



Proposals to amend the New Zealand Food (Supplemented Food) Standard 2013 under the Food Act 2014

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1 Introduction

The purpose of this consultation document is to seek submissions on a proposal to make administrative changes to the New Zealand Food (Supplemented Food) Standard 2013 (Supplemented Food Standard). These changes will:

- ensure that the Supplemented Food Standard is treated as a New Zealand-only food standard (and not an adopted joint food standard) when the Food Act 2014 (Food Act) commences on 1 March 2016;
- align with changes to the numbering of standards in the Australia New Zealand Food Standards Code (the Code);
- remove Part 2 of the Supplemented Food Standard as it has expired; and
- re-format the Supplemented Food Standard, including using (the Food Act) template without changing the policy intent.

The proposed changes are not intended to alter the substance of the Supplemented Food Standard; the proposed changes are to ensure the standard continues to operate effectively until it is reviewed in full.

MPI is intending to conduct a general review of the standard in 2016.

2 Submissions

The Ministry for Primary Industries (MPI) is seeking submissions from interested parties on proposals for administrative and technical changes to the Supplemented Food Standard.

This document sets out proposals for the Supplemented Food Standard. A draft amended standard, in appendix 1, shows MPI's proposals. The drafting is indicative only and may change.

The submissions will help MPI assess whether we need to amend these proposals to better meet your needs, while still fulfilling the purpose of the Food Act.

2.1 HOW TO HAVE YOUR SAY

The deadline for submissions is **5pm on Tuesday, 5 January 2016**.

Please make sure you include the following information in your submission:

- the title of this discussion document;
- your name and title;
- your organisation's name (if you are submitting on behalf of an organisation); and
- your contact details (e.g. phone number, address and email).

Also:

- please make sure that your comments can be clearly read; and
- state the page your comments are referring to; or

- state the notice or section of the notice (including the page number) your comments are referring to.

You can return your submission in any of these ways:

Email: foodact2014@mpi.govt.nz

Mail: Consultation: Proposals to amend the New Zealand Food (Supplemented Food) Standard 2013 under the Food Act 2014
Ministry for Primary Industries
PO Box 2526
Wellington 6104

Or hand delivery: Consultation: Proposals to amend the New Zealand Food (Supplemented Food) Standard 2013 under the Food Act 2014
Ministry for Primary Industries
Pastoral House
25 The Terrace
Wellington

Please make sure your submission gets to us no later than 5pm on the closing date above.

2.2 OFFICIAL INFORMATION ACT REQUIREMENTS

Under the Official Information Act 1982 (OIA), information held by MPI is to be made available to requestors unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA.

If you are making a submission, you may wish to indicate any grounds for withholding information contained in your submission. Reasons for withholding information could include that information is commercially sensitive or that you wish personal information, such as names or contact details, to be withheld. An automatic confidentiality disclaimer from your IT system will not be considered as grounds for withholding information.

We will take your 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.

2.3 WHAT HAPPENS NEXT

After the consultation period has closed, we will take into account all submissions and amend the proposed Supplemented Food Standard as necessary.

A summary of submissions will be sent to all submitters and will be made available on the MPI website.

The standard will be submitted to the Minister for Food Safety for signing prior to gazettal.

We are recommending that the Supplemented Food Standard be in place by 1 February 2016 in order to commence by 1 March 2016 when the Food Act fully commences.

3 Background

The Food Act was passed into law in June 2014 and will fully commence on 1 March 2016, when the Food Act 1981 will be repealed. The Food Act provides for New Zealand-only food standards ('domestic food standards') and adopted joint food standards, which we share with Australia.

The Supplemented Food Standard is a food standard issued under section 11C of the Food Act 1981. The current Supplemented Food Standard can be found at <http://www.foodsafety.govt.nz/elibrary/industry/nzfood-supplementedfood-standard-2013.pdf>

3.1 AMENDMENTS TO REFLECT THE FOOD ACT

When the Food Act comes into full force, it will distinguish between domestic food standards and adopted joint food standards. Because of the way the Supplemented Food Standard is currently drafted, it will be treated as an adopted joint food standard instead of a domestic food standard unless it is amended prior to 1 March 2016. Without amendment the Minister for Food Safety would be constrained in her ability to amend or revoke the Supplemented Food Standard after the Food Act commences. In order to rectify this situation, we need to change the way that the standard refers to the Code.

3.2 CONSEQUENTIAL AMENDMENTS DUE TO REVISION OF THE CODE

The Code has recently been revised to make it easier to read and work with. Drafting changes in the Code under Proposal P1025 - Code Revision come into effect on 1 March 2016. This will result in changes to the numbering of standards within the Code. As a consequence, numbering references to the Code will need to be changed in the Supplemented Food Standard. In particular, Clauses 7 and 8 of the Supplemented Food Standard list parts of the Code that apply to supplemented food in New Zealand.

The current Code and the link to the revised Code that commences on 1 March 2016 can be found at <http://www.foodstandards.govt.nz/code/Pages/default.aspx>

3.3 REMOVAL OF PART 2 OF THE SUPPLEMENTED FOOD STANDARD

Part 2 of the Supplemented Food Standard will expire on 17 January 2016 before the commencement of the Food Act. There is therefore no need for Part 2 to exist beyond 17 January 2016.

3.4 REFORMATING THE SUPPLEMENTED FOOD STANDARD

To assist in the readability of legal documents under the Food Act, MPI has developed a template format. The Supplemented Food Standard comes under the Food Act and is not currently in the template format. The template and format of the Supplemented Food Standard will change for consistency with other instruments issued under the Food Act.

4 What we propose

We are proposing that the Supplemented Food Standard be amended before 1 March 2016.

4.1 AMENDMENTS TO REFLECT THE FOOD ACT

Currently, the Supplemented Food Standard applies parts of the Code to supplemented food in New Zealand, and is silent about those parts of the Code that do not apply to supplemented food. Under our proposal, we will reverse this by allowing the Code to apply generally to supplemented food through the Food Act, except for specified parts of the Code that will be disapplied.

We are not proposing to change which parts of the Code apply to supplemented food; we are only proposing to change the way they are listed in the standard. Instead of listing all the parts of the Code that do apply to supplemented food (as in clause 8 of the current standard), the amended standard will list those parts of the Code that do not apply to supplemented food.

The Code generally applies to all foods in New Zealand, including supplemented food, so there is no reason to apply parts of the Code through the Supplemented Food Standard. Instead, it makes more sense to exclude specified parts of the Code from supplemented foods.

4.2 CONSEQUENTIAL AMENDMENTS DUE TO REVISION OF THE CODE

In order to reflect the changes in how the Code is numbered, which also take effect on 1 March 2016, references to the Code will be updated to reflect the numbering of standards under Food Standards Australia New Zealand's (FSANZ) Proposal P1025 – Code Revision. Again, we are not proposing to change the parts of the Code that apply to supplemented food.

These proposed changes are purely technical to reflect the changes to the numbering of standards in the Code, and to ensure that the Supplemented Food Standard is treated as a domestic food standard (and not an adopted joint food standard) when the new Food Act commences on 1 March 2016.

4.3 REMOVAL OF PART 2 OF THE SUPPLEMENTED FOOD STANDARD AND REFORMATTING

We propose to draft an amended Supplemented Food Standard using the new Food Act template. The amended standard would delete Part 2 of the current standard as it will not apply on 1 March 2016. Stylistic changes will also be made to assist with clarity but without changing the policy.

The proposed draft New Zealand Food (Supplemented Food) Standard 2016 is in Appendix 1.

5 Options

The options considered are:

Option 1: Do not proceed with the proposal

Option 2: Proceed with the proposal as outlined above (that is, amend the Supplemented Food Standard to exclude (rather than include) specific parts of the Code, remove Part 2 and reformat, including using the template under the new Food Act).

5.1 ANALYSIS OF THE OPTIONS

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

Option 1: Do not proceed with proposal	
Benefits	Costs
<ul style="list-style-type: none"> no benefits have been identified 	<ul style="list-style-type: none"> references to clauses in the Code that do not exist or have expired may cause confusion; from 1 March 2016, any changes to the standard would need to be progressed through the Australia and New Zealand Ministerial Forum on Food Regulation and FSANZ. The consequences would be potential cost and policy issues; there would be an unintended change to the administration of the standard compared to the status quo; Part 2 of the Supplemented Food Standard would remain in legislation contrary to good legislation drafting practice; the format and template would not be consistent with other Food Act legislation
Option 2: Proceed with proposal as outlined	
Benefits	Costs
<ul style="list-style-type: none"> option 2 would reduce confusion with regard to the numbers referred to in the Code; option 2 would result in no policy change and would therefore maintain the status quo; it would be possible for the Minister to amend or revoke the standard after 1 March 2016, in line with a planned review of the standard; removal of Part 2 of the Supplemented Food Standard makes the standard tidier. the format and template are consistent with other Food Act legislation. 	<ul style="list-style-type: none"> Government would need to commit a small amount of resources to make the necessary changes.

6 Preferred option

MPI's preferred option is to proceed with the proposal (Option 2) as outlined in this consultation document. The proposal would maintain New Zealand's policy for supplemented food and tidy up the drafting of the Supplemented Food Standard.

MPI considers the proposal would not impose any costs on businesses or consumers as the changes are administrative and are intended to preserve the status quo.

Questions

Will the proposed change have any consequences for you or your business?

If the proposed change goes ahead, what communication or guidance will be required?

7 Implementation and enforcement

The Supplemented Food Standard User Guide, located on the MPI website <http://www.foodsafety.govt.nz/elibrary/industry/nz-supplemented-food-standard-guidance-02-2014.pdf> will be updated if the standard is amended.

As the proposed change is intended to preserve the status quo, it will not result in changes to enforcement.

8 APPENDIX 1; Proposed draft New Zealand Food (Supplemented Food) Standard 2016

(see Appendix pages 1 – 10)



Food Standard

New Zealand Food (Supplemented Food) Standard 2016

Draft

TITLE

Food Standard: New Zealand Food (Supplemented Food) Standard 2016

COMMENCEMENT

This Food Standard comes into force on 29 February 2016.

REVOCATION

This Food Standard revokes and replaces the New Zealand Food (Supplemented Food) Standard 2013.

ISSUING AUTHORITY

This Food Standard is issued under section 11C of the Food Act 1981.

Dated at Wellington this ... day of 2016

Hon Jo Goodhew
Minister for Food Safety

Draft

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Draft

Introduction

This introduction is not part of the Food Standard, but is intended to indicate its general effect.

Purpose

- (1) The purpose of this standard is to-
 - a) Provide an interim regulatory arrangement for supplemented food until there are appropriate provisions in the Australia New Zealand Food Standards Code (the **Code**); and
 - b) Regulate the "food-type" dietary supplements that were formerly regulated under the Dietary Supplements Regulations 1985.

Background

- (1) The kind of food covered by this standard (**supplemented food**) used to be regulated under the Dietary Supplement Regulations 1985. Those regulations were amended on 31 March 2010 so that they no longer applied to supplemented food. Instead, supplemented food is covered by the Code.
- (2) However, the Code includes certain requirements that New Zealand does not wish to apply to supplemented food, and does not include other requirements that New Zealand wants to retain. This standard therefore excludes certain aspects of the Code from supplemented food and adds some other specific requirements.
- (3) Once the Food Act 2014 is in force, this standard is treated as a domestic food standard, under section 421(2) of that Act.
- (4) This standard retains the policy set out in the 2013 standard, but recasts it to-
 - a) set it out in the new MPI format; and
 - b) identify those parts of the Code that do not apply, instead of identifying those parts that do; and
 - c) omit Part 2 of the 2013 standard, because it has expired.

Who should read this Food Standard?

- (1) Everyone who manufactures, sells, or prepares for sale any supplemented food should read this standard.

Why is this important?

- (1) Failure to comply with this standard may lead to prosecution under the Food Act 2014.

Document history

- (1) This standard replaces the New Zealand Food (Supplemented Food) Standard) 2013.

Part 1: Requirements

1.1 Application

- (1) This standard applies to everyone who manufactures, sells, or prepares for sale any supplemented food.

1.2 Definitions

- (1) In this standard, unless the context otherwise requires,-
Act means the Food Act 2014
Code means the Australia New Zealand Food Standards Code.
- (2) Words and expressions defined in the Act or the Code and used but not defined in this standard have the meanings given in the Act or the Code.

1.3 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) The following products are not supplemented foods:
 - a) a dietary supplement (as defined in the Dietary Supplements Regulations 1985):
 - b) a medicine (as defined in the Medicines Act 1981):
 - c) a controlled drug or restricted substance (as defined in the Misuse of Drugs Act 1975):
 - d) a formulated meal replacement or a formulated supplementary food (as defined in standard 1.1.2-6 of the Code):
 - e) a formulated caffeinated beverage (as defined in standard 1.1.2-6 of the Code).
- (3) To avoid doubt, subclause (2) does not contain an exhaustive list of products that are not supplemented foods.

1.4 Modification of application of Code

- (1) The standards listed in column 2 of the table do not apply to supplemented foods, and the standards listed in column 3 apply only as modified as shown in that column.
- (2) Other parts of the Code that ordinarily apply in New Zealand continue to apply to supplemented food without modification.

Topic of standard in Code	Standards of the Code that do not apply to supplemented food	Standards of the Code that are modified in their application to supplemented foods
Structure of Code and General Provisions	1.1.1-9 1.1.1-7	

	1.1.1-13 1.1.1 Schedule 17-2 1.1.1 Schedule 17-3	
Transitional standards	2.9.6	
Transitional standards	1.2.12	
Labelling and other information		1.2.1: omit reference to Standard 1.2.2
Food identification	1.2.2	
Statement of ingredients	1.2.4-2(3)(b) 1.2.4-5(8)	
Nutrition, health and related claims		1.2.7-18(3)(b): replace "Chief Executive Officer of the Authority (FSANZ)" with "Director-General of the Ministry for Primary Industries" 1.2.7-19(1)(a): omit "Australia or" 1.2.7-19(1)(b): replace "Authority" with "Ministry for Primary Industries" 1.2.7 Schedule 4-3, column 2: omit condition (c) in relation to a vitamin or mineral (not including potassium or sodium) 1.2.7 Schedule 4-3: replace "RDI or ESADDI" with "RDI or AI of the NRV (2006)"
Nutrition information	1.2.8-5(2)(a)(i), (xiv), (xv), and (xvi)	
Characterising ingredients and components	1.2.10-3(3)(d), (f), and (g)	
Food additives	1.3.1 Schedule 15-5, classes of food 13.1, 13.2, 13.3, 14.2, 14.3	
Vitamins and minerals	1.3.2	
Prohibited and restricted plants and fungi		1.4.4 Schedule 24: omit references to Hypericum

		perforatum, St John's wort, and Hypericine
Novel foods	the note to 1.5.1-3	
Fruit and Vegetables	2.3.1	
Edible oil spread	2.4.2-3(3)	
Milk	2.5.1-6	
Fermented milk products	2.5.3-5	
Kava	2.6.3	
Formulated caffeinated beverages	2.6.4	
Labelling of alcoholic beverages etc	2.7.1	
Beer	2.7.2	
Fruit wine and vegetable wine	2.7.3	
Wine and wine product	2.7.4	
Spirits	2.7.5	
Infant formula products	2.9.1	
Food for infants	2.9.2	
Formulated meal replacements and supplemented foods	2.9.3	
Formulated supplemented sports foods	2.9.4	
Food for special medical purposes	2.9.5	
Chewing gum	2.10.3	

1.5 Prohibition on supplemented food for infants and young children

- (1) Supplemented food must not be specifically formulated or marketed for the purpose of sale for consumption by infants or children under the age of 4 years.

1.6 Identification requirements

- (1) The words “supplemented food” must be placed in a prominent position on the label of every package of supplemented food.
- (2) The words “supplemented food” must be placed in a prominent position on all 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-
 - a) the supplemented food is in small packages; and
 - b) 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.

1.7 Restriction on including intoxicating substances

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

1.8 Safe daily consumption

- (1) 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 the supplemented food must-
 - a) Specify an appropriate daily consumption; and
 - b) Include an advisory statement to the effect that exceeding that daily consumption may cause harm.

1.9 Caffeine added to supplemented food

- (1) Supplemented food may contain caffeine for a purpose other than as a food additive (but see Table 1).

1.10 Restrictions on substances added to supplemented food

- (1) The substances listed in column 1 of Table 1 may only be added to supplemented food if the applicable restriction in column 2 is complied with:

Table 1

	Substance	Restriction
(a)	<i>Hypericum perforatum</i> (St John's Wort)	Only to be used in herbal infusions. The label on the package must include the following warning statement: "If you take prescription medicines, consult your doctor before using this product. Do not take if pregnant."
(b)	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 must include the following: <ul style="list-style-type: none"> • An advisory statement to the effect that the food contains caffeine and is not recommended for children, pregnant and lactating women, or individuals sensitive to caffeine: • The following details in the nutrition information panel: <ul style="list-style-type: none"> (i) The average quantity of caffeine per serve: (ii) The average quantity of caffeine per 100 ml or 100 gm.
(c)	Guarana	The label on the package must include an advisory statement to the effect that the supplemented food contains caffeine.

1.11 Substances prohibited in supplemented food

- (1) The following substances must not be added to supplemented food:

Table 2

	Scientific name	Common name
(a)	<i>Actaea/Cimicifuga racemosa</i>	Black Cohosh
(b)	<i>Piper methysticum</i>	Kava

1.12 Restrictions on addition of vitamins and minerals

- (1) Vitamin K must not be added to supplemented food unless the package contains the following warning statement:

"Contains Vitamin K. People taking warfarin should seek medical advice before starting consumption."

- (1) The vitamins and minerals listed in column 1 of Table 3 must not be added to supplemented food if the total of the naturally occurring and the added quantity of vitamin or mineral exceeds the maximum per one day quantity listed in column 2.
- (1) 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 the added quantity of that vitamin or mineral present in the supplemented food exceeds the quantity specified in column 3, the label on the package 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	Maximum per one day quantity	Maximum per one day quantity above which an advisory statement is required
Vitamins		
Choline	1750 mg	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
Iodine	300 mcg	150 mcg
Magnesium	175 mg	55 mg
Molybdenum	175 mg	55 mg

Phosphorous	2000 mg	1500 mg
Selenium	150 mg	75 mg
Sodium	1150 mg	700 mg
Zinc	20 mg	6 mg

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