Restriction on including intoxicating substance

A supplemented food must not contain any substance that is intended to have an intoxicating effect on any person who consumes it.

12 Safe daily consumption statements

If there is a risk to a person in consuming more than an appropriate daily consumption of a supplemented food, the label on the package of a supplemented food must—

(1) specify an appropriate daily consumption; and

(2) include an advisory statement to the effect that exceeding that daily consumption may cause harm.

13 Substances that may be added to supplemented food

(1) A supplemented food may contain caffeine for a purpose other than as a food additive.

(2) The substances listed in column 1 of Table 1 may only be added to supplemented food if there is compliance with the applicable restriction specified in column 2.

Table 1

Substance - Column 1	***Restrictions Column 2***
Hypericum perforatum (St John's Wort)	*Only to be used in herbal infusions.* *The label on the package must contain the following warning statement: "If you take prescription medicines, consult your doctor before using this product. Do not take if pregnant."*
Caffeine	*If the supplemented food contains a greater level of caffeine than is required to achieve a technological function under conditions of Good Manufacturing Practice the label on the package of supplemented food must include:* *(a) an advisory statement to the effect that the food contains caffeine, and is not recommended for children, pregnant or lactating women, or individuals sensitive to caffeine; and* *(b) the following details in the nutrition information panel:* *(i) the average quantity of caffeine per serve; and* *(ii) the average quantity of caffeine per 100ml or 100gm.*
Guarana	*The label on the package of a supplemented food containing guarana must include an advisory statement to the effect that the supplemented food contains caffeine.*

14 Substances prohibited in supplemented food

The substances listed in column 1 of Table 2 (with the common name in column 2) must not be added to supplemented food.

Table 2

Substance - Species name **Column 1**	***Substance - Common name*** ***Column 2***
Actaea/Cimicifuga racemosa	*Black Cohosh*
Piper methysticum	*Kava*

15 Restrictions on the addition of vitamins and minerals to supplemented food

(1) The vitamins and minerals listed in column 1 of Table 3 may be added to a supplemented food provided that the total of the naturally occurring and added quantity of that vitamin or mineral present in the supplemented food does not exceed the maximum per one day quantity specified in column 2 of Table 3.

(2) If a vitamin or mineral listed in column 1 of Table 3 is added to a supplemented food and as a result the total of the naturally occurring and added quantity of that vitamin or mineral present in the supplemented food exceeds the quantity specified in column 3 of Table 3, the label on the package of the supplemented food must include an advisory statement to the effect that the product is intended for consumption only by persons of or over the age of 14 years.

Table 3

Vitamin or mineral ***Column 1***	**Maximum Per One Day Quantity** ***Column 2***	***Maximum Per One Day Quantity above which an advisory statement is required*** ***Column 3***
Vitamins		
Choline	1750mg	*500 mg*
Folic acid	500 mcg	*200 mcg*

Nicotinic Acid	17.5 mg	*7.5 mg*
Nicotinamide	450 mg	*125 mg*
Retinol	1500 mcg	*450 mcg*
Pyridoxine	25 mg	*10 mg*
Vitamin C	500 mg	*500 mg*
Vitamin D	40 mcg	*40 mcg*
Vitamin E (as alpha-tocopherol equivalents)	150 mg	*50 mg*
Minerals		
Calcium	1250 mg	*1250 mg*
Copper	5 mg	*1.5 mg*
Fluoride	5 mg	*1.1 mg*
Iodine	300 mcg	*150 mcg*
Iron	22.5 mg	*20 mg*
Magnesium	175 mg	*55 mg*
Molybdenum	1000 mcg	*300 mcg*
Phosphorous	2000 mg	*1500 mg*
Selenium	150 mcg	*75 mcg*
Sodium	1150 mg	*700 mg*
Zinc	*20 mg*	*6 mg*

(3) The vitamins and minerals listed in column 1 of Table 4 may only be added to supplemented food if the label on the package contains the warning statement set out in column 2 of Table 4.

Table 4

Column 1	***Column 2***
Vitamin or mineral	***Warning statement***
Vitamin K	*"Contains Vitamin K. People taking warfarin should seek medical advice before starting consumption"*

Part 2
Temporary Supplemented Food Requirements

16 Expiry of Part 2

This part expires at the end of 17 January 2016.

17 Interpretation for Part 2

(1) In this standard, unless the context otherwise requires,—

Act means the Food Act 1981

Code means the Australia New Zealand Food Standards Code

warning statement has the same meaning as provided in the Code in addition to a statement to be expressed in the text as so prescribed in this standard, in —

(a) clause 26 Table 1; and

(b) clause 28(3) Table 4.

(2) Any words or expressions defined in the Act or the Code and used but not defined in this standard have the same meaning as in the Act or in the Code.

(3) References to adequate intake (AI) and recommended dietary intake (RDI) mean the age-appropriate figures published by the National Health and Medical Research Council of Australia and the New Zealand Ministry of Health "Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes (2006)" (NRV) (2006)).

18 Meaning of supplemented food

(1) A supplemented food is a product that is represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement.

(2) A product is not a supplemented food if it is—

(a) a dietary supplement (as defined in the Dietary Supplements Regulations 1985); or

(b) a medicine (as defined in the Medicines Act 1981); or

(c) a controlled drug or restricted substance (as defined in the Misuse of Drugs Act 1975); or

(d) a formulated meal replacement or a formulated supplementary food (as defined in standard 2.9.3 of the Code); or

(e) a formulated caffeinated beverage (as defined in standard 2.6.4 of the Code).

(3) For the avoidance of doubt subclause (2) does not contain an exhaustive list of products that are not supplemented food.

19 Certain aspects of the Code apply

The following standards in the Code apply, with all necessary modifications, to supplemented food manufactured, sold, or prepared for sale in New Zealand, or imported into New Zealand for sale:

Clauses 1(2), 6, 7, 8, 11 and columns 1 and 2 of the schedule of **Standard 1.1.1** Preliminary provisions – application, interpretation and general prohibitions

Standard 1.2.1 Application of labelling and other information requirements (excluding any references to Standard 1.2.2)

Standard 1.2.3 Mandatory warning and advisory statements and declarations

Standard 1.2.4 Labelling of ingredients (excluding clause 2(b), and clause 6(3))

Standard 1.2.5 Date marking of food

Standard 1.2.6 Directions for use and storage

Standard 1.2.8 Nutrition information requirements (excluding clause 3(b), (o), (p), and (q))

Standard 1.2.9 Legibility requirements

Standard 1.2.10 Characterising ingredients and components of food (excluding clause 2(4)(g), (i) and (j))

Standard 1.3.1 Food additives (excluding clauses 13.1, 13.2, 13.3, 14.2, 14.3 in Schedule 1 of that standard)

Standard 1.3.3 Processing aids

Standard 1.3.4 Identity and purity

Standard 1.4.1 Contaminants and natural toxicants

Standard 1.4.3 Articles and materials in contact with food

Standard 1.4.4 Prohibited and restricted plants and fungi (excluding references to Hypericum perforatum, St John's wort, or Hypericine)

Clause 3 of **Standard 1.5.1** Novel Foods

Standard 1.5.2 Food produced using gene technology

Standard 1.5.3 Irradiation of food

Standard 1.6.1 Microbiological limits for food

Standard 2.1.1 Cereals and cereal products

Standard 2.2.1 Meat and meat products

Standard 2.2.2 Egg and egg products

Standard 2.2.3 Fish and fish products

Standard 2.3.2 Jam

Standard 2.4.1 Edible oils

Standard 2.4.2 Edible oil spreads (excluding clause 2 (1) (g))

Standard 2.5.1 Milk (excluding clause 5)

Standard 2.5.2 Cream

Standard 2.5.3 Fermented milk products (excluding clause 4)

Standard 2.5.4 Cheese

Standard 2.5.5 Butter

Standard 2.5.6 Ice cream

Standard 2.5.7 Dried milks, evaporated milks and condensed milks

Standard 2.6.1 Fruit juice and vegetable juice

Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks

Standard 2.8.1 Sugars

Standard 2.8.2 Honey

Standard 2.10.1 Vinegar and related products

Standard 2.10.2 Salt and salt products

20 Prohibition on supplemented food for infants or young children under four years of age

Supplemented food must not be specifically formulated or marketed for the purpose of sale for consumption by infants or young children under the age of four years.

21 Identification requirements

(1) The words “supplemented food” must be placed in a prominent position on the label of a package of supplemented food.

(2) The words “supplemented food” must be placed in a prominent position on any material advertising supplemented food.

(3) The label on a package of supplemented food must include a name or a description of the food sufficient to indicate the true nature of the food.

(4) The label on a package of supplemented food must include its lot identification, unless the supplemented food is in small packages, and the bulk packages and the bulk container in which the supplemented food is stored or displayed for sale includes its lot identification.

(5) The label on a package of supplemented food must include the name and business address in New Zealand of the supplier of the supplemented food.

22 Restrictions on advertising and labelling supplemented food

(1) Subclauses (2) and (3) apply to any—

(a) advertisement for a supplemented food; and

(b) container or package in which a supplemented food is sold; and

(c) label on a package or container in which a supplemented food is sold.

(2) An item listed in subclause (1) must not claim or make a statement, express or implied, relating to any of the following matters:

(a) that the supplemented food treats or prevents disease:

(b) that the supplemented food diagnoses disease or ascertains the existence, degree, or extent of a physiological condition:

(c) that the supplemented food alters the shape, structure, size, or weight of the human body; or has slimming or intrinsic weight reducing properties:

(d) that the supplemented food prevents the normal operation of a physiological function (whether permanently, temporarily, or by way of terminating, reducing, postponing, increasing, or accelerating the operation of that function or in any other way).

(3) An item listed in subclause (1) must not—

(a) include on it or on its label the word “health” or any word or words of similar import as a part of or in conjunction with the name of the supplemented food; or

(b) contain or have a label that contains any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person.

23 Restrictions on content claims of vitamins and minerals

(1) A claim must not be made in relation to the presence of a vitamin or mineral in a supplemented food unless—

(a) the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1 of the Code; and

(b) a reference quantity of the food contains at least 10% of the RDI or AI for that vitamin or mineral.

(2) A claim must not be made in relation to a supplemented food being a good source of a vitamin or mineral unless–

(a) the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1 of the Code; and

(b) a reference quantity of the food contains at least 25% of the RDI or AI for that vitamin or mineral.

24 Restriction on including intoxicating substance

A supplemented food must not contain any substance that is intended to have an intoxicating effect on any person who consumes it.

25 Safe daily consumption statements

If there is a risk to a person in consuming more than an appropriate daily consumption of a supplemented food, the label on the package of a supplemented food must—

(1) specify an appropriate daily consumption; and

(2) include an advisory statement to the effect that exceeding that daily consumption may cause harm.

26 Substances that may be added to supplemented food subject to restrictions

(1) A supplemented food may contain caffeine for a purpose other than as a food additive.

(2) The substances listed in column 1 of Table 1 may only be added to supplemented food if there is compliance with the applicable restriction specified in column 2.

Table 1

Substance - Column 1	***Restrictions Column 2***
Hypericum perforatum (St John's Wort)	*Only to be used in herbal infusions.* *The label on the package must contain the following warning statement: "If you take prescription medicines, consult your doctor before using this product. Do not take if pregnant."*
Caffeine	*If the supplemented food contains a greater level of caffeine than is required to achieve a technological function under conditions of Good Manufacturing Practice the label on the package of supplemented food must include:* *(a) an advisory statement to the effect that the food contains caffeine, and is not recommended for children, pregnant or lactating women, or individuals sensitive to caffeine; and* *(b) the following details in the nutrition information panel:* *(i) the average quantity of caffeine per serve; and* *(ii) the average quantity of caffeine per 100ml or 100gm.*
Guarana	*The label on the package of a supplemented food containing guarana must include an advisory statement to the effect that the supplemented food contains caffeine.*

27 Substances prohibited in supplemented food

The substances listed in column 1 of Table 2 (with the common name in column 2) must not be added to supplemented food.

Table 2

Substance - Species name **Column 1**	***Substance - Common name*** ***Column 2***
Actaea/Cimicifuga racemosa	*Black Cohosh*
Piper methysticum	*Kava*

28 Restrictions on the addition of vitamins and minerals to supplemented food

(1) The vitamins and minerals listed in column 1 of Table 3 may be added to a supplemented food provided that the total of the naturally occurring and added quantity of that vitamin or mineral present in the supplemented food does not exceed the maximum per one day quantity specified in column 2 of Table 3.

(2) If a vitamin or mineral listed in column 1 of Table 3 is added to a supplemented food and as a result the total of the naturally occurring and added quantity of that vitamin or mineral present in the supplemented food exceeds the quantity specified in column 3 of Table 3, the label on the package of the supplemented food must include an advisory statement to the effect that the product is intended for consumption only by persons of or over the age of 14 years.

Table 3

Vitamin or mineral ***Column 1***	**Maximum Per One Day Quantity** ***Column 2***	***Maximum Per One Day Quantity above which an advisory statement is required*** ***Column 3***
Vitamins		
Choline	1750mg	*500 mg*
Folic acid	500 mcg	*200 mcg*

Nicotinic Acid	17.5 mg	*7.5 mg*
Nicotinamide	450 mg	*125 mg*
Retinol	1500 mcg	*450 mcg*
Pyridoxine	25 mg	*10 mg*
Vitamin C	500 mg	*500 mg*
Vitamin D	40 mcg	*40 mcg*
Vitamin E (as alpha-tocopherol equivalents)	150 mg	*50 mg*
Minerals		
Calcium	1250 mg	*1250 mg*
Copper	5 mg	*1.5 mg*
Fluoride	5 mg	*1.1 mg*
Iodine	300 mcg	*150 mcg*
Iron	22.5 mg	*20 mg*
Magnesium	175 mg	*55 mg*
Molybdenum	1000 mcg	*300 mcg*
Phosphorous	2000 mg	*1500 mg*
Selenium	150 mcg	*75 mcg*
Sodium	1150 mg	*700 mg*
Zinc	*20 mg*	*6 mg*

(3) The vitamins and minerals listed in column 1 of Table 4 may only be added to supplemented food if the label on the package contains the warning statement set out in column 2 of Table 4.

Table 4

Column 1	***Column 2***
Vitamin or mineral	***Warning statement***
Vitamin K	*"Contains Vitamin K. People taking warfarin should seek medical advice before starting consumption"*

Issued under section 11C of the Food Act 1981.

Date of notification in Gazette: [ ]

This standard is administered by the Ministry for Primary Industries.

Explanatory Note

This note is not part of the standard and has been included to explain its general effect.

The Dietary Supplements Regulations 1985 previously regulated 'therapeutic-type' dietary supplements and 'food-type dietary' supplements. 'Food-type' dietary supplements have now been excluded from the ambit of the Dietary Supplements Regulations 1985 and are now regulated by this standard. 'Food-type' dietary supplements fall within the definition of 'supplemented food' in this standard.

It is intended that 'supplemented food' will eventually be provided for under the Code, and accordingly this standard is intended to be an interim arrangement.

Food standards subject to Regulations (Disallowance) Act 1989

Food standards are subject to the Regulations (Disallowance) Act 1989. Any person has the right to make a complaint about a food standard to the Regulations Review Committee.

Availability of food law

An outline of New Zealand food law, and further advisory information on this amendment, can be viewed on the Ministry for Primary Industries (MPI) website: www.mpi.govt.nz or can be obtained from the MPI, Food Policy Group, Pastoral House, 25 The Terrace, PO Box 2526, Wellington 6140.