



Proposed Standard for Supplemented Food

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New Zealand Food Safety Authority

P O Box 2835

WELLINGTON

Telephone : (04) 894-2500

Fax : (04) 894-2501

Website

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NZFSA seeks submissions from all interested parties on any technical aspect of the proposed Supplemented Food Standard

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section of the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Omissions should be clearly and separately indicated.
- Comments should be to the point and, where possible, reasons and data to support comment are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, please make sure the comments are clearly hand-written in black or blue ink.

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- Your name and title (if applicable);
- Your organisation's name (if applicable);
- Your address;
- The number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on 25 September 2008

Your comments should be sent to:

Policy Group

New Zealand Food Safety Authority

PO Box 2835, Wellington

Fax: (04) 894 2583

Email: policy@nzfsa.govt.nz

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Table of Contents

1	Introduction	5
2	Background	6
	2.1 The Supplemented Food Standard	6
3	Problem Definition	8
4	Proposal.....	9
	4.1 Supplemented Food Standard	9
	4.1.1 Application.....	9
	4.1.2 Interpretation	9
	4.1.3 Meaning of supplemented food.....	9
	4.1.4 Certain aspects of the Code apply	10
	4.1.5 Restrictions on claims relating to supplemented foods.....	10
	4.1.6 Restrictions on claims with respect to substances content.....	10
	4.1.7 Restriction on including intoxicating substances.....	11
	4.1.8 Other substances that may be added with restrictions	11
	4.1.9 Additional prohibited substances	11
	4.1.10Restrictions on the addition of vitamins and minerals.....	11
	4.2 Dietary Supplements Regulations 1985	12
	4.3 Food-medicine interface.....	13
5	Legislative Framework	14
6	Implementation, Review and Enforcement	16
	6.1 Transitional period	16
	6.2 Review	16
	6.3 Enforcement	17

1 Introduction

The purpose of this discussion paper is to outline the technical detail proposed as part of the New Zealand Food (Supplemented Food) Standard (attached as Appendix 1). The Standard was developed following submissions received on the consultation document, *Changes to the Regulation of Dietary Supplements*, released by NZFSA in February 2007.

The proposals in this document do not revisit earlier options discussed during the first round of consultation on changes to the regulation of dietary supplements in 2004, but provide the technical detail relating to the preferred option outlined in February 2007.

Comments are sought on the detail of the draft standard.

2 Background

The Dietary Supplements Regulations (1985) have been under review for some time. In 2004 NZFSA released a discussion document proposing that the regulation of food-type and therapeutic-type dietary supplements be separated. The 2004 proposal was predicated on the establishment of the joint Australia and New Zealand therapeutic product regulatory scheme (for therapeutic-type dietary supplements) and the development of permissions in the Australia New Zealand Food Standards Code (the Code) for food-type dietary supplements. Although submissions to the 2004 proposals were supportive, neither of the two pre-requisites occurred and the proposal could not be implemented.

In February 2007 a further document was released proposing the regulatory separation of food-type and therapeutic-type dietary supplements. Recognising that there were difficulties associated with the pre-requisites for the 2004 proposal, the 2007 document provided for regulatory separation by promulgating separate New Zealand regulations for food-type and retaining the Dietary Supplements Regulations, amended to exclude food-type supplements and to require therapeutic-type dietary supplements to be registered on a database (to be held by Medsafe).

2.1 The Supplemented Food Standard

After considering submissions, Government agreed that food-type dietary supplements (supplemented foods) would be regulated in New Zealand through the promulgation of a food standard, the New Zealand Food (Supplemented Food) Standard (the Supplemented Food Standard). The long term objective is that these products will be regulated under the Code. The proposed Supplemented Food Standard would, in the short to medium term, provide for the regulation of supplemented food products pending the development of the necessary permissions in the Code.

The objectives of the proposed Supplemented Food Standard are to provide adequate regulatory coverage for supplemented food in order to:

- protect public health and safety while maintaining consumer choice;
- support economic growth (the trade in supplemented food is estimated at \$30 million annually);
- and

- maintain an existing right for New Zealand consumers, manufacturers, importers and exporters to access and supply these products.
- align supplemented food with the requirements of the Code to the maximum extent possible pending the development of appropriate permissions in the Code. This is consistent with the objectives of the Single Economic Market (with Australia) and the Trans Tasman Mutual Recognition Arrangement. The proposed Standard will also facilitate the transfer of products to regulation under the Code when appropriate permissions become available; and
- prevent the addition of substances to food that have a function of and/or have a purpose of intoxication.

Therapeutic-type dietary supplements will remain under the existing Dietary Supplements Regulations 1985, which are proposed to be amended to exclude supplemented food and to require sponsors (those responsible for putting a product on the market) of therapeutic-type dietary supplement products to register their products on a database operated by Medsafe.

There would be no changes to the requirements placed on the therapeutic-type dietary supplements themselves. However, a permission increasing the allowable level of folic acid in dietary supplement tablets is proposed to be added for products that are made under standards of Good Manufacturing Practice. The purpose of this additional permission is to align the regulation of folic acid supplements with the policy providing for the mandatory fortification of bread with folic acid, recognising that the current 300mcg permission is too restrictive to meet the objective of reducing the prevalence of neural tube defects in pregnancy.

3 Problem Definition

The problems associated with the regulation of dietary supplements in New Zealand were canvassed in the February 2007 discussion document *Proposed Changes to the Regulation of Dietary Supplements* (available at www.nzfsa.govt.nz/consultation). In summary, the range of dietary supplements, which originally comprised substances derived from food in tablet, capsule or powder form, has expanded to include highly fortified foods, such as muesli bars and drinks. Many dietary supplements are also now presented as having a therapeutic use as well as a nutritional effect.

The Dietary Supplements Regulations are empowered under the Food Act 1981. When the Regulations were promulgated, administration of the Food Act was the responsibility of the Ministry of Health. The New Zealand Food Safety Authority (NZFSA), the core business of which is to promote and ensure food safety, became responsible for the administration of the Food Act and its regulations in 2002. The legislation administered by NZFSA does not provide coverage for products intended for therapeutic purposes and NZFSA does not have the capacity or mandate to provide effective regulatory coverage for dietary supplements presented as therapeutic products.

In addition to the issues associated with the expanding range of dietary supplements, the regulation of food-type dietary supplements in New Zealand has been subject to review under the joint food regulation system since the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty) was signed in 1996. It has always been intended that these products would be regulated under a joint standard in the Code but currently there is a vast difference between the requirements of the Dietary Supplements Regulations and those of the Code. These differences generally relate to the permissible levels of vitamins and minerals, the use of fractionated or functional foods, and the addition of other substances. Common examples of supplemented foods include sports foods and drinks. Alignment between the two sets of requirements will greatly enhance the transition of food-type dietary supplements into the Code when suitable permissions become available.

4 Proposal

4.1 Supplemented Food Standard

This discussion document only deals with the future regulation of food-type dietary supplements. As noted in section 2.1 above, therapeutic-type dietary supplements will remain under the existing Dietary Supplements Regulations pending further decisions on the regulation of these products.

The New Zealand (Supplemented Food) Standard (the Supplemented Food Standard) describes the intended scope and the labelling and composition requirements that will apply to supplemented foods. Key sections of the Standard are described below.

4.1.1 Application

Part 1 of the Standard sets out the new requirements and permissions while Part 2 carries over the existing requirements and permissions of the Dietary Supplements Regulations 1985 as transitional provisions.

The transitional provisions will allow products to continue to be sold under the existing requirements for a 24 month period from the date the Standard is issued. This reduces the regulatory impact by giving manufacturers time to plan any necessary changes to their products. Manufacturers can choose to comply with Part 1 before the close of the 24 month transition period, but must comply with Part 1 *or* Part 2: it will not be possible to 'mix and match' requirements and permissions from both parts. After the 24 month transitional period Part 2 will be revoked.

4.1.2 Interpretation

Terms that are specific to the Standard are defined in this section. Other terms that are common to both the Standard and the Code conform to the interpretation set out in the Code.

4.1.3 Meaning of supplemented food

The definition of 'supplemented food' outlines the difference between ordinary foods that are regulated under the Code and the fortified foods that are intended to be regulated under the Standard. The

definition also describes those products that are outside the scope of the Standard. Such products include therapeutic-type dietary supplements (to be regulated under the amended Dietary Supplements Regulations), medicines, and food for which there is a food standard in the Code.

4.1.4 Certain aspects of the Code apply

There are 54 standards in the Code that apply to New Zealand, of these 41 standards from the Code are referenced in the Supplemented Food Standard either in full or in part. These Standards relate to matters such as labelling, microbiological limits, contaminants, processing aids etc. Where there are exclusions to the adoption of the Code standards, the exclusions are identified.

The remaining 13 that have not been included are outside the policy intention and scope of the Standard including alcoholic beverages etc: Part 2.9, special purpose foods (infant formula etc); the addition of vitamins and minerals; novel foods; kava; and formulated caffeinated beverages.

Any amendments to Code standards that are referenced in Part 1 will apply on their gazettal (subject to whatever transitional arrangements concerning the Code standards), whether such changes occur during the transitional period, or subsequent to the close of that period.

4.1.5 Restrictions on claims relating to supplemented foods

The existing provisions for advertising and claims from the Dietary Supplements Regulations are carried forward to both Parts 1 and 2 of the Supplemented Food Standard. If the proposed Health Claims Standard currently being developed by FSANZ is approved and included in the Code, it is intended that Part 1 of the Supplemented Food Standard will be amended to incorporate its provisions.

4.1.6 Restrictions on claims with respect to substances content

Many consumers rely on the label information to make informed choices about the products they use to supplement their diet. Inaccurate or false labelling can mislead consumers and present a health risk if consumers are relying on label information to balance their nutritional intake.

Claims that a supplemented food contains an ingredient that is a good source of a vitamin or mineral should not be made unless that ingredient, vitamin or mineral is present in an adequate quantity (defined as 25 per cent of the Recommended Daily Intake). For example, a claim that a supplemented food contains milk, and that milk is a good source of calcium, is not valid if there is very little milk present (and therefore calcium) in the final product.

4.1.7 Restriction on including intoxicating substances

Supplemented foods are foods that are intended for use by the general population. Allowing foods to be fortified to intoxicating effect would not meet the public health and safety objectives of standards issued under the Food Act 1981.

4.1.8 Other substances that may be added with restrictions

This section lists substances in addition to those listed in Standard 1.4.4 *Prohibited and Restricted Plants and Fungi* of the Code. Currently there are three substances listed in the proposed Standard that could be used subject to certain restrictions (such as mandatory warning labels): St Johns Wort, Glucosamine and Caffeine. These substances have associated risks (allergens and contra-indications) that need to be identified on a warning label.

4.1.9 Additional prohibited substances

Black Cohosh is listed as a prohibited substance in the proposal in addition to those substances listed in Standard 1.4.4. If evidence comes to hand that raises safety issues about other substances in the future, it is intended that the Standard would be amended to add such substances to the restricted or prohibited list.

4.1.10 Restrictions on the addition of vitamins and minerals

Just as there are potential health risks associated with inadequate levels of claimed substances, potential risks also exist in relation to the excessive consumption of some vitamins or minerals (specified in the relevant table). This is a particular concern for supplemented food due to the higher concentration of substances present and the impact that the consumption of such products can have on the overall dietary intake.

The proposed restriction of 50 per cent of the upper levels (ULs) of the specified vitamins and minerals is based on Codex Alimentarius guidelines and are generally accepted dietary safeguards. The restriction does not mitigate all of the risk as there will be some individuals and some younger population groups who risk intakes of vitamins and minerals above the UL when consuming supplemented food. However, there will be appropriate labelling of the products that identifies the addition of vitamins and minerals. Further it is not expected that younger populations will be large consumers of these food products.

The Adequate Intakes (AIs), Recommended Daily Intakes (RDIs) and Upper Limits (ULs) used in this standard are based on those published by the National Health and Medical Research Council (NHMRC) of Australia in 2005, “*Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes (2005)*” found at <http://www.moh.govt.nz/moh.nsf/pagesmh/4678>.

Amendments to the maximum amounts of vitamins and minerals in supplemented food products per maximum quantity per one day serving specified in Table 2 of the Standard will be made, taking the following criteria into account:

- ULs of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups
- the daily intake of vitamins and minerals from other dietary sources
- the contribution of individual products to the overall diet of the population in general or of sub-groups of the population.

4.2 Dietary Supplements Regulations 1985

As proposed in the February 2007 Discussion Document, the Dietary Supplements Regulations will be administered by the Ministry of Health (Medsafe) pending updated therapeutic products legislation. The Regulations will be amended to exclude supplemented foods from their coverage and to require the person(s) responsible for the entry onto the market of a therapeutic-type dietary supplement to register their product or products on a database maintained by the Ministry of Health.

There will also be an amendment to provide an increase in the permissible level of folic acid to 500mcg for supplements that have been produced under Good Manufacturing Practice (GMP). This additional permission is voluntary and the current 300mcg permission will remain for products not made under GMP.

While it is acknowledged that the amended Dietary Supplements Regulations will be an interim arrangement, no decisions have yet been made as to the long-term regulation of these products. Any proposals for the future regulation of therapeutic-type dietary supplements will be consulted on separately to this proposal.

4.3 Food-medicine interface

Many dietary supplements sit at the interface between foods and medicines. This interface area is most succinctly described by the explanatory note to the Dietary Supplements Regulations which states:

'These Regulations, in a sense, fill the gap between the Food Regulations 1984 and the Medicines Regulations 1984, in that dietary supplements are not food or medicine in the ordinary sense of those words'.

The current range of dietary supplements includes distinctly food-type supplements as well as the traditional therapeutic-type supplements presented in a medicinal dose form (pills, capsules etc). In addition, many of these therapeutic-type supplements have become more sophisticated and are consumed for a therapeutic (as opposed to nutritional) effect. The distinction between the categories cannot be clearly defined for all cases; some products require a case-by-case assessment. To assist regulators, industry, and consumers to determine the likely regulatory category under which a product may be considered, guidelines have been developed that identify characteristics that may position a product in one regulatory system or the other. The guidelines were included in the February 2007 discussion document. In summary, the guidelines for assessing the appropriate regulatory system for products include an assessment of:

- Form and presentation: how is the consumer likely to perceive the product; is it in a pharmaceutical form (a pill or capsule); is it a liquid with measured doses; or is it in a traditional food form (a bottle of drink, a pre-mix drink, a muesli bar etc)?
- Dose instructions: do the instructions say 'take two, three times a day'; or does it have a serving instruction such as 'sprinkle two spoons of product x on your cereal to supplement your dietary needs'?
- Traditional use: has the product been consumed as a food (tea, for example); or is it traditionally used for a therapeutic purpose at the level presented in the final product (extracts of Echinacea, for example)
- Therapeutic claims: noting that therapeutic claims are not permitted under the existing Dietary Supplements Regulations nor will be permitted under the proposed Supplemented Food Standard, is the product claimed to have a therapeutic use?

The purpose in making it clear whether a product is a food or a therapeutic product is in line with the general purpose of food regulation to protect health and safety and ensure consumers have adequate information to make informed choices.

5 Legislative Framework

The proposed Standard would be issued by the Minister for Food Safety under Section 11C of the Food Act 1981. The general obligation under the Food Act 1981 to sell, manufacture or import safe and suitable food applies to all food sold in New Zealand and will accordingly apply to food sold under the proposed Supplemented Food Standard.

The proposed Standard will be a deemed regulation for the purposes of the Regulations (Disallowance) Act 1989.

Before the Minister may issue a standard under section 11C of the Food Act, the following preconditions must be met.

In issuing any food standard, the Minister shall take into account the following:

- a. The need to protect public health
- b. The desirability of avoiding unnecessary restrictions on trade
- c. The desirability of maintaining consistency between New Zealand's food standards and those applying internationally
- d. New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australian-New Zealand Joint Food Standards Agreement
- e. Such other matters as the Minister considers appropriate.

The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation)—

- a. Adequate and appropriate notice of the intention to issue the food standard; and
- b. A reasonable opportunity for interested persons to make submissions; and
- c. Adequate and appropriate consideration of any such submissions.

Appendix 2 provides the detail on the criteria under section 11E and assesses the proposal against those criteria.

The authority to incorporate standards from the Code is contained within section 8ZO of the Food Act. This section also describes NZFSA's obligations in ensuring access to the incorporated material is

provided. Accordingly, copies of the Code are held by NZFSA free for inspection or available at a reasonable cost. The Code is also available on the FSANZ website at <http://www.foodstandards.govt.nz/thecode/foodstandardscode.cfm>.

6 Implementation, Review and Enforcement

6.1 Transitional period

As many submissions in response to the February 2007 Discussion Document strongly supported a two year transition period, and as some submitters wished to access the new standard as soon as possible, it is proposed that the new Supplemented Food Standard be divided into two parts. Part 1 will provide the new requirements and Part 2 will make provision to retain the existing Dietary Supplements Regulations requirements as they apply to food-type supplements. Manufacturers can comply with either Part 1 or Part 2 (but not a mixture of both). After two years, Part 2 will be revoked and it will be mandatory for supplemented food manufacturers to comply with Part 1.

For manufacturers that elect to operate under Part 1 of the proposed Standard, any updates to the Code will apply to Part 1 of the Standard.

6.2 Review

There is a general prohibition under section 9 of the Food Act 1981 against packing for sale or selling food that is unsound or unfit for human consumption or is injurious to health or harmful. This general prohibition applies to the Standard regardless of any previous permission that may have been given for a substance. The provision also relates to a specific food safety incident i.e. it may be the result of a contamination event rather than the result of an inherent risk associated with that substance or food. Such events can be managed in the short term through the application of an emergency standard.

Where new evidence becomes available regarding inherent safety issues associated with a food or substance, the Standard will be amended to incorporate such substances in the table specifying *Restricted and Prohibited Substances* to ensure that the risk management controls are current and are adequate to protect public health and safety.

NZFSA operates a three-tier compliance monitoring system: complaint driven; targeted surveys; and compliance audits. During the first year of the Standard, an implementation survey will be conducted to assess the level of awareness with the requirements of the new Standard. The implementation survey will be followed by a compliance survey to be undertaken in the first year following the end of the transitional period.

6.3 Enforcement

The Supplemented Food Standard will be issued under the Food Act 1981. The enforcement provisions of that Act will apply to those importing, manufacturing and selling supplemented food products. The NZFSA enforcement principles were described in the 2007 discussion document. In summary these are to ensure people take responsibility for the safe and suitable manufacture and sale of supplemented food; to encourage maximum compliance; and to ensure that enforcement action is commensurate with the degree of seriousness and is applied consistently across all food sectors.