TE MANA WHAKARITE KAI
MO AHITEREIRIA ME AOTEAROA

17 February 1999
8/99

Development of Joint Australia New Zealand Food Standards

As part of the process of the Review of the *Food Standards Code*

FORMULATED MEAL REPLACEMENTS AND FORMULATED SUPPLEMENTARY FOODS

Full Assessment Report

Proposal P199 - February 1999

The Authority should receive written submissions
no later than **31 March 1999**

Submissions should be sent to:

The Project Manager - Proposal P199
Australia New Zealand Food Authority

at one of the following addresses:

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or

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Submissions will be placed on the Authority's public register
(unless a claim of commercial confidentiality is made and accepted

by the Authority) and may therefore be open to public scrutiny.

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General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at one of the above addresses.

This paper was prepared by the Australia New Zealand Food Authority with assistance from the following:

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The Authority appreciates the knowledge and expertise contributed by the above people, and acknowledges that the views contained in this paper do not necessarily represent the views of the individuals or their organisations.

List of abbreviations used in this paper

AFSC	Australian *Food Standards Code*
ANZFA	Australia New Zealand Food Authority
ANZFSC	Australia New Zealand Food Standards Council
NZFR	New Zealand *Food Regulations 1984*
Codex	Codex Standard for Formula Foods for use in Weight Control Diets Codex Standard 181 -1991
COAG	Council of Australian Governments
RIS	Regulatory Impact Statement
SPS	Sanitary or Phytosanitary
TBT	Technical Barrier to Trade
joint FSC	Joint Australia New Zealand Food Standards Code
WTO	World Trade Organization
RDI	Recommended Dietary Intake
DRV	Dietary Reference Value
ESADDI	Estimated Safe and Adequate Daily Dietary Intake

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Executive summary

This paper reviews the regulations in Australia and New Zealand for formula dietary foods (Standard R4) and supplementary foods (Standard R9) of the Australian Food Standards Code (AFSC) and the equivalent regulations in the New Zealand Food Regulations (NZFR) having regard to section 10 of the Australia New Zealand Food Authority Act 1991 and the policies of the Australia New Zealand Food Authority (ANZFA). This proposal has been developed to assist the Authority to develop a revised joint Australia New Zealand standard/s for formula dietary foods and supplementary foods.

The Authority proposes a joint standard for formulated meal replacements and supplementary foods that:

- combines the current standards for formula dietary foods and supplementary foods into one standard - *Formulated meal replacements and formulated supplementary foods*;
- includes specific definitions and prescribed names for formulated meal replacements and formulated supplementary foods;
- substitutes ingredient-based criteria with macronutrient criteria related to energy and protein content but not fat or dietary fibre content, for meal replacements and supplementary foods;
- prescribes compositional parameters in relation to manufacturers' serve sizes;
- for meal replacements, prescribes vitamin and mineral composition to:
  - set a minimum vitamin and mineral content of 25% Recommended Dietary Intake (RDI)/one-meal serve for the 16 vitamins and minerals currently permitted to be added;
  - permit the voluntary addition of selenium, biotin, pantothenic acid, vitamin K, chromium, molybdenum, manganese and copper
  - set a maximum claim of 25% or lower RDI or Estimated Safe and Adequate Daily Dietary Intake (ESADDI)/ one-meal serve for selenium, biotin, pantothenic acid, chromium, molybdenum, manganese and copper; 40% RDI/one-meal serve for vitamins A and D, and iron and zinc; and 50% RDI/ one-meal serve for all other permitted vitamins and minerals;
  - set maximum amounts/ one-meal serve equivalent to the maximum claim for vitamins A and D, and for iodine, selenium, chromium, molybdenum, manganese and copper;
- for supplementary foods, prescribes vitamin and mineral composition to:
  - decrease the number of vitamins and minerals from 5 to 1 that are required to meet a minimum content, and increase that minimum content from 10% to 20% RDI/serve of the final food;
  - extend the permission for voluntary addition of vitamins and minerals to include vitamins B6, B12, E and folate; and magnesium, iodine and zinc;
  - set a maximum claim of 25% RDI/serve of the final food for vitamins A and D, and iron, magnesium and zinc; and 50% RDI/ serve of the final food for all other permitted vitamins and minerals
  - set maximum amounts/ serve of the final food equivalent to the maximum claim for vitamins A and D, and iodine;

- permits all food additives currently permitted in formula dietary foods and supplementary foods by both the AFSC and the NZFR to be in formulated meal replacements and formulated supplementary foods with the addition of intense sweeteners, except for cyclamate and saccharin;
- requires an advisory statement on meal replacements to the effect that meal replacements are not to be consumed as total diet replacements;
- permits nutrient claims and nutrient declarations within a Nutrition Information Panel, to be made on meal replacements and supplementary foods providing the food contains a minimum of 10% RDI or ESADDI per appropriate serve;
- removes the current prohibition on declaration of nutrient claims on supplementary foods; and
- requires the purpose for which each supplementary food is intended to be stated on the label.

In the joint FSC for formulated meal replacements and formulated supplementary foods the Authority proposes not to:

- require protein quality criteria;
- require a mandatory Nutrition Information Panel;
- prescribe compositional parameters in relation to reference quantities;
- require a warning statement on meal replacements that if used as a total diet replacement the food should be used only under medical supervision;
- require ingredient composition criteria for supplementary foods; and
- require the label of meal replacements and supplementary foods to provide directions for preparation use and recommended frequency of use.

The following issues will be assessed in other Authority review projects:

- the review of standards for health claims (Proposal P153) will assess the need for regulations on slimming claims;
- the general review of food additives (P150) will adopt the recommendations for additive permissions in formulated meal replacements and formulated supplementary foods;
- the reviews of maximum permitted concentrations of metals and non-metals in food (P157 and P158) will consider those contaminants in commodity products used in the preparation of formulated meal replacements and formulated supplementary foods where there are public health and safety implications;
- the review of directions for use (P165) will address the public health and safety issues relating to directions for use in these products; and
- the review of Non Alcoholic Beverages will determine appropriate regulation of some electrolyte drinks, other electrolyte drinks will be addressed in any review of Sports Foods (Standard R10).

Simplified procedures

This proposal raises issues of minor significance and complexity only. To omit to invite public submissions in relation to the application will not significantly adversely affect

the interests of any person or body. The Authority has therefore decided to omit to invite public submissions prior to making a full assessment of the application.

Regulatory impact summary

Regulatory impact statements have been made within each relevant section of the report. The overall proposed revised standard supports a less prescriptive regulatory approach and one that is more consistent with current international standards.

TBT / SPS notification

The review of standards for formulated meal replacements and formulated supplementary foods will require an SPS notification because of the lack of an international standard for supplementary foods, and the nature of the compositional parameters prescribed in the standard to protect public health and safety.

Background

Australia New Zealand Food Authority (ANZFA)

The ANZFA is a joint statutory body responsible for making recommendations on food standards which, when approved by the Australia New Zealand Food Standards Council (ANZFSC), are adopted by reference and without amendment into the food laws of the Australian States and Territories. In New Zealand for the time being, such standards apply as part of a system of dual standards, where the AFSC is recognised as an alternative to the NZFR. At a future date, standards in the NZFR will be repealed and the standards developed under the joint system will apply in both countries.

ANZFA's other functions include developing codes of practice for industry on any matter that may be included in a food standard, coordinating the surveillance of food in Australia and liaising with the Ministry of Health in New Zealand on arrangements for imported foods, conducting research and surveys in relation to food standards matters, developing food safety education initiatives in cooperation with the States and Territories, and assisting in the coordination of food recalls in Australia. The Ministry of Health manages recalls in New Zealand. In Australia, ANZFA develops assessment policies in relation to imported food.

Review of food standards

In July 1996 an agreement between Australia and New Zealand came into force which established the ANZFA - a system for developing joint food standards and a joint FSC.

The aim of the Agreement is to extend the Australian food standard system to include New Zealand so that food standards developed by the ANZFA and approved by ANZFSC can be adopted throughout Australia and in New Zealand. The current review of the AFSC is an important element in developing joint standards. The provisions of the Agreement provide common policy objectives for developing food

standards and a common approach to a transparent, timely, consultative and accountable standards setting process—both key features of the review process. The Authority is seeking to ensure full New Zealand participation in the standards setting process and the review of food standards.

In developing or reviewing food standards, the Authority must have regard to the objectives outlined in section 10 of the *Australia New Zealand Food Authority Act 1991*.

Consistent with these statutory objectives and the policies of the Authority, the review will, where possible:

- reduce the level of prescriptiveness of standards to facilitate innovation by allowing wider permission on the use of ingredients and additives, but with consideration of the possible increased need for consumer information;
- develop standards which are easier to understand and make amendment more straightforward;
- replace standards which regulate individual foods with standards that apply across all foods or a range of foods;
- consider the possibility of industry codes of practice as an alternative to regulation; and
- facilitate harmonisation of food standards between Australia and New Zealand.

The review will also be carried out in accordance with the competition policy principles which have been adopted by the COAG and the draft Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to remove unnecessary obstacles to competition, and assess social, environmental, health and economic impacts of proposed regulation on all affected sectors of the community.

Food standards setting in Australia and New Zealand

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. ANZFA is now developing a joint FSC which will provide compositional and labelling standards for food in both Australia and New Zealand.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia must** comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia other than from New Zealand** must comply solely with the Australian *Food Standards Cod*

- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination of both.

- **Food imported into Australia from New Zealand** must comply with the Australian *Food Standards Code*. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must for most products comply solely with the Australian *Food Standards Code.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974,* and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

Regulatory impact analyses

ANZFA is required, in the course of development of regulations suitable for adoption in Australia and New Zealand, to consider the impact of various options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of the regulatory impact statement. Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

World Trade Organization (WTO) notification

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the COAG requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the Agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

Matters relating to public health and safety may be notified as a SPS notification, and other matters relating to trade may be notified as a TBT notification.

This matter is considered to be both an SPS matter because the preferred regulatory option for formulated meal replacements and formulated supplementary foods:

- proposes the regulation of supplementary foods where no relevant international standard exists; and
- prescribes compositional parameters relating to protein, vitamin, mineral and energy content for the protection of public health and safety.

Invitation for public submissions

Simplified procedures. The Authority has decided, pursuant to section 36 of the *Australia New Zealand Food Authority Act 1991*, to omit to invite public submissions in relation to the proposal prior to making a full assessment. The Authority is satisfied that the proposal raises issues of minor significance and complexity only, and that to omit to invite public submissions prior to making a full assessment will not significantly adversely affect the interests of any person or body.

Section 63 of the Act provides that, subject to the *Administrative Appeals Tribunal Act 1975,* an application for a review of the Authority's decision may be made to the Administrative Appeals Tribunal by a person whose interests are significantly affected by the decision to The Authority has completed a full assessment of the proposal, prepared draft variations to the AFSC and will now conduct an inquiry to consider the draft variations and its regulatory impact.

Written submissions containing technical or other relevant information which will assist the Authority in undertaking an inquiry on matters relevant to the proposal, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. the Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for public inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in

confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions should be received by the Authority by **31 March 1999.** All correspondence and submissions on this matter should quote the full title, Proposal No. P199 and be addressed to one of the addresses on the front page of this document.

1. Philosophy of the Food Standards for Special Purpose Foods

General policy for the review of food regulation

All food regulation has as its primary objective, the protection of public health and safety. Within that framework however, the Authority is required to develop and review standards that provide minimum effective regulation based on an assessment of risk.

Codex standards, where they exist, provide an internationally accepted benchmark. Regulation can be more prescriptive than Codex providing there is sound justification in terms of public health and safety for such provisions. There is no theoretical requirement to adopt all provisions of the Codex standards if it is not considered necessary nor appropriate.

Background to the review of Special Purpose Foods regulation

Part R of the AFSC is devoted to Special Purpose Foods, however, the term *special purpose* is not defined. The New Zealand regulations provide guidance by defining 'special purpose foods':

(1) Special purpose foods shall be foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of -
(a) A particular physical or physiological condition; or
(b) A specific disease or disorder; or
(c) Both such a condition and a disease or disorder, - and are presented as such.

This categorisation depends on a definition of terms such as 'dietary requirement' and 'physiological condition'. Observation of the current Australian and New Zealand markets indicate that the boundary separating special purpose foods from general purpose foods has become blurred over time. Examples of foods that do not clearly differentiate into one or other category are electrolyte drinks, breakfast replacements manufactured to meet the lifestyle needs of otherwise 'breakfast skippers', and fortified beverage flavourings. Some of these foods have been available for decades and are now considered by consumers as part of their routine food choice, rather than as a supplement to an inadequate diet.

General Principles

Definition of special purpose

Special purpose foods shall be foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological need.

The above definition broadens the scope of 'special purpose' from a conventional disease and disorder paradigm to include physiological need such as pregnancy and lactation; and physical need such as enhancing physical performance, meeting dietary

requirements created by lifestyle (eg convenience meal replacements) or use as a prophylactic measure. The definition caters more broadly for products that may be used for health or performance promotion.

It is proposed that all special purpose foods should exhibit all of the following characteristics and that 'special purpose' should be linked to 'particular dietary requirements':

- significant nutritional modification to the content of at least one vitamin or mineral (usually enhancement) while also achieving an appropriate macronutrient content when compared with regular foods including generally fortified foods;
- ease or convenience of delivery of nutrition as either food replacement or diet supplementation which may involve concentration of nutrient content, modification of texture etc;
- additional labelling that is specifically directed to the target groups;
- few or no restrictions on the types or contents of ingredients.

Appropriate nutrient content

The nutritional profile of special purpose products should be appropriate to the intended purpose of the product and should not be confined to only the micronutrients but cover relevant macronutrients and energy content. This is consistent with the approach taken by the Codex Alimentarius *General Principles for the Addition of Essential Nutrients to Foods* in which it states that for special purpose foods "nutrients may be added to special purpose foods including foods for special dietary uses to ensure an appropriate and adequate nutrient content".

The range of permitted vitamins and minerals and the setting of either minimum and/or maximum nutrient content criteria should be determined according to the intended purpose of the product and be informed by risk assessment and dietary modelling to assure protection of public health and safety. It is anticipated that most special purpose products would be more nutritionally complete than any general purpose food, including a fortified food.

For foods that are dietary adjuncts, such as supplementary foods including sports foods, the range of permitted fortificant vitamins and minerals is guided by potential dietary need balanced by consideration of appropriate controls to guard against inappropriate consumption of supplementary foods by non-target groups. For example, a wide range of fortificant vitamins and minerals are permitted in sports foods, but this is balanced by controls over content and label statements warning against consumption by some population groups.

However for supplementary foods, it is proposed that a smaller range of fortificant vitamins and minerals be permitted for which Australian Recommended Dietary Intakes (RDIs) exist. Not surprisingly, most information about the adequacy of the Australian and New Zealand diet is confined to this range of micronutrients.

The proposed approach is to appropriately control vitamin and mineral content that is both efficacious and safe, and to prescribe labelling that informs the consumer of the purpose and content of the product. This approach to labelling is particularly important because of the duration of some widely available supplementary beverage flavourings in Australian and New Zealand markets which, over time, has led to a lack of consumer recognition of the special purpose nature of these products. A flexible approach to the number of fortificant vitamins and minerals provides for products to be tailored to meet a broad range of situations of dietary inadequacy, yet it maintains a distinction between supplementary *foods*, and other forms of dietary supplementation.

For diet replacements such as meal replacements, it is not necessary to establish controls over macronutrient and energy content. The range of vitamins and minerals should reflect the likely range of these nutrients that would be otherwise consumed from that proportion of the regular diet.

Controls over minimum nutrient content

Minimum content criteria for essential macronutrient content should be prescribed according to the product's intended purpose. In the case of sports foods, no general minimum protein or energy criteria are set (although compositional parameters may need to be met before certain claims could be made), but the converse is the case for supplementary foods. Minimum vitamin and mineral criteria would be prescribed according to the product's intended purpose, taking into account industry response to consumer demand. For example, there are no generally applicable minimum content criteria for vitamins and minerals in sports foods because of the high demand of the target market for fortified product, whereas for supplementary foods, minimum criteria have been set at 10% RDI/serve consistent with the purpose of supplementary foods to provide nutrition in situations of inadequate dietary intake. Minimum vitamin and mineral criteria for meal replacements are based on the principle that a total diet replacement should provide at least 100% RDI/total day's intake of essential nutrients; for a one-meal replacement, this is proportional to at least 33% RDI/one-meal serve.

Controls over maximum nutrient content

Generally, maximum criteria for macronutrients and energy are not necessary because these constituents are inherently related to the product formulation which must meet consumer expectation.

Controls on the maximum amounts of vitamins and minerals are determined according to the risk to public health from potential overfortification taking into account the promotion of the product to target groups and surveyed national nutrient intake from other dietary sources. Depending on the risk, maximum claims for individual vitamin or mineral content may deliver sufficient control over vitamin and mineral addition, otherwise maximum amounts might also be prescribed in regulation. Dietary modelling is used to estimate potential nutrient intake from a diet containing high levels of consumption of the proposed fortified foods. Baseline diets are derived from national food consumption data. Modelling is likely to be more informative of risk in cases where foods are intended to supplement the diet, rather than act as dietary

replacements. Unfortunately, there is no established official Australian or New Zealand advice on upper safe limits of vitamin and mineral intake. This new area of health advice is now emerging from the United States' review of recommended dietary allowances. Such information can be used as reference values for dietary modelling where available, however, in the absence of such information, an upper level of dietary intake of about 3-4 times Australian age/sex specific RDIs or US ESADDI's has been used in conservative models of high consumption of the relevant special purpose food.

Labelling

Consideration of labelling requirements should be made in the context of the controls imposed on compositional parameters which, in turn, are determined according to the risk to public health and safety. Labelling should inform consumers of the nature of the product, the special purpose for which it is intended (which may take the form of exemptions to the general prohibition on health claims), and the closely-related appropriate use of the product.

2. Introduction

This review forms part of the Authority's review of food regulations and examines both local and international regulations for meal replacements (formula dietary foods) and supplementary foods. At present there are differences in the way that both meal replacement products and supplementary foods are regulated in the:

- AFSC Standards R4 and R9 (Appendices One and Two respectively);
- NZFR 237 and 244 (Appendix Three); and
- Codex Alimentarius standards which cover meal and total diet replacements, but not supplementary foods. Codex Alimentarius also has established General Principles for the Addition of Essential Nutrients to Foods.

Within the AFSC formula dietary foods and supplementary foods are currently regulated as two separate standards.

The following matters have been identified as requiring resolution in the development of a joint food standard for meal replacements and supplementary foods:

- the need for definitions;
- compositional requirements especially nutritional composition;
- labelling requirements; and
- food safety requirements.

3. Definitions

There may be a need to include definitions for formulated meal replacements and formulated supplementary foods to define the scope of the standard/s for use by manufacturers and enforcement officers;

- if a common understanding of the terms for formulated meal replacements and formulated supplementary foods does not exist; and

- there are specific compositional or labelling provisions for formulated meal replacements and formulated supplementary foods.

The following section discusses the need for definitions for formulated meal replacements and formulated supplementary foods.

3.1 Current Requirements

The AFSC contains definitions for formula dietary foods (meal replacements) and supplementary foods - including supplemented drink base and supplemented drink. The definitions of supplemented drink base and supplemented drink are based on ingredient compositional criteria.

In the NZFR there is no definition for formula dietary foods. Under Regulation 237, meal replacements for weight reduction diets and meal replacements for special medical nutritional products are addressed. Within the NZFR a definition is provided for *meal replacement for weight maintenance or weight reduction diet*. Medical nutritional products are also defined. Both definitions provide for products that are total diet replacements and not only meal replacements.

There is no definition for supplementary foods in the NZFR. Under Regulation 244 a *food drink and food drink base* are defined equivalent to that given for *supplemented drink* and *supplemented drink base* in Standard R9 of the AFSC.

Codex defines *formula foods for use in weight control diets* as:

> "foods which when presented as 'ready to serve' or when prepared in conformity with the directions for use, are presented as a replacement for all or part of the total daily diet".

The major distinguishing feature between supplementary foods and their generic counterparts is the addition of essential nutrients, particularly vitamins and minerals. Codex Alimentarius has not developed a category of special purpose foods equivalent to the AFSC Standard R9 - Supplementary Foods. However, Codex Alimentarius has established General Principles for the Addition of Essential Nutrients to Foods (GL 09-1987) which provides guidance for the addition of vitamins and minerals to both general purpose, and special purpose foods.

3.2 Assessment

The purpose of the definition is to define the scope of the standard and it is for the use of enforcement agencies and manufacturers. As there are particular compositional requirements for both meal replacements and supplementary foods, it is proposed that definitions are required for both categories.

The definitions within the current Standard R9 for both supplementary drinks and supplementary drink bases (and food drinks and food drink bases in the NZFR) are problematic. The title of the standard and first definition refer to supplementary foods

yet subsequent definitions and related provisions refer only to drink bases and their liquid counterparts thus not providing coverage of solid food products such as supplementary food bars. To broaden the scope of the draft revised standard, it is proposed to retain only the definition that refers to supplementary foods. This change will significantly broaden the range of ingredients that can be used to formulate these foods.

The proposed definitions are as follows:

formulated meal replacements *means a single food or prepackaged selection of foods that is sold as a replacement as one or more of the daily meals but not as a total diet replacement*.

formulated supplementary foods *means a single food specifically designed as a supplement to a normal diet to address situations where intakes of energy or nutrients may not be adequate to meet an individual's requirements*.

Because of the considerable similarity in the regulations of the two product categories, it is proposed to develop one standard divided into two parts to cover (i) meal replacements and (ii) supplementary foods. Both (i) and (ii) would need to be defined to determine the scope of the standard. To overcome possible confusion with the term 'formula dietary foods' it is proposed to name the revised standard "Formulated meal replacements and formulated supplementary foods".
It is recommended that the standard regulate meal replacements other than those intended to be total diet replacements and all supplementary foods other than those regulated by Standard R10 - Formulated Supplementary Sports Foods.

It is well recognised that consumption of total diet replacements is not an ideal approach to weight reduction unless used under very controlled conditions including medical supervision. This is particularly the case with very low energy diets. Very low energy diets are not currently regulated by Standard R4 and will be addressed in the joint FSC as part of "medical foods" to be developed at a later date.

3.3 Conclusion

The Authority proposes to combine the current standards into a single standard titled "Formulated meal replacements and formulated supplementary foods" that will separately define *formulated meal replacements* and *formulated supplementary foods* . The standard will not regulate total diet replacements, nor sports foods including electrolyte drinks.

4. Essential composition

4.1 Reference quantity

4.1.1 Current Requirements

Meal replacements
Nutrient criteria given in both AFSC and NZFR are specified according to a reference quantity that is equivalent to the amount recommended by the manufacturer to replace one meal. Codex also uses the same amount as the unit quantity.

Supplementary foods
The unit quantity given in AFSC and NZFR for supplementary drinks and drink bases as made up is 200 mL.

4.1.2 Assessment

Meal Replacements
The unit quantity is proposed to be retained as the amount recommended to replace one meal. This does not inhibit manufacturers from directing consumers to replace more than one meal per day providing the product is not being represented as a total diet replacement.

Supplementary foods
The setting of a reference quantity has the effect of standardising the concentrations of nutrients in the supplementary food. Reference quantities have no bearing on the label serve size selected by the manufacturer.

Rather than prescribe reference quantities for supplementary solid foods, semisolid foods as well as liquids, it is proposed to delete the prescribed unit quantity and substitute a reference quantity of one serve as recommended by the manufacturer. Further the serve will be specified as the amount of food prepared ready to consume. The minimum protein and energy requirements will also influence the setting of appropriate serve sizes.

4.1.3 Regulatory Impact Statement

The Authority has investigated the regulatory impact of two main options.

Option (1): to retain the status quo of having a reference quantity of 200 mL for supplementary drinks and drink bases.

Option (2): to delete the prescribed reference quantity for supplementary drinks and supplementary drink bases and substitute a reference quantity of one serve as recommended by the manufacturer.

Option (1) does not cater for supplementary foods that are either solid or semi liquid. The prescribed reference quantity of 200 mL may not be appropriate for a number of specific products that are being produced and where the reference quantity and recommended serve may differ significantly. There are no additional costs associated with this option although there are no significant benefits.

Option (2) allows for manufacturers to determine an appropriate reference quantity as equivalent to one serve. This option allows for the appropriate nutrient composition to be provided in an amount of product likely to be consumed in one serving. This option is more appropriate to cater for the range of foods being produced as the serve will indicate the nutrient profile as consumed and will therefore more truly reflect the use of the product. This will benefit consumers in providing more meaningful information and there are no associated costs.

4.1.4 Conclusion

It is proposed to delete prescribed unit quantities for supplementary foods, and substitute the amount recommended by the manufacturer as one serve of the food as prepared ready to consume.

4.2 Macronutrient Composition Criteria

4.2.1 Current Requirements

Meal replacements
No criteria for macronutrient composition of meal replacements are given in either the AFSC or NZFR. However Codex specifies a meal as replacing either 25% or 33% of daily nutrients depending on how many meals are recommended each day. Codex also sets a maximum fat content of meal replacement products such that not more than 30% of the energy available from the food shall be derived from fat including not less than 3% of the energy available derived from linoleic acid—an essential fatty acid (in the form of a glyceride).

The amount of dietary fibre in meal replacements is not specified in AFSC, NZFR or Codex. The EC and the UK both require that the dietary fibre content of meal replacement products shall not be less than 10 g and shall not exceed 30 g for the daily ration.

Supplementary foods
Neither AFSC nor NZFR directly prescribe macronutrient composition of supplementary foods in terms of nutrient content. Instead, ingredient-based compositional criteria are given within the definitions of supplemented drink/drink base [NZ food drink/drink base]. As previously stated, Codex has not developed a standard to regulate supplementary foods.

4.2.2 Assessment

Meal Replacements
Nutritional composition criteria are required to ensure a nutrient profile is set equivalent to that provided in one meal. Given the proposal that the draft revised standard would not cover products that are complete dietary replacements, it is recommended that the regulatory basis for nutrient and energy quantity be the nutrient quantity and energy quantity to be consumed in one meal which equates to not less than one quarter of the daily amount of each relevant nutrient.

Protein: not less than 12g protein/one-meal serve.
Energy content: not less than 850 kJ/one-meal serve.

These nutritional criteria are similar to the current Codex requirements where minimum amount of energy to be provided per serve is 835 kJ and a minimum of 25% of the energy available from food shall be derived from protein. A protein value of 12 g is approximately 25% of the current adult RDI. This is consistent with the general principles for meal replacements with both proximates and micronutrients providing at least 25% of the RDI per one meal serve.

Neither the AFSC nor the NZFR prescribe protein quality criteria however Codex does so based on equivalence to milk or egg protein. Protein quality requirements for meal replacement products have not been previously prescribed in Australia and New Zealand and there is no evidence to suggest that such an omission has resulted in any public health risk or concern. Also the Authority does not believe that it is necessary to prescribe criteria for protein quality because both Australians and New Zealanders generally consume more than adequate amounts of protein and there is limited risk of protein deficiency or inadequate protein intake.

Because of the variety of types of meals that could be substituted by meal replacements, it is not considered appropriate to impose a maximum fat content. For meal replacements intended for use in weight reduction, the fat content would be automatically limited by the need to perform that function.

Both meal replacements and supplementary foods are intended to be consumed as part of a mixed diet and it is therefore unnecessary to require minimum amounts of linoleic acid even though it is an essential nutrient. Given that the proposed standard would not regulate total diet replacements, meal replacements should not be the sole daily nutrient source. This same contention supports the decision not to specify a minimum dietary fibre requirement.

Supplementary Foods

Macronutrient composition criteria are required to ensure that only products that make significant nutritional contributions to the diet are regulated as supplementary foods. However, a more flexible approach to permit the marketing of solid foods would be to establish nutrient criteria rather than retaining the current ingredient-based criteria which are unnecessarily restrictive and favour milk- and cereal-based drinks and drink bases.

It is recommended that macronutrient criteria be set for protein and energy content which has a slightly greater nutrient density than whole milk (whole milk/200mL, 6.6 g protein; 560 kJ). It is not proposed to establish protein quality criteria which would thus enable a broader range of base ingredients to be used in supplementary foods. It is expected that reasonable quality protein would be the source of the minimum protein content.

Protein: not less than 8 g protein/serve as ready to consume.
Energy content: not less than 550 kJ/serve as ready to consume.

With regards to fat composition, it is not considered appropriate to restrict the maximum fat content as the purpose of the products and target groups will vary. As supplementary foods would not replace the total diet, there is no need for a minimum dietary fibre requirement.

4.2.3 Regulatory Impact Statement

There are a number of options associated with the compositional criteria for meal replacements and supplementary foods. The Authority has considered the impact of two of these:

Option (1) to retain the status quo of no specific compositional criteria for meal replacements and ingredient-based criteria for supplementary foods; or

Option (2) to prescribe nutrient composition criteria for both meal replacements and supplementary foods using as a guide, the protein and energy contributions of whole milk.

Under Option (1), the costs of retaining the status quo with respect to compositional criteria are mostly those associated with loss of opportunity to develop a broader range of products, especially for supplementary foods.

The benefits associated with retaining the status quo are that there would be no reformulation or associated labelling costs.

Under Option (2), the macronutrient compositional criteria protect public health of consumers. The industry and consumer would benefit from the proposed compositional criteria as they are less restrictive and would allow for a wider range of product on the market.

Enforcement of the current ingredient compositional criteria for supplementary foods is more time consuming and involved than the proposed energy and protein criteria which, in most cases, would be easily identified on the label. The overall effect would be a reduction in enforcement costs.

4.2.4 Conclusion

The Authority proposes to prescribe protein and energy content criteria but not protein quality criteria for both formulated meal replacements and formulated supplementary foods.

Such criteria provide a fairer and more flexible basis for products regulated as supplementary foods. The criteria also ensure that dietary supplement products that contribute vitamins and minerals alone, could not be regulated as supplementary foods.

4.3 Vitamin and Mineral Composition

Appendix Four provides a comparative table of current permissions for vitamin and mineral content in Standards R4, R9 and R10 -Formulated Supplementary Sports Foods of the AFSC.

4.3.1 Current Requirements

Meal Replacements
Standard R4 of the AFSC requires that a formula dietary food shall contain in the quantity stated in the label as the quantity to be consumed in one day, not less than the daily allowance of each vitamin and mineral (16 in all) specified in the Schedule to Standard A9.

This range of nutrients differs from those listed in the NZFR, which in addition to those required by AFSC, permit biotin, pantothenic acid, vitamin K, chromium, copper, manganese, selenium and molybdenum. No minimum or maximum quantities are prescribed in NZFR for these additional nutrients. In contrast to the AFSC, the NZFR permits all vitamin and mineral addition on a voluntary basis.

The fact that selenium, chromium and molybdenum can be added as micronutrients to meal replacements under the NZFR but not by the equivalent provisions of the AFSC was believed at the time to give products from New Zealand a competitive advantage. A dual standard using Standard T1 of the AFSC was developed as an interim measure to allow certain foods to be manufactured in Australia in accordance with either the AFSC or the NZFR, until food standards could be harmonised between the two countries. Following the commencement of the Trans Tasman Mutual Recognition Arrangement in May 1998, foods complying with the provisions of the NZFR can be imported into Australia from New Zealand and foods complying with the AFSC can be imported into New Zealand.

Codex states that single meal replacements shall provide a minimum of 33% or 25% of the daily amount of vitamins and minerals depending on the number of serves recommended in a day. Codex does not prescribe upper limits of vitamins and minerals for meal replacement products. Codex also states that other essential nutrients not specified in the list of vitamins and minerals may also be included.

The major differences between the AFSC, the NZFR and Codex appear to be:

- the prohibition within the AFSC on the addition of biotin, pantothenic acid, vitamin K, chromium, manganese, selenium and molybdenum. Codex permits these nutrients (or any essential nutrients) to be added to meal replacements to ensure an appropriate and adequate nutrient content. The NZFR also permits the voluntary addition of these nutrients in unprescribed amounts.

- the restriction on the maximum amounts of nutrients in meal replacements. Both the NZFR and Codex do not prescribe maximum limits on vitamin and mineral addition to meal replacements. The AFSC prescribes maximum amounts of nutrients where there are known issues of public health and safety - for only vitamins A and D, and iodine. For all permitted vitamins and minerals, AFSC prescribes maximum claim of 50% RDI/one-meal serve which is comparable to the

maximum claims established for vitamins and minerals added to general purpose foods listed in Standard A9 - Vitamins and Minerals.

Supplementary Foods

Supplementary foods are intended to be consumed for the purpose of supplementing an otherwise inadequate diet. However, a number of products regulated by Standard R9 that are regularly consumed by children and young adults are arguably not perceived by the general community as supplementary special purpose foods. The permissions for vitamins and minerals have taken this into account and previously been more restrictive than for meal replacement products.

Standard R9 requires that a supplemented drink base or supplemented drink must contain at least 10% RDI/reference quantity of five or more of the 9 permitted vitamins and minerals. The current maximum claim for all permitted vitamins and minerals added to supplementary food ranges from 20-47% RDI/reference quantity of the food as ready to consume. In addition, a supplemented drink base or a supplemented drink must not contain more than 33% RDI vitamin A or 30% RDI vitamin D in the reference quantity.

The NZFR does not set minimum vitamin and mineral amounts in food drinks and food drink bases, however, the first table to Regulation 20A (Amendment 12), prescribes the same maximum claims and maximum amounts as Standard R9 (see Appendix Three).

4.3.2 Assessment

Recommended Dietary Intakes provide a guide to the safe and adequate levels of vitamins and minerals in diets consumed in Australia and New Zealand. These recommendations however are now more than eight years old and there are moves underway to update them. The United States of America has more recently reviewed its equivalents of RDIs which includes reference values for nutrients not included in the Australian RDIs. In the absence of RDIs for several trace elements and some vitamins that are permitted to be added to meal replacements by NZFR and Codex, the US Estimated Safe and Adequate Dietary Intakes (ESADDI) provide a basis for setting compositional limits for these nutrients. Some of these ESADDI values have already been used in Standard R10 of the AFSC.

Codex recommends that only vitamins and minerals for which intakes have been established and/or which are of nutritional importance in the country concerned should be permitted.

There are no Australian RDIs for biotin, pantothenic acid, vitamin K, chromium, manganese or molybdenum. Toxic levels of all of the above nutrients are either not established or at levels considerably higher than normally consumed from the diet (see Appendix Five). There are however RDIs for copper and selenium.

Meal Replacements

Minimum Vitamin and Mineral Composition

Mandatory minimum nutrient requirements are based on those in Codex where a minimum nutrient requirement is equivalent to 33% or 25% of the RDI per meal. On this basis, three or four servings of a meal replacement would constitute 100% RDI or ESADDI although it is clearly stated that the Codex standard should not be used to regulate total diet replacements.

It is proposed that a similar approach be adopted to require a minimum content of vitamins and minerals equivalent to 25% RDI or ESADDI per one-meal serve, where a serve is equivalent to replacement of one meal.

The Authority proposes to continue to require a minimum content of the 16 current vitamins and minerals in meal replacements, but to permit the voluntary addition of several other micronutrients: biotin, pantothenic acid, chromium, manganese, vitamin K, copper, selenium and molybdenum.

Maximum Vitamin and Mineral Composition

The proposed maximum amounts of vitamins and minerals in meal replacements are established on the basis of prevention of adverse health effects and undesirable nutrient-nutrient interactions.

Maximum amounts are proposed for vitamins and minerals for which there are known adverse health effects. These are vitamins A and D, iodine, selenium, manganese, molybdenum, chromium and copper. Although this approach is not consistent with Codex Alimentarius, the Authority considers that there is sufficient scientific evidence to warrant the establishment of maximum amounts of these vitamins and minerals.

The Authority proposes that no maximum amounts be set for other vitamins and minerals permitted to be added to meal replacements. This approach is consistent with the current AFSC as well as the NZFR, and Codex Alimentarius. However, maximum claims are proposed for all permitted vitamins and minerals. A maximum claim, equivalent to the maximum amount, of 25% RDI or ESADDI/ one-meal serve or lower is proposed for selenium, biotin, pantothenic acid, chromium, molybdenum, manganese and copper; 40% RDI/ one-meal serve for vitamins A and D, and iron and zinc; and 50% RDI/ one-meal serve for all other permitted vitamins and minerals (Appendix Six). This is consistent with current provisions in Standard A9 and the approach taken in Standard R10.

The level of 50% RDI, where there are unknown adverse effects, was used to ensure that a maximum daily intake of each of the vitamins and mineral does not exceed about 200% RDI (using 4 serves per day as a maximum intake).

Supplementary Foods

Minimum Vitamin and Mineral Composition

The minimum criteria for vitamin and mineral content in Standard R9 state that the product must contain at least 10% RDI/reference quantity for five or more of the 9 permitted vitamins and minerals. The minimum content of at least 10% RDI/serve is proposed to be increased to 20% RDI/serve and the number of vitamins and minerals permitted in supplementary foods increased to 16 vitamins and minerals. It is therefore proposed that the criteria be relaxed to require that products in this category must contain at least 20% RDI/serve of only *one* or more permitted vitamins and minerals.

The decision to reduce the mandatory number of vitamins and minerals from five to at least one is based on recent Australian data indicating that, of those members of the Australian population who consumed less than 50% RDI/day of any number of vitamins or minerals, the majority (14 - 17%) consumed inadequate amounts of only one vitamin or mineral. Although the reviewed criteria permit a broader range of vitamins and minerals to be added to supplementary foods than previously, a clear distinction will be maintained between supplementary foods and dietary supplements by virtue of controls on protein and energy content, and appropriate labelling.

It is proposed that vitamins and minerals for which Australian RDIs exist be permitted in supplementary foods. This approach extends the current range of fortificant vitamins and minerals to include: vitamin B6, vitamin B12, vitamin E, folate, zinc, iodine and magnesium.

Maximum Vitamin and Mineral Composition

The current maximum claim for 9 vitamins and minerals permitted to be added to supplementary food by AFSC and NZFR ranges from 20-47% RDI/reference quantity. However there appears to be no sound rationale for the range of RDIs given for the maximum claim.

Based on dietary modelling of high consumers of supplementary foods at the 95th percentile of intakes - including young children- and risk assessments (Appendix Five), the Authority proposes to set a maximum claim of 50% RDI/serve of the food ready to consume for all permitted fortificant vitamins and minerals in supplementary foods except for vitamins A and D, iron, magnesium and zinc for which maximum claims of 25% RDI/serve are proposed (Appendix Seven). The maximum claims for iron, magnesium and zinc are proposed at lower levels to account for potential adverse nutrient interactions between these nutrients and calcium and copper respectively.

In addition to the use of maximum claims for all permitted vitamins and minerals, it is proposed to set maximum amounts for vitamin A, vitamin D and iodine equivalent to the maximum claim.

4.3.3 Regulatory Impact Statement

There are a number of potential options for the addition of vitamins and minerals to meal replacements and supplementary foods. The Authority has undertaken a regulatory impact assessment on two of these options.

Option (1): to retain the current permissions for addition of vitamins and minerals to both meal replacements and to supplementary foods which refer to the specific vitamins and minerals as well as prescribed maximum limits.

Option (2): to increase the range of vitamins and minerals as recommended above consistent with protection of public health and safety.

Option (1) has major difficulties for meal replacements as there is currently discrepancy between the AFSC and the NZFR. Although it is possible to recommend that the AFSC be the approach adopted, it is currently more prescriptive than the NZFR. There is no evidence that the current requirements in the NZFR have resulted in any public health and safety concern. Adoption of option (1) may result is costs of reformulation for some New Zealand product.

Option (2) provides a much less restrictive approach.
The benefits of option two provide for increased industry innovation. There is also the potential for an increased range of products for consumers.

4.3.4 Conclusion

Meal replacements
The proposed range of fortificant vitamins and minerals for meal replacements is in accordance with New Zealand's Regulation 237 and as such is wider than the range of vitamins and minerals permitted in general purpose foods under the provisions of Standard A9. The Authority proposes that biotin, pantothenic acid, vitamin K, chromium, copper, manganese, selenium and molybdenum be permitted to be voluntarily added to formulated meal replacements.

The basis for mandatory minimum nutrient requirements was determined according to Codex requirements where a minimum nutrient requirement is equivalent to one quarter or one third of the RDI (or other reference such as ESADDI) per meal.

To protect public health and safety, it is considered appropriate to prescribe maximum amounts for the following vitamins and minerals: vitamin A, vitamin D, selenium, copper, manganese, iodine, molybdenum, and chromium.

Based on a nutrition risk profile and dietary modelling, a maximum claim of 50% RDI/one-meal serve is proposed for most fortificant vitamins and minerals, except for vitamin A, vitamin D, iron and zinc for which 40% RDI/one-meal serve is proposed; 25% RDI is the proposed maximum for selenium, and 17% ESADDI/one-meal serve is proposed for other trace elements.

It is proposed that more comprehensive dietary modelling will be undertaken for inquiry once the DIAMOND modelling system nutrient module is operational.

Supplementary Foods
The Authority proposes that the minimum vitamin and mineral content be amended from 10% to 20% RDI/serve and that the number of vitamins and minerals required to meet that minimum content be reduced from at least five to at least one. This reduction is based on dietary data previously described.

It is proposed that vitamins and minerals for which Australian RDIs exist be permitted in supplementary foods. This approach extends the current range of fortificant vitamins and minerals to include: vitamin B6, vitamin B12, vitamin E, folate, zinc, iodine and magnesium.

Based on dietary modelling of high consumers of supplementary foods at the 95th percentile of intakes - including young children and risk assessment, the Authority proposes to set a maximum claim of 50% RDI/serve of the food ready to consume for all permitted fortificant vitamins and minerals in supplementary foods except for vitamins A and D, iron, magnesium and zinc for which maximum claims of 25% RDI/serve are proposed. The maximum claims for iron and zinc are proposed at lower levels to account for potential adverse nutrient interactions between these nutrients and calcium and copper. In addition to the use of maximum claims for all permitted vitamins and minerals, it is proposed to set maximum amounts for vitamin A, vitamin D and iodine equivalent to the maximum claim. It should be noted that maximum claim applies to the total nutrient content of the food and not just the level of added nutrient.

4.3.5 Permitted forms of vitamins and minerals

The chemical forms of vitamins and minerals permitted to be added to meal replacements and supplementary foods include the relevant forms listed in the Schedule to Standards A9, R10 in the AFSC as well as those permitted by the NZFR Regulation 237. The proposal differentiates between the inorganic and the organic forms of trace minerals on the basis that the organic forms have higher bio-availability than the inorganic forms. The maximum amounts and maximum permitted claims for the organic chemical forms of trace minerals are set at 50% of the corresponding amounts for the inorganic forms, consistent with Standard R10 - Formulated Supplementary Sports Foods.

5. Additives and processing aids

5.1 Current Requirements

Standard R4 permits addition of any of the modifying agents specified in Standard A10.

Standard R9 states that a supplemented drink base or supplemented drink may contain:
(a) other foods
(b) colourings
(c) modifying agents specified in Groups I, II, III and IV of Table 1 of Standard A10.

The additives permitted in NZFR are stated in Appendix Three.

Current provisions do not permit artificial sweeteners to be added to meal replacement products or supplementary foods.

5.2 Assessment

The Authority's full assessment report on food additives (P150) establishes general principles to be applied to the regulation of food additives for the purposes of reviewing the Food Standards Code. This regulatory approach is intended to provide a framework which allows innovation in the food industry while protecting public health and safety and the integrity of the food supply.

Intense Sweeteners:

It is proposed that all additives currently permitted in meal replacements and supplementary foods in both the AFSC and the NZFR be permitted within the revised standard. In addition it is recommended that intense sweeteners, excluding saccharin and cyclamate, be permitted in meal replacements and supplementary foods.

Therefore it is recommended that meal replacements and supplementary foods be permitted to contain all food additives listed in Schedule 2 of P150 (which includes some intense sweeteners).

In addition it is recommended that acesulphame K be permitted at 500 mg/kg or mg/L and alitame at maximum level of 85 mg/kg.

5.3 Regulatory Impact Statement

The Authority has investigated two options:

Option (1): to retain the status quo with respect to current additive permissions; or

Option (2): to increase the additive permissions to allow any additives currently in the AFSC and the NZFR for these products with the addition of intense sweeteners, except for saccharin and cyclamate.

Option (1) does not address the differences in permissions that currently exist between the AFSC and the NZFR for these products.

Option (2) with the addition of intense sweeteners provides for increased product innovation and therefore provides general benefits to manufacturers and consumers.

5.4 Conclusion

It is recommended that all food additives currently permitted in formula dietary foods and supplementary foods in both the AFSC and the NZFR be permitted in formulated meal replacements and formulated supplementary foods with the addition of intense sweeteners, except for cyclamate and saccharin.

6. Labelling

General labelling provisions are being reviewed by labelling review teams. Most food labelling requirements will be removed from the commodity standards and included in a general standard for food labelling, unless specific labelling in the standard can be justified on the grounds of protecting public health and safety or preventing fraud and deception.

6.1 Prescribed names for meal replacements and supplementary foods.

Currently prescribed names are required for *formula dietary foods*, for *supplementary drinks* and for *supplementary drink bases*. The Authority is proposing to change the title of the standard to more truly reflect the type of product regulated. In revising the title, it is recommended that the prescribed names also more truly reflect the type of products being regulated. It is proposed that *formulated meal replacement* and *formulated supplementary food* should be prescribed names so that the specific compositional requirements can be enforced.

6.1.1 Regulatory Impact Statement

The Authority has investigated the regulatory impact of two options.

Option (1): to retain the status quo with prescribed names for formula *dietary foods*, for *supplementary drinks* and for *supplementary drink bases*.

Option (2): to require prescribed names for *formulated meal replacement* and *formulated supplementary foods*.

The only cost associated with Option (1) is that the current names do not bear any resemblance to the product and are therefore not easy for enforcement officers to interpret. Option (1) has the benefit of requiring no labelling changes with respect to prescribed names.

Option (2) more truly reflects the type of product being regulated and therefore would facilitate enforcement. Costs associated with option (2) are those required for labelling changes although it is likely that manufacturers will need to change some aspects of their product labelling.

6.1.2 Conclusion

It is proposed that "formulated meal replacement" and "formulated supplementary food" should be prescribed names so that the specific compositional requirements can be enforced. Any of the names given to particular products within the draft variation are not prescribed names.

6.2 General naming of meal replacements and supplementary foods.

The Authority's review of naming of food (P156) proposes that food not be required to be labelled with an appropriate designation. This is because it already would be in manufacturers' best interests to provide a name for their food or at least represent the food so that consumers are aware of the nature of the food. This is particularly so for formulated meal replacements and formulated supplementary foods.

If consumers did not recognise the name of a food or nature of the food then they would be unlikely to buy the food. If the name and representation of the food was false, misleading or deceptive then this would be an offence and could continue to be regulated by the prohibitions in food law and fair trading law on false, misleading and deceptive representations.

Unless further justification can be provided on the grounds of protecting public health and safety, the Authority proposes not to regulate specific naming of formulated meal replacements and supplementary foods other than prescribed names. These naming representations are adequately assessed by the prohibitions on false, misleading and deceptive representations in food law and fair trading law.

6.3 Nutrition Labelling

The current regulations for supplementary foods requires a nutrition information panel (NIP) based on the average quantity of nutrients in a serving of the food. If a NIP is not provided on the label of a meal replacement, specific nutrition information is required expressed as %RDI/serve.

Currently within the AFSC standards for meal replacements and for supplementary foods as well as the equivalent regulations in the NZFR, there is no requirement for directions on use of the product. However manufactures are already providing this information because they believe it is useful for the consumer.

The current Standard R4 has a requirement for a warning statement that the product should not be used as a total diet replacement unless under medical supervision. There is no such requirement in the NZFR.

The current standards for both meal replacements and supplementary foods do not require that the purpose of the food be stated. In the NZFR the purpose of meal replacement products must be stated but not of supplementary foods as they re not deemed special purpose foods.

6.3.1 Assessment

Formulated meal replacements and supplementary foods are specially formulated to support the diet by either:

replacing a meal or meals; or
supplementing an inadequate diet.

The Authority considered whether a nutrition information panel should be required and if so, whether the proportion of the RDI of each vitamin and mineral contributed per serving of food should be required.

With respect to an NIP, it is believed that manufacturers of meal replacements and supplementary foods would wish to promote the nutritional qualities of their product and therefore make a nutrition claim. A nutrition claim means a *representation that states, suggests, or implies that a food has a nutritional property whether general or specific and whether expressed affirmatively or negatively.* Making a nutrition claim results in a mandatory declaration of a NIP, therefore it is considered that mandating the use of an NIP would be unnecessary. Nutrients for which no RDI has been prescribed in the regulations cannot currently be declared in an NIP. This issue however will be addressed in the review of vitamins and minerals (P166) and nutrition labelling (P167).

Currently neither the AFSC Standards R4 and R9, the NZFR regulations 237 and 244 nor Codex require information on preparation instructions. Manufacturers appear to be already providing this information. The review of directions for use (P165) will have mandatory directions for use where there are new products that may be a public health and safety concern.

In the case of meal replacements only, where the product is more likely to replace significant portions of the diet, there are some population groups who should not be consuming meal replacement products on a regular basis. It is therefore proposed that meal replacement products, in addition to the labelling requirements stated above, also require the following advisory statement or words of similar import:

- this product is not to be used as a total diet replacement.

This is significantly less prescriptive than the current regulations where the words of a statement are prescribed that warn against meal replacement products being used as the principal source of diet unless under medical supervision.

With respect to the purpose of the food, it is considered that the purpose of meal replacements will be clearly evident however this may not be the case for supplementary foods. It is therefore proposed that the purpose of the supplementary food ie *to supplement an inadequate diet* be stated on the label, particularly as the revised standard proposes to permit an increased range of fortificant vitamins and minerals in foods that could for all intents and purposes, appear to be the same as a food not regulated as a supplementary food.

Statement of the purpose of use is currently not required for supplementary foods in the AFSC or the NZFR.

6.3.2 Regulatory Impact Statement

There are a number of options that the Authority could consider with respect to labelling. Two of these are discussed.

Option (1): to retain the status quo with respect to labelling provisions; and

Option (2): to remove current labelling requirements, apart from an advisory statement on meal replacement products and require the purpose of supplementary foods to be stated.

Option (1) retains quite cumbersome labelling requirements which, although intended to protect public health and safety and provide consumer information, are often redundant.

Option (2) provides no less information to consumers but the mechanism of its provision is more straight forward from a regulatory point of view. Option 2 may require changes to current labels for the manufacturers of supplementary foods which may involve be an additional cost.

6.3.3 Conclusion

As a result of the unique nature of formulated meal replacements and supplementary foods in providing special nutritional products, most of the key labelling information is currently either being provided voluntarily by manufacturers or will be required

through other general labelling provisions eg NIP. It is proposed that the only requirement be that the purpose of the food be stated on the label ie to supplement an inadequate diet.
Other labelling including the directions shall comply with all the general labelling requirements for packaged foods eg ingredient listing, date marking etc.

Meal replacement products will be required to provide an information statement that products should not be used as a total diet replacement.

6.4 Permitted Claims

6.4.1 Assessment

The features that differentiate meal replacements and supplementary foods from other general foods is their composition and ability to provide specific dietary components or affect physiological states. If a product is a reasonable source of a given nutrient or nutrients it should be permitted to state that information. If there is concern about the safety of the nutrients in the product this should be addressed in the compositional requirements.

The ability to claim the presence of a specific nutrient, if present in amounts greater than 10% RDI/serve, as it applies to general purpose foods, is in the best interests of both the consumer and the manufacturer. Given the minimum vitamin and mineral requirements for meal replacements and supplementary foods, any claimed level between 10% RDI and the minimum content requirements would apply only to naturally occurring micronutrients.

According to Standard R9, a claim must not be made in the label on or attached to a package or in the advertising, as to the presence in the food of the vitamin or mineral. It is recommended that there be no such prohibition in the revised standard as this is restricting the provision of useful information for consumers. If the prohibition on claims is removed it is expected that the provisions for general purpose foods in clauses 4, 5 and 6 of Standard A9, except for claimable foods in clause 4(1)(b)(ii), would apply. These clauses address issues of nutrition labelling and prohibit claims such as fortified or enriched, and comparative claims. To achieve this outcome, a consequential amendment to the purpose clause of Standard A9 is required because it currently excludes Standard R9 (but not Standard R4) from its scope. No decision has yet been made as to the placement of tabulated proposed vitamins and minerals permissions, but because these labelling clauses refer specifically to the table to clause 3, and the Schedule to Standard A9, further amendments may be necessary. This will also be addressed in the review of Standard A9 (P166).

A claim as to the effects of specific nutrients on physiological states would constitute a health claim and will be considered under the review of health claims (P153) as will slimming claims.

6.4.2 Regulatory Impact Statement

The Authority has investigated the regulatory impact of the two key options.

Option (1): to retain the status quo of prohibiting nutrition claims on these products; or

Option (2): to permit nutrition claims on all products in the revised standard if they meet the required criteria.

Option (1) continues to be a deterrent for manufacturers as they are unable to inform consumers of the specific nutritional value of their products except through the NIP. Manufacturers may consider it not worth developing new products in the supplementary food area if they are unable to advise consumers of specific nutrient contributions.

Option (2) provides a fairer basis for manufacturers of both supplementary foods and meal replacements in that they can advise consumers of specific nutrient contributions of their products. There may be additional costs to manufacturers in making changes to labels if they do want to make a claim but this would be totally voluntary.

6.4.3 Conclusion

The Authority proposes to permit the use of nutrition claims in the revised standard. However, it is also recommended that there be a consequential amendment to Standard A9 that would include Standard R9 within the scope of Standard A9 particularly as it relates to claims.

7. Contaminants and hygiene

7.1 Current provisions

Codex standard for meal replacements contains specific provisions relating to contaminants, hygiene, weights and measures. The standards for meal replacements and supplementary foods in the AFSC and NZFR do not contain similar specific provisions.

7.2 Assessment

Some of the current Codex standard permissions for contaminants are included for quality reasons. The Codex Working Group on contaminants and natural toxins are proposing to regulate contaminants which relate to safety matters and not quality. The Authority's reviews of maximum permitted concentrations of metals and non-metals in food (Proposals P157 and P158) will therefore consider those contaminants in commodities that may be used in meal replacements and supplementary foods where there are public health and safety implications but not quality issues.

The separate review of food safety (hygiene) standards in Australia and food safety programs in New Zealand will assess food hygiene aspects relating to all food.

7.3 Conclusion

The Authority proposes not to include specific provisions for contaminants and hygiene in formulated meal replacements and formulated supplementary foods.

8. Conclusions

The Authority proposes a joint standard for formulated meal replacements and supplementary foods that:

- combines the current standards for formula dietary foods and supplementary foods into one standard - *Formulated meal replacements and formulated supplementary foods*;
- includes specific definitions and prescribed names for formulated meal replacements and formulated supplementary foods;
- substitutes ingredient-based criteria with macronutrient criteria related to energy and protein content but not fat or dietary fibre content, for meal replacements and supplementary foods;
- prescribes compositional parameters in relation to manufacturers' serve sizes;
- for meal replacements, prescribes vitamin and mineral composition to:
  - set a minimum vitamin and mineral content of 25% RDI/one-meal serve for the 16 vitamins and minerals currently permitted to be added;
  - permit the voluntary addition of selenium, biotin, pantothenic acid, vitamin K, chromium, molybdenum, manganese and copper
  - set a maximum claim of 25% or lower RDI or ESADDI/one-meal serve for selenium, biotin, pantothenic acid, chromium, molybdenum, manganese and copper; 40% RDI/one-meal serve for vitamins A and D, and iron and zinc; and 50% RDI/one-meal serve for all other permitted vitamins and minerals;
  - set maximum amounts/ one-meal serve equivalent to the maximum claim for vitamins A and D, and for iodine, selenium, chromium, molybdenum, manganese and copper;
- for supplementary foods, prescribes vitamin and mineral composition to:
  - decrease the number of vitamins and minerals from 5 to 1 that are required to meet a minimum content, and increase that minimum content from 10% to 20% RDI/serve of the final food;
  - extend the permission for voluntary addition of vitamins and minerals to include vitamins B6, B12, E and folate; and magnesium, iodine and zinc;
  - set a maximum claim of 25% RDI/ serve of the final food for vitamins A and D, and iron, magnesium and zinc; and 50% RDI/ serve of the final food for all other permitted vitamins and minerals
  - set maximum amounts/ serve of the final food equivalent to the maximum claim for vitamins A and D, and iodine;
- permits all food additives currently permitted in formula dietary foods and supplementary foods by both the AFSC and the NZFR to be in formulated meal replacements and formulated supplementary foods with the addition of intense sweeteners, except for cyclamate and saccharin;
- requires an advisory statement on meal replacements to the effect that meal replacements are not to be consumed as total diet replacements;
- permits nutrient claims, included within a Nutrition Information Panel, to be made on meal replacements and supplementary foods providing the food contains a minimum of 10% RDI or ESADDI as appropriate/ serve;
- removes the current prohibition on declaration of nutrient claims on supplementary foods; and

- requires the purpose for which each supplementary food is intended to be stated on the label.

In the joint FSC for formulated meal replacements and formulated supplementary foods the Authority proposes not to :

- require protein quality criteria;
- require a mandatory Nutrition Information Panel;
- prescribe compositional parameters in relation to reference quantities;
- require a warning statement on meal replacements that if used as a total diet replacement the food should be used only under medical supervision;
- require ingredient composition criteria for supplementary foods; and
- require the label of meal replacements and supplementary foods to provide directions for preparation use and recommended frequency of use.

The following issues will be assessed in other Authority review projects:

- the review of standards for health claims (Proposal P153) will assess the need for regulations on slimming claims;
- the general review of food additives (P150) will adopt the recommendations for additive permissions in formulated meal replacements and formulated supplementary foods;
- the reviews of maximum permitted concentrations of metals and non-metals in food (P157 and P158) will consider those contaminants in commodity products used in the preparation of formulated meal replacements and formulated supplementary foods where there are public health and safety implications;
- the review of directions for use (P165) will address the public health and safety issues relating to directions for use in these products; and
- the review of Non Alcoholic Beverages will determine appropriate regulation of some electrolyte drinks, other electrolyte drinks will be addressed in any review of Sports Foods (Standard R10).

Appendix One:

STANDARD R4

FORMULA DIETARY FOODS

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(1) A formula dietary food is a food that is described in the label on or attached to a package containing that food as being suitable as a meal replacement when consumed in accordance with the directions contained in that label.

(2) A formula dietary food -

(a) shall contain, in the quantity stated in the label as the quantity to be consumed in one day, not less than the daily allowance of each vitamin and mineral specified in the Schedule to Standard A9;

(b) may contain -

(i) any of the modifying agents specified in Standard A10;
(ii) added vitamins and minerals in accordance with Standard A9.

(3) There shall be written in the label on or attached to a package containing formula dietary food -

(a) the words -

'FORMULA DIETARY FOOD'

immediately followed by the statement, in standard type of 3 mm -

'NOT TO BE USED AS THE PRINCIPAL OR ONLY SOURCE OF DIET EXCEPT UNDER MEDICAL DIRECTION';

(b) in standard type -

(i) a statement of the quantity of the food to be consumed in one day;
(ii) a statement of the energy yield, expressed in kilojoules, of that quantity of the food;
(iii) the proportions of protein, fat and carbohydrate in the food.

(4) The statements referred to in subparagraphs (3)(b)(ii) and (iii) are not required if the label includes a nutrition information panel.

Appendix Two:

STANDARD R9

SUPPLEMENTARY FOODS

PART 1

DEFINITIONS

Interpretation

1. In this Standard:

'supplementary food' means a food specifically designed as a supplement to a normal diet to address situations when intakes of energy or nutrients may not be adequate to meet an individual's requirements;

'electrolyte drink base' means a solid or liquid which, when mixed with water, produces an electrolyte drink;

'electrolyte drink' means a supplementary food, consisting of water together with those substances required or permitted by Part 3 of this Standard, which is described in the label on or attached to a package containing that food as suitable for the replacement of fluid, carbohydrate and electrolytes when used in relation to sustained strenuous exercise;

'supplemented drink base' means a supplementary food -

(a) containing not less than 51% milk powder or skim milk powder; or

(b) intended to be consumed with milk and containing not less than 25% of solids derived from cereals;

'supplemented drink' means a supplementary food which is a ready-to-drink liquid made either from a supplemented drink base or from the components of a supplemented drink base;

'reference quantity' means -

(a) in relation to a supplemented drink base, that quantity which, when made up according to directions in the label, yields 200 mL;

(b) in relation to a supplemented drink, 200 mL;

(c) in relation to an electrolyte drink, 100 mL;

(d) in relation to an electrolyte drink base, that quantity which, when made up with water according to directions in the label, yields 100 mL;

'recommended dietary intake' means that quantity specified in column 3 of the Schedule to Standard A9 in relation to a vitamin or mineral specified in column 1 of that Schedule;

'average quantity' has the meaning assigned to it in clause A1(13).

PART 2

SUPPLEMENTED DRINK BASES AND SUPPLEMENTED DRINKS

Composition

2. A supplemented drink base or a supplemented drink must contain in the reference quantity at least one tenth of the recommended dietary intake of five or more of the substances listed in column 2 of the Schedule to this Standard.

Ingredients

3. A supplemented drink base or a supplemented drink may contain:

(a) other foods
(b) colourings
(c) flavourings
(d) modifying agents specified in Groups I, II, III and IV of Table 1 of Standard A10
(e) substances specified in column 2 of the Schedule to this Standard.

Restriction on vitamins A and D

4. A supplemented drink base or a supplemented drink must not contain in the reference quantity vitamin A or vitamin D in greater proportion than that specified in column 4 of the Schedule in relation thereto.

Labelling

5. (1) The label on or attached to a package containing a supplemented drink base or a supplemented drink must include:

(a) a statement in the form of a nutrition information panel in accordance with clause (13) of Standard A1 as if the label contained a nutrition claim;

(b) a statement containing the following information:

(i) the average quantity in a serving of the food, expressed in micrograms or milligrams as the case requires, of those substances required to be present in the food by clause 2; and

(ii) the proportion of the recommended dietary intake of each substance referred to in subparagraph (i) contributed by one serving of the food.

(2) The statement referred to in paragraph (1)(b) must immediately follow or form part of the nutrition information panel.

(3) The statement required by paragraph (1)(b) may include a reference to vitamins and minerals other than those referred to in subparagraph (i) of paragraph (b) provided:

(a) the vitamin or mineral is specified in the Schedule of Standard A9; and

(b) a reference quantity of the food contains not less than one tenth of the recommended dietary intake of that vitamin or mineral.

(4) The label on or attached to a package containing a supplemented drink base or a supplemented drink may include, in a description of the role of the food as a supplement to a normal diet, a reference to the presence in the food of any vitamin or mineral provided:

(a) the vitamin or mineral is specified in the Schedule of Standard A9; and

(b) a reference quantity of the food contains not less than one tenth of the recommended dietary intake of that vitamin or mineral.

Prohibited claims

6. (1) Subject to clause 5 of this Standard, a claim must not be made in the label on or attached to a package containing a food standardised in this Part of this Standard, or in an advertisement for such a food, as to the presence in the food of a vitamin or mineral.

(2) For the purposes of this Part of this Standard, the inclusion of vitamins or minerals in a statement of ingredients required by clause (5) of Standard A1 is not a claim.

(3) The statements required by subclause 5(1) must not represent a supplemented drink base or supplemented drink to contain a vitamin or mineral in greater proportion than that specified in column 3 of the Schedule to this Standard.

(4) Claims or pictorial representations that indicate that a food standardised in this Part of this Standard enhances performance are prohibited.

Exemption

7. *deleted*.

PART 3

ELECTROLYTE DRINK BASES AND ELECTROLYTE DRINKS

Composition

8. (1) An electrolyte drink, or an electrolyte drink base when made up according to directions, must contain -

(a) not less than 50 g/L and not more than 100 g/L of glucose syrup, dextrose, fructose, sucrose or maltodextrin, or any combination thereof, provided that the total fructose present is not more than 50 g/L;

(b) not less than 10 mmol/L and not more than 25 mmol/L of sodium.

(2) An electrolyte drink or an electrolyte drink base may contain -

(a) potassium chloride
(b) sodium chloride
(c) magnesium sulphate
(d) calcium chloride
(e) modifying agents specified in Group III of Table 1 to Standard A10
(f) artificial sweetening substances in accordance with Standard A8
(f•) antioxidants in accordance with Standard A7
(g) colourings
(h) flavourings.

(3) An electrolyte drink, or an electrolyte drink base when made up according to directions, must not contain more than -

(a) 6 mmol/L of potassium
(b) 2 mmol/L of magnesium
(c) 2 mmol/L of calcium.

(4) An electrolyte drink base may contain silicon dioxide.

(5) An electrolyte drink may be carbonated.

(6) An electrolyte drink or an electrolyte drink base when made up according to directions may contain not more than 120 mg/kg of sucrose acetate isobutyrate.

(7) An electrolyte drink may have added to it not more than 250 mg/kg of dimethyl dicarbonate.

Labelling

9. (1) The label on or attached to a package containing an electrolyte drink base must include specific directions for mixing with water to produce an electrolyte drink which complies with this Standard.

(2) The label on or attached to a package containing an electrolyte drink or an electrolyte drink base must include a statement, in standard type, of a typical analysis of a reference quantity of the electrolyte drink or, as the case may be, the electrolyte drink base, in relation to:

(a) average energy value
(b) total carbohydrate and each type of sugar or related product present
(c) milligrams and millimoles of sodium ions
(d) milligrams and millimoles of potassium ions
(e) milligrams and millimoles of magnesium ions.

(3) The label on or attached to a package containing an electrolyte drink or an electrolyte drink base must include -

(a) advice on the role of the product in conjunction with an adequate and balanced diet;
(b) advice that the product is most useful during and after strenuous sustained exercise;
(c) advice on the volume and frequency of intake of the product during and after the period of exercise;
(d) advice that the level of sodium may not be adequate for all exercise regimes;
(e) a statement that the product is designed to promote the availability of energy and to prevent or treat mild dehydration that may occur as the result of sustained strenuous exercise.

(4) 'Electrolyte drink' and 'electrolyte drink base' are not prescribed names, but the appropriate designation of an electrolyte drink or an electrolyte drink base must include the word 'ELECTROLYTE'.

Claims

10. (1) The label on or attached to a package containing an electrolyte drink or an electrolyte drink base may include the following statement -

'Appropriate usage may assist in the performance of sustained, strenuous exercise'.

(2) Subject to subclause (1), claims or pictorial representations that indicate that a food standardised in this Part enhances performance are prohibited.

SCHEDULE

Column 1 Food	Column 2 Substances	Column 3 Maximum permitted claim for substance in column 2 per reference quantity	Column 4 Maximum permitted level of vitamin A and vitamin D per reference quantity
Supplemented drink base and supplemented drink	vitamin A thiamin riboflavin niacin vitamin C vitamin D calcium phosphorus iron	200 mg *(27% RDI)* 0.4 mg *(44% RDI)* 0.8 mg *(47% RDI)* 3.5 mg *(35% RDI)* 15 mg *(38% RDI)* 2.6 mg 250 mg *(31% RDI)* 200 mg *(20% RDI)* 5.0 mg *(42 % RDI)*	250 mg 3.0 mg

Note Data in italics added in to indicate current percentages of RDI

Appendix Three:

New Zealand *Food Regulations 1984*

Special Purpose Foods

237. Special purpose foods

(1) Special purpose foods shall be foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of -

(a) A particular physical or physiological condition; or

(b) A specific disease or disorder; or

(c) Both such a condition and a disease or disorder, - and are presented as such.

(2) The composition of special purpose foods shall differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

(3) Special purpose foods shall include the following:

(a) Foods with modified composition:

(i) Low sodium foods and salt substitutes:
(ii) Gluten-free foods:
(iii) Amino acid modified foods:
(iv) Carbohydrate modified foods:
(v) Low energy and reduced energy foods:

(b) Foods that meet the special physiological needs of infants and young children:

(i) Infant formula:
(ii) Supplementary foods for infants and young children:

(c) Meal replacements:

(i) Meal replacements for weight reduction diets:

(ii) Complete meal replacements other than for weight reduction.

(4) For the purposes of these regulations, an infant shall be a person not more than 12 months of age, and young children shall be persons from the age of 12 months up to the age of 3 years.

(5) Special purpose foods shall be prepared from wholesome foodstuffs, and may contain salt.

(6) Special purpose foods with modified composition, other than salt substitutes, shall comply with the compositional standard set for the normal counterpart, except for the changes necessary to comply with the particular special purpose food standard.

(7) Special purpose foods for which no standard is prescribed in this Part of these regulations may contain, where appropriate, the following food additives:

(a) Any food conditioner [EMULSIFIERS, ANTI-FOAMING AGENTS, STABILISERS, THICKENERS, MODIFIED STARCHES, GELLING AGENTS, ACIDITY REGULATORS, ENZYMES, HUMECTANTS] specified in regulation 253(2) of these regulations:

(b) Any anticaking agent specified in regulation 254(2) of these regulations:

(c)[9] Permitted flavouring substances:

(ca)[9] Spices:

(d) Any colouring substance specified in the table to regulation 250(2) of these regulations:

(e) Any propellant specified in regulation 255(2) of these regulations:

(f) Any preservative specified in the table to subclause (7) of regulation 248 of these regulations in relation to special purpose foods for which no standard is prescribed in this Part of these regulations, in a proportion not exceeding the maximum permitted by that regulation:

(g) Vitamins and minerals.

(8) The label on each package of special purpose food, other than salt substitutes, amino acid modified food, infant formula, and supplementary foods for infants and young children, shall bear a statement of -

(a) The proportion of protein, fat, and carbohydrate in the food; and

(b) The energy content of the food.

(9) The particulars required by subclause (8) of this regulation shall be declared in accordance with the provisions of regulation 13A of these regulations.

(10) to (12) *{REVOKED}*[5]

(13) No label on a package of a food, except a special purpose food, shall bear the words "special purpose food", or words of similar meaning (such as, food for a specific dietary use).

(14) Every label used in connection with a special purpose food shall state the special purpose of the food.

(15) No food shall be described, expressly or by implication, as a special purpose food unless the food complies with the requirements of these regulations.

(16) No label on a package of any special purpose food, except an amino acid modified food, shall contain the name of any disease, disorder, or physiological condition in association with the name of the food.

(17) No label on a package of any special purpose food shall include, in the principal display panel, the word "health", or words of similar meaning, or any word of which "health" forms a part, except as part of the trading name in the statement required by regulation 4(1)(c) of these regulations.

(18)[9] Where a standard exists for the normal counterpart of a special purpose food with modified composition, and that standard contains a particular flavouring provision regarding the labelling of flavour in that food, then that labelling provision shall also apply to the special purpose food. If there are no specific labelling requirements, then the provisions of regulation 252F of these regulations shall apply.

PART III FOOD NOT ELSEWHERE STANDARDISED

244. Food not elsewhere standardised
[9]

(1) In this Part of these regulations, 'a food not elsewhere standardised' means a food for which a standard has not been prescribed in Part II of these regulations, and that is prepared, manufactured, or processed wholly or in part from 2 or more wholesome foodstuffs.

(2) Except as specifically permitted by these regulations, a food not elsewhere standardised shall not have added to it any food additive.

(3) A food not elsewhere standardised may contain any of the following:

(a) Any colouring substance specified in the table to regulation 250(2) of these regulations:

(b) Permitted flavouring substances:

(c) Spices:

(d) Any food conditioner specified in regulation 253(2) of these regulations: [EMULSIFIERS, ANTI-FOAMING AGENTS, STABILISERS, THICKENERS, MODIFIED STARCHES, GELLING AGENTS, ACIDITY REGULATORS, ENZYMES, HUMECTANTS]

(e) Any anticaking agent specified in regulation 254(2) of these regulations:

(f) Any propellant specified in regulation 255(2) of these regulations.

(4) A food not elsewhere standardised may contain salt.

(5) A protein product that is an analogue for a food such as a meat or a particular meat product, fish or a particular fish product, milk or a particular milk product, or eggs or a particular egg product, may contain added vitamins, minerals, and amino acids so that such nutrients are present in the protein product at levels typical of the product of which it is an analogue.

(6) Soybean curd or tofu may also contain calcium sulphate and magnesium chloride.

Regulation 2: Interpretation

"Meal replacement for weight maintenance or weight reduction diet" means a single food, or pre-packed selection of foods, that is sold as a replacement for one or more daily meals and is represented for use in a weight reduction diet or weight maintenance diet.

"Medical nutritional product" means a complete meal replacement other than weight reduction that is the form of a powder or liquid, and that is suitable for administering via a feeding tube, or for administering orally, and that is capable of providing the sole source of nutrition.

Regulation 20A

Permitted Addition of Vitamins and Minerals

Food	Reference Quantity	Vitamins and Minerals	Maximum claim per reference quantity	Maximum permitted level of vitamin or mineral per reference quantity
food drinks and food drink bases (regulation 244)	200 ml ready to drink or the amount of base that, when prepared according to the directions, yields 200 ml ready to drink.	vitamin A thiamin riboflavin niacin vitamin C vitamin D iron calcium phosphorus	200 mcg (25%) 0.4 mg (35%) 0.8 mg (45%) 3.5 mg (35%) 15 mg (40%) 2.6 mcg (25%) 5 mg (40%) 250 mg (30%) 200mg (20%)	250 mcg 3.0 mcg

Appendix Four:

Comparison of permitted vitamins and minerals in Standards R4, R9, R10

Vitamins & Minerals	**R9 part 4** Maximum Claimed Amount Per Reference Quantity	**R9 part 4** Maximum Amount Per Reference Quantity	**R4** Maximum Claim Per Reference Quantity (proportion RDI)*	**R4** Maximum Permitted Level of Vitamin or Mineral per Reference Quantity	**R10** Maximum claimed amount per one day	**R10** Maximum amount per one day quantity
Reference Quantity	**200 mL**	**200 mL**	**Amount recommended to replace one meal**	**Amount recommended to replace one meal**	**(per day)**	**(per day)**
vitamin A	200 µg	250 µg	375 µg (50%)	375 µg	375 ug	375 ug
thiamin	0.4 mg		0.55 mg (50%)		2.2 mg	NS
riboflavin	0.8 mg		0.85 mg (50%)		3.4 mg	NS
niacin	3.5mg		9.5 mg (95%)		20 mg	NS
vitamin B_6			0.8 mg (50%)		3.2 mg	NS
vitamin B_{12}			1.0 µg (50%)		4.0 µg	NS
vitamin C	15 mg		20 mg (50%)		80 mg	NS
vitamin D	2.6 µg	3 µg	2.5 µg (25%)	2.5 µg	2.5 µg chole-calciferol	2.5 µg chole-calciferol
vitamin E			5.0 mg (50%)		20 mg	NS
folate			100 µg (50%)		400 µg	NS
vitamin K						NS
biotin					50 µg	NS
pantothenic acid					3.5mg	NS
calcium	250 mg		400 mg (50%)		1600 mg	NS
chloride						NS
chromium					100 ug	
- inorganic forms					50 ug	
- organic forms						
copper					1.5 mg	
- inorganic forms					750 ug	
- organic forms						
iodine			75 µg (50%)	75 µg	75 µg	2000 µg
iron	5 mg		6.0 mg (50%)		12 mg	NS
magnesium			160 mg (50%)		640 mg	NS
manganese					2.5 mg	
- inorganic forms					1.25 mg	
- organic forms						
molybdenum					125 ug	
- inorganic forms					62.5 ug	
- organic forms						
phosphorus			500 mg (50%)		1000 mg	NS
potassium						90 mmol
sodium						70 mmol
selenium						
- inorganic forms					52 µg	52 µg
- organic forms					26 µg	26 µg

zinc			6.0 mg (50%)		12 mg	NS

Appendix Five:

Nutrient Risk Profile and Dietary Modelling

Note: more comprehensive dietary modelling will be undertaken at Inquiry if required, once the nutrient module in the DIAMOND computer modelling system is fully operational.

Meal Replacements

Pantothenic Acid
The United States have established Dietary Reference Intakes for pantothenic acid (5 mg/d). It is estimated that 10 - 20 mg/day may lead to diarrhoea and water retention.

Current intakes in New Zealand show a mean intake of 4.7 mg/day with the highest intakes in the 75th percentile of young men at 7.7 mg/day. These intakes include the consumption of meal replacement products that are allowed to contain pantothenic acid.

The allowance for pantothenic acid within the standard for formulated sports foods is 3.5 mg as a maximum permitted claimed amount per reference quantity. This has been set at 0.5 x ESADDI.

It is proposed that Meal Replacement products be allowed to claim a maximum amount of pantothenic acid at a similar level to sports foods of 0.5 x ESADDI/day. This equates to a third of this value per serve where a serve is one meal (ie 0.17 x ESADDI/serve). The ESADDIs are attached in Appendix Eight.

Biotin
The United States have established Dietary Reference Intakes for biotin (30 ug/d). There have been no reports of adverse health effects at dietary intakes up to 10 mg /day.

The current mean intake of biotin in the New Zealand diet is 33 ug/day with a maximum intake in young adults where the 75th percentile intake is 62 ug/day. These figures include the consumption of meal replacement products that are allowed to add biotin.

The maximum claimed amount within Standard R10 has been set at 50 ug/day (0.5 x ESADDI).

It is proposed that Meal Replacement products be allowed to make a maximum claim for biotin at a similar level to sports foods of 0.5 x ESADDI/day. This equates to a third of this value per serve where a serve is one meal (ie 0.17 x ESADDI/serve). The ESADDIs are given in Appendix Eight.

Chromium

In the development of the United Kingdoms Dietary Reference Value it was noted that no adverse effects have been noted from Cr III but intakes of 1 -2 g/day of the hexavalent form can cause renal and hepatic necrosis (COMA 1991).

An assessment on safe and adequate daily dietary amounts of vitamins and minerals was conducted during the assessment of Standard R10 figures for chromium of a recommended safe upper intake of 250 ug (WHO 1996) were set. In setting the maximum amount of chromium allowed to be used in Formulated Sports Foods, 0.5 x ESADDI/day has been set for inorganic forms and 0.25 x ESADDI for organic forms.

It is proposed that Meal Replacement products be allowed contain a maximum amount of chromium at a similar level to sports foods. This equates to a third of these values per serve where a serve is one meal (ie 0.17 x ESADDI/serve for inorganic chromium and .08 x ESADDI/serve for organic chromium). The ESADDIs are attached in Appendix Eight.

Molybdenum
In the development of the United Kingdom Dietary Reference Value there was no Recommended Nutrient Intake (RNI) set for molybdenum but safe intakes were believed to be 50 - 400 ug/day for adults (COMA 1991).

Standard R10 sets figures for molybdenum of 125 µg (inorganic forms) and 62.5 µg (organic forms) as the maximum claimed amount per reference quantity. Intakes of 0.54 mg/day can increase copper excretion.

Other nutrients allowed within Codex and the EC/UK but not in the AFSC include copper, potassium, sodium, manganese and selenium. There are Australian Recommended Dietary Intakes (RDI) for potassium (1950 - 5460 mg/d ie 50 - 140 mmol/day), sodium (920 - 2300 mg/d, ie 40 - 100 mmol/day) and selenium (70 -85 ug/d) but not for copper and manganese.

An assessment of safe and adequate daily dietary amounts of vitamins and minerals was conducted during assessment of Standard R10 and figures for molybdenum of a recommended safe upper intake of 250 ug (WHO 1996) were set. In setting the maximum amount of molybdenum allowed to be used in Formulated Sports Foods, 0.5 x ESADDI/day has been set for inorganic forms and 0.25 x ESADDI for organic forms.

It is proposed that Meal Replacement products be allowed contain a maximum amount of molybdenum at a similar level to sports foods. This equates to a third of these values per serve where a serve is one meal (ie 0.17 x ESADDI/serve for inorganic chromium and .08 x ESADDI/serve for organic chromium). The ESADDIs are attached in Appendix Eight.

Copper
The UK have established a RNI for copper at 1.2 mg/day but no Dietary Reference Value due to lack of data. Copper adverse health effects in humans is rare and has been most often associated with contaminated water (COMA 1991).

Copper is permitted to be added to formulated sports foods within Standard R10. Copper has been allowed at levels of 1.5 mg (inorganic forms) and 750 ug (organic forms) per reference quantity (one day). High copper intakes can interfere with iron and zinc metabolism.

In setting the maximum amount of copper allowed to be used in Formulated Sports Foods, 0.5 x ESADDI/day has been set for inorganic forms and 0.25 x ESADDI for organic forms.

It is proposed that Meal Replacement products be allowed contain a maximum amount of copper at a similar level to sports foods. This equates to a third of these values per serve where a serve is one meal (ie 0.17 x ESADDI/serve for inorganic chromium and .08 x ESADDI/serve for organic chromium). The ESADDIs are attached in Appendix Eight.

Potassium and Sodium
The AFSC does not specifically regulate for the addition of sodium and potassium to foods. The NZFR allows for both of these minerals to be added to meal replacements but does not prescribe minimum or maximum levels. The overall effect of both approaches is essentially the same. Codex however require minimum amounts of both sodium and potassium in meal replacements.

Intake of potassium from diet does not usually exceed 134 mmol/day (5200 mg/day)

Codex require a minimum amount of potassium of 1600 mg/day (40 mmol) ie 500 mg/serve (13 mmol). Standard R10 allows a maximum daily intake of 95 mmol (3700 mg) of potassium.

Codex have set minimum intakes of sodium at 1.0 g/day (ie 333 mg/serve). One third of the Australian RDI would provide for a minimum intake of sodium per serve of 300-760 mg/serve. Standard R10 allows a maximum amount per day of 70 mmol (1600 mg of sodium).

Manganese
There are no RDIs, or RNIs for manganese although safe intakes have been recommended in the UK at 1.4 mg/day. Manganese is one of the least toxic of all elements (COMA 1991).

Manganese is allowed to be added to formulated sports food within Standard R10 to a maximum claimed amount per day of 2.5 mg (inorganic forms) and 1.25 mg (organic forms). No human deficiencies of manganese have been observed.

In setting the maximum amount of manganese allowed to be used in Formulated Sports Foods, 0.5 x ESADDI/day has been set for inorganic forms and 0.25 x ESADDI for organic forms.

It is proposed that Meal Replacement products be allowed contain a maximum amount of manganese at a similar level to sports foods. This equates to a third of these values

per serve where a serve is one meal (ie 0.17 x ESADDI/serve for inorganic chromium and .08 x ESADDI/serve for organic chromium). The ESADDIs are attached in Appendix Eight.

Vitamin D
Vitamin D can be toxic in all individuals if consumed in pharmacological doses. It is proposed that permissions for vitamin D remain at the current levels and in accordance with the provisions for general foods as specified in Standard A9.

Selenium
Standard R10 allows selenium addition to a maximum claimable amount and a maximum addition per day of 52 ug (inorganic forms) and 26 ug (organic forms). Selenium is essential in the enzyme glutathione peroxidase which destroys lipid peroxide. There is a growing interest in the protective role of selenium in heart disease and cancer and in its role in the immune system. The Australian RDI for selenium has been set at 70 -85 ug/day. The margins between requirement and toxic effects is quite narrow. Chronic adverse health effects has been identified at levels of 1000- 2000 ug/d but recommendations for an upper limit are at 200 ug/d.

Supplementary Foods

Vitamin B6
The current Australian RDIs for vitamin B6 ranges from 0.9 - 1.9 mg/day with a recommendation that upper levels should not be more than 10 mg/day on a regular basis in normal individuals.

The current mean intake of vitamin B6 in New Zealand is 1.4 mg/day. There are no data on Australian intakes of vitamin B6.

Dietary modelling on the potential intakes of vitamin B6 from a fortified food supply in the New Zealand population show the highest potential intakes are among young males with the 90th percentile intake being 6.3 mg/day. This is a worst case scenario and is well below the level of 10 mg/day. Allowing for the addition of vitamin B6 to supplementary foods would not appear to result in consumption levels of vitamin B6 that could be considered in any way a danger to health.

Dietary modelling on the potential intakes of vitamins and minerals for Australians from supplementary foods is attached in Tables A(i), A(ii) and B at the end of this appendix. As there are no intake data for vitamin B6 an assumption has been made and a consumption figure of 1.8 ug/day (1 x RDI) used.
With the addition of three serves of a supplementary food a maximum intake of vitamin B6 is estimated at 4.5 mg/day. At this level there does not appear to be any public health and safety concerns.

Vitamin B12
The current Australian RDI for vitamin B12 is 2 ug/day. There does not appear to be a concern with adverse health effects of vitamin B12 at up to levels of 20 times the recommended intakes.

The current mean intakes of vitamin B12 in New Zealand is 4.9 ug/day. There are no national data on vitamin B12 intakes.

Dietary modelling undertaken on the potential intakes of vitamin B12 from a fortified food supply in New Zealand show the highest potential consumption among young males with levels of 12.9 ug/day for the 90th percentile. These potential levels of intake do not appear to be of concern.

Dietary modelling on the potential intakes of vitamins and minerals for Australians from supplementary foods is attached in Tables A(i), A(ii) and B at the end of this appendix. As there are no intake data for vitamin B12 an assumption has been made and a consumption figure of 2 ug/day (1 x RDI) used. With the addition of three serves of a supplementary food a maximum intake of vitamin B12 is estimated at 5 ug/day. At this level there does not appear to be any public health and safety concerns.

Vitamin E

The current Australian RDI for vitamin E is 7 -10 mg alpha-Tocopherol Equivalents (TE)/day. From adverse health effects data, little evidence exists for adverse effects at daily intakes up to 200mg alpha-TE.

The current mean intake of vitamin E in New Zealand is 8 mg alpha-TE/day. Dietary modelling undertaken on the potential intakes of vitamin E from fortified foods in New Zealand show potential intakes among young males of 24.5 mg alpha -TE for the 90th percentile. These levels are well below levels of concern and it appears there is no public health and safety concern with increase the provisions for fortification with vitamin E within supplementary foods.

Dietary modelling on the potential intakes of vitamins and minerals for Australians from supplementary foods is attached in Tables A(i), A(ii) and B at the end of this appendix. As there are no intake data for vitamin E an assumption has been made and a consumption figure of 10 mg/day (1 x RDI) used. With the addition of three serves of a supplementary food a maximum intake of vitamin E is estimated at 25 mg alpha-TE/day. At this level there does not appear to be any public health and safety concerns.

Folate

The current Australian RDI for folate is 200 ug/day. Maximum levels have been set at 1000 ug/day although this level is not associated with any toxic side effects. Dietary modelling undertaken on the potential intakes of folate should supplementary foods be permitted to add folate indicate that even at levels of fortification with folate to supplementary foods of 50% RDI and high consumption of supplementary foods as well as consumption of some fortified cereals and fruit juice, the highest consumers (young men) would have intakes of approximately 845 ug/day in New Zealand and of up to 1000 ug/day in Australia.
As this is seen as a worst case scenario and is still considered to be appropriate daily intake there appears to be no public health and safety concern regarding increasing the

fortification of supplementary foods to include folate. Supplementary foods may be an appropriate vehicle to increase folate consumption in some groups.

Zinc
The current Australian RDI for zinc is 12 mg/day. Levels of 50 mg per day may compromise copper status. Daily intakes approaching 150 mg may cause nausea and intakes over 500 mg/day are potentially toxic.

Dietary modelling on the potential intakes of zinc from fortified foods in New Zealand show maximum intakes of 33.6 mg/day amongst the highest consumers. This being the 90th percentile value for young males. These potential intakes not impose a risk for the public and may be of benefit to those with marginal zinc intakes.

Dietary modelling on the potential intakes of zinc for Australians should supplementary foods be permitted to fortify with zinc at 25% x RDI show the highest potential zinc intakes to be children at 2.3 x RDI (12.5 mg). Young adults, who are the highest consumers of supplementary foods have intakes of zinc at 2 x RDI (26 mg)/day.

The modelling has assumed that three full serves will be consumed each day . For young children, only one percent of the population consumed 3 serves of a supplemented food in a day. At this age it is also questionable as to whether a full serve would be consumed. Most dry powders recommend a serve as 15 - 20 g or 200 - 250 mL of made up product. The original nutrient intake data used in the modelling already included the nutrients provided from supplementary foods. Hence the modelling has overestimated nutrient intakes.

Current mean intakes of zinc for Australian adults range from 9.7 - 14.4 mg/day and the mean intake in New Zealand is 11 mg/day.

Iodine
Levels of iodine associated with adverse health effects have been set at 2000 ug/day. The current RDI for iodine is 120 ug/day for women and 150 ug/day for men. Current intakes of iodine in Australia and New Zealand are not available due to limited food composition data. New Zealand has a history of low iodine intakes and it is believed that the potential for high iodine intakes from diet is very unlikely. The only population groups likely to have higher iodine intakes are those consuming dietary supplements or kelp products. Permissions for iodine within the sports food standard are at a maximum amount per reference quantity of 75 ug (0.5 x RDI).

Supplementary foods have adopted the same maximum amount of iodine per serve at 50% x RDI.

Magnesium

The RDI for magnesium is 270mg /day for females and 320 mg/day for males. There are no reports of adverse health effects from magnesium when consumed from dietary sources.

Based on dietary modelling of potential intakes of magnesium from the consumption of fortified foods in New Zealand the highest potential intakes were for young men at 1139 mg/day.

Dietary modelling on potential intakes of magnesium in Australia from supplementary drinks at 25% x RDI (see Tables A(i), A(ii) and B) show that the high consumers, young adults, have potential intakes of 1.6 x RDI (499 mg/day). The modelling for young children shows intakes of up to 3 x RDI/day (at 345 mg).
For the reasons stated above under zinc, these figures are likely to be significantly overestimated.

Current mean intakes of magnesium for Australian adults range from 280 - 380 mg/day and the mean intake in New Zealand is 329 mg/day.

Nutrients Currently Permitted in Supplementary Foods

Dietary modelling on nutrients currently permitted in supplementary foods has been carried out using data from the (Australian) 1995 National Nutrition Survey. The modelling has been undertaken to take account of any proposed changes to permitted levels of the nutrients (see Tables A(i), A(ii) and B).

Vitamin A
Vitamin A is already permitted to be added to supplementary foods at levels of 0.3 x RDI/serve. The Authority is proposing to permit 0.25 x RDI/serve.

Thiamin
Thiamin is already permitted to be added to supplementary foods at levels of 0.45 x RDI/serve. The Authority is proposing to increase this permission to levels of 0.5 x RDI/serve.

Riboflavin
Riboflavin is already permitted to be added to supplementary foods at levels of 0.6 x RDI/serve. The Authority is proposing to reduce this permission to levels of 0.5 x RDI/serve and has therefore not provided modelling on riboflavin.

Niacin
Niacin is already permitted to be added to supplementary foods at levels of 0.25 x RDI/serve. The Authority is proposing to increase this permission to levels of 0.5 x RDI/serve.

Dietary modelling on Australian nutrient intake data shows that potential intakes of niacin from three serves of supplementary foods/day are highest for young children at 2.7 x RDI/serve (27.8 mg) and adults at 3 x RDI/serve (65 mg). There does not appear to be any public health concern at these levels.

Vitamin C
Vitamin C is already permitted to be added to supplementary foods at levels of 0.4 x RDI/serve. The Authority is proposing to increase this permission to levels of 0.5 x RDI/serve.

Dietary modelling on Australian nutrient intake data shows that potential intakes of vitamin C from three serves of supplementary foods/day with the increased permitted levels are highest for young adults at 4.4 x RDI (133 mg/day). There are no public health and safety concerns at these levels of vitamin C.

Calcium
Calcium is already permitted to be added to supplementary foods at levels of 0.3 x RDI/serve. The Authority is proposing to increase this permission to levels of 0.5 x RDI/serve.

Dietary modelling on Australian nutrient intake data shows that potential intakes of calcium from three serves of supplementary foods/day with the increased permitted levels are highest for young children and adults at 2 and 2.6 x RDI/serve (1392 mg and 2145 mg respectively). These levels would be advantageous for most consumers and pose no public health and safety risk.

Phosphorus
Phosphorus is already permitted to be added to supplementary foods at levels of 0.2 x RDI/serve. The Authority is proposing to increase this permission to levels of 0.5 x RDI/serve.

Dietary modelling on Australian nutrient intake data shows that potential intakes of phosphorus from three serves of supplementary foods/day with the increased permitted levels are highest for young children at 3 x RDI /day (1467 mg). There are no public health and safety concerns at these proposed levels.

Iron
Iron is already permitted to be added to supplementary foods at levels of 30% RDI/serve. The Authority is proposing to reduce this level to 25% RDI/serve.

Dietary modelling on Australian nutrient intake data shows that potential intakes of iron from three serves of supplementary foods/day are highest for children aged 8 - 11 years at 2.2 x RDI/day (17.5 mg/day). These levels however are not considered excessive or a public health and safety risk and the extra iron may be advantageous to a number in this group.

References:

Australian Bureau of Statistics and the Commonwealth Department of Health and Family Services. 1997. *National Nutrition Survey Selected Highlights Australia 1995.* Australian Bureau of Statistics: Canberra.

Department of Health (UK). 1991. *Dietary Reference Values for Food Energy and Nutrients for the United Kingdom: Report of the Panel on Dietary Reference Values of the Committee on Medical Aspects of Food Policy.* London: HMSO.

Life in New Zealand Activity and Health Research Unit. 1995. *Nutrient Analysis of Selected Fortified Products: Technical Report 31.* University of Otago: Dunedin.

Truswell et al. 1990. *Recommended Nutrient Intakes : Australian Papers.* Australian Professional Publications: Sydney.

World Health Organization. 1996.

Appendix Five (cont):

Dietary Modelling

Dietary modelling of potential nutrient intakes from diets of male high consumers of supplementary foods was undertaken using the recent food and nutrient intakes reported in the (Australian) 1995 National Nutrition Survey (NNS). Data from the Survey indicated that 96% of those consuming supplementary foods consumed fewer than 4 serves/day of supplementary foods. This correlated with the 95th percentile consumption of supplementary beverage flavourings which ranged from 12 g for children aged 2-3 years, to 42.5 g for men aged 16 - 18 years. The serve size suggested by these data was likely to be about 10 g of drink base for persons aged 12 years and over, and 3-4g of drink base for children aged 2-11 years.

The modelling involved summing the nutrient contribution of 3 serves of maximally fortified supplementary drink to the mean nutrient intake found in the NNS for individual age groups. Two separate fortified formulations were used: one using maximum claim proportions of the specified RDIs in AFSC which are based on adult RDIs, and the other using the same proportions of RDIs based on those set for children aged 1-3 years (see Appendix Eight). The first mentioned formulation was modelled in the diets of males aged 4 and over, and the second was modelled in the diets of the 2-3 year olds. Because supplemented drink bases and drinks were included in the original results of the NNS, the modelled intakes are conservative and overestimate the likely long term vitamin and mineral intake. The results are given Table A (i) as amounts of vitamin or mineral, and expressed in Table A(ii) as a proportion of National Health and Medical Research Council age-specific RDIs.

Not all vitamins and minerals proposed to be permitted in supplementary foods are reported in the NNS. The mean intake of these other vitamins and minerals from the regular diet was assumed to be 1 x RDI in the modelling. This is a conservative estimate based on the reported distributions of nutrient intakes. The results are given in Table B.

Table A (i) Mean daily nutrient intake from regular diet plus 3 servings of maximally fortified supplementary food, (Males)

	Age (Years)					
	2-3	**4-7**	**8-11**	**12-15**	**16-18**	**19+**
Vitamin A (µg)	898	1094	1276	1913	1792	1861
Thiamin (mg)	1.6	2.5	2.8	4.1	4	3.6
Riboflavin (mg)	2.5	2.9	3.3	4.5	4.5	3.8
Niacin (mg)	27.8	36.5	44.5	57	68	65
Folate (µg)	232	332	375	571	612	606
Vitamin C (mg)	133	136	150	181	213	195
Calcium (mg)	1392	1430	1537	2292	2480	2145
Phosphorus (mg)	1467	1927	2200	3240	3565	3275
Magnesium (mg)	233	345	396	443	499	621
Iron (mg)	11	14.8	17.5	25	27	25
Zinc (mg)	8.7	12.5	14.5	21.8	23.8	23.8

Table A(ii) Mean daily intake plus 3 serving of a maximally fortified supplementary food expressed as a proportion of RDI (Males)

	Age (Years)					
	2-3	**4-7**	**8-11**	**12-15**	**16-18**	**19+**
Vitamin A	2.9	3	2.5	2.6	2.3	2.5
Thiamin	3	3.5	3.1	3.4	3.3	3.2
Riboflavin	3	2.6	2.3	2.5	2.3	2.2
Niacin	2.7	2.7	2.7	2.5	3	3
Folate	2.3	3.3	2.5	2.8	3	3
Vitamin C	4.4	4.5	5	6	5	5
Calcium	2	1.7	1.9	1.9	2.4	2.6
Phosphorus	3	2.7	2.7	2.7	3.2	3.2
Magnesium	2.9	3	2.2	1.7	1.6	1.9
Iron	1.3	1.8	2.2	1.9	2.0	1.9
Zinc	1.9	2.3	1.6	2	2	2

Table B **Estimated Daily Nutrient Intake from regular diet plus 3 servings of a Supplementary Food, also expressed as a proportion of RDI (Males)**

	Estimated Daily Nutrient Intake	**Proportion RDI**
Vitamin B6 (mg)	4.5	2.8
VitaminB12 (µg)	5	2.5
Vitamin D (µg)	25	2.5
Vitamin E (mg)	25	2.5
Iodine (µg)	375	2.5

Appendix Six:

Proposed Maximum Amounts of Vitamins and Minerals in Meal Replacements (expressed as proportion RDI or ESADDI)

Nutrient	Maximum claimed amount per serve	Maximum amount per serve
vitamin A	40%	40% x RDI
vitamin D	40% x RDI	40% x RDI
vitamin E	50% x RDI	
vitamin C	50% x RDI	
thiamin	50% x RDI	
riboflavin	50% x RDI	
niacin	50% x RDI	
vitamin B6	50% x RDI	
vitamin B12	50% x RDI	
folate	50% x RDI	
calcium	50% x RDI	
phosphorus	50% x RDI	
iron	40% x RDI	
iodine	50% x RDI	50% x RDI
magnesium	50% x RDI	
copper: inorganic	17% x ESADDI	17% x ESADDI
organic	8% x ESADDI	8% x ESADDI
chromium:		
inorganic	17% x ESADDI	17% x ESADDI
organic	8%x ESADDI	8% x ESADDI
zinc	40% x RDI	
manganese:		
inorganic	17% x ESADDI	17% x ESADDI
organic	8% x ESADDI	8% x ESADDI
selenium:		
inorganic	25% x RDI	25% x RDI
organic	13% x RDI	13% x RDI
vitamin K	50% x USA RDI	
biotin	17% x ESADDI	
pantothenic acid	17% x ESADDI	
molybdenum:		
inorganic	17% x ESADDI	17% x ESADDI
organic	8% x ESADDI	8% x ESADDI

Appendix Seven:

Proposed Schedule for addition of vitamins and minerals to supplementary foods

Column 1 **Food**	Column 2 **Substances**	Column 3 **Maximum claim (%RDI) per serve**	Column 4 **Maximum permitted level (%RDI) per serve**
formulated supplementary foods	vitamin A	25%*	25%
	thiamin	50%	
	riboflavin	50%	
	niacin	50%	
	vitamin C	50%	
	vitamin D	25%	25%
	calcium	50%	
	phosphorus	50%	
	iron	25%	
	vitamin B6	50%	
	vitamin B12	50%	
	vitamin E	50%	
	folate	50%	
	zinc	25%	
	iodine	50%	50%
	magnesium	25%	

* RDI refers to the current reference values given in Standard A9, or those proposed for young children in Appendix Eight.

Appendix Eight:

Proposed RDIs and ESADDI for Use in Meal Replacements and Supplementary Foods, according to age group

(i) RDIs (Australian)

	1 - 3 years	4 years and over
Vitamin A (ug)	300	700
Thiamin (mg)	0.5	1.1
Riboflavin (mg)	0.8	1.7
Niacin (mg)	5	10
Vitamin B6 (mg)	0.7	1.6
Folate (ug)	100	200
Vitamin B12 (ug)	1.0	2.0
Vitamin C (mg)	30	40
Vitamin D (ug)	5	10
Vitamin E (mg)	5.0	10
Calcium (mg)	700	800
Phosphorus (mg)	500	1000
Magnesium (mg)	80	320
Iron (mg)	6	12
Zinc (mg)	4.5	12
Iodine (ug)	70	150
Vitamin K (ug)	15	80
Selenium (ug)	25	70

* vitamin K is based on USA RDI.

(ii) ESADDI (USA)

Biotin (ug)	100
Pantothenic Acid (mg)	7.0
Copper (mg)	3.0
Manganese (mg)	5.0
Chromium (ug)	200
Molybdenum (ug)	250

Standard 2.9.5

Formulated meal replacements and formulated supplementary foods

NOT TO PROCEED AHEAD OF LABELLING AND ADDITIVE AND MICROBIOLOGICAL STANDARDS

Purpose

This Standard provides compositional and labelling requirements specifically applicable to formulated meal replacements and formulated supplementary foods. General labelling requirements are contained in Part 1.2.

Table of Provisions

Clauses

1 Interpretation

In this Standard-

formulated meal replacement means a single food or prepackaged selection of foods that is sold as a replacement for one or more of the daily meals but not as a total diet replacement

formulated supplementary food means a food specifically designed as a supplement to a normal diet to address situations where intakes of energy or nutrients may not be adequate to meet an individual's requirements.

RDI means the Recommended Dietary Intake specified in Table 4 of this Standard.

ESADDI means the Estimated Safe and Adequate Daily Dietary Intake specified in Table 5 of this Standard.

Drafting Note:
The RDIs and ESADDIs for the nutrients relevant to this Standard are listed in Table 4 and Table 5 in this draft Standard. The ultimate placement of these Tables will also be considered in the review of the Standard A9 of the Food Standards Code.

serve means an amount of the food which constitutes one normal serving when made up according to manufacturer's directions or when the food requires no further preparation before consumption.

2 Prescribed names

'Formulated meal replacement' and 'formulated supplementary food' are prescribed names.

3 Compositional requirements for formulated meal replacements

(1) Formulated meal replacements must contain per serve:

(a) a minimum 12g protein;
(b) a minimum 850 kJ; and
(c) at least 25 per cent of the RDI of each of those nutrients listed in column 1 of Table 1 in this Standard, but the amount of each nutrient must not exceed the amount set out in relation to that nutrient in column 2 of Table 1 in this Standard.

(2) Formulated meal replacements may contain one or more of those nutrients listed in column 1 of Table 2 in this Standard, but the amount of each nutrient must not exceed the amount set out in relation to that nutrient in column 2 of Table 2 in this Standard.

4 Compositional requirements for formulated supplementary foods

(1) Formulated supplementary foods must contain per serve:

(a) a minimum of 8g protein;
(b) a minimum of 550 kJ; and
(c) no less than 20 per cent of the RDI of at least one of those nutrients listed in column 1 of Table 3 in this Standard, but the amount of each nutrient must not exceed the amount set out in relation to that nutrient in column 2 of Table 3 in this Standard.

(2) One or more of those nutrients listed in column 1 of Table 3 in this Standard may be added to formulated supplementary foods, but the total amount of each nutrient in a formulated supplementary food must not exceed the amount set out in relation to that nutrient in column 2 of Table 3 in this Standard.

5 Labelling of formulated meal replacements

(1) A claim as to the presence in a formulated meal replacement, of one or more of the nutrients listed in column 1 of Table 1 in this Standard, may be made on the label of a formulated meal replacement, provided the claim does not exceed the amount set out in relation to that nutrient in column 3 in Table 1 in this Standard.

(2) A claim as to the presence in a formulated meal replacement, of a nutrient listed in Table 2 in this Standard may only be made on the label of a formulated meal replacement, provided at least 10 per cent of the RDI or ESADDI of the nutrients are present per serve of the food, and that the claim does not exceed the amount in relation to that nutrient set out in column 3 in Table 2 in this Standard.

(3) A formulated meal replacement, must be labelled with words to the effect that the product is not to be used as a total diet replacement.

6 Labelling of formulated supplementary foods

(1) A claim as to the presence of one or more of the nutrients listed in column 1 of Table 3 to this Standard may only be made on the label of a formulated supplementary food provided at least 10 per cent of the RDI of the nutrients listed in column 1 of Table 3 is present per serve of the food, and that the claim does not exceed the amount in relation to that nutrient set out in column 3 in Table 3 in this Standard.

(2) The label on or attached to a formulated supplementary food must include a description of the role of the food as a supplement to a normal diet to address situations where intakes of energy or nutrients may not be adequate to meet an individual's requirements.

Table 1

Column 1 Nutrient	**Column 2 Maximum amount per one-meal serve**	**Column 3 Maximum claim per one-meal serve**
vitamin A	40% x RDI	40% x RDI
vitamin D	40% x RDI	40% x RDI
vitamin E	No amount set	50% x RDI
vitamin C	No amount set	50% x RDI
thiamin	No amount set	50% x RDI
riboflavin	No amount set	50% x RDI
niacin	No amount set	50% x RDI
vitamin B6	No amount set	50% x RDI
vitamin B12	No amount set	50% x RDI
folate	No amount set	50% x RDI
vitamin K	No amount set	50% x RDI
calcium	No amount set	50% x RDI
phosphorus	No amount set	50% x RDI
iron	No amount set	40% x RDI
iodine	50% x RDI	50% x RDI
magnesium	No amount set	50% x RDI
zinc	No amount set	40% x RDI

Table 2

Column 1 Nutrient	**Column 2 Maximum amount per one-meal serve**	**Column 3 Maximum claim per one-meal serve**
biotin	No amount set	17% x ESADDI
pantothenic acid	No amount set	17% x ESADDI
chromium:		
inorganic	17% x ESADDI	17% x ESADDI
organic	8% x ESADDI	8% x ESADDI
manganese:		
inorganic	17% x ESADDI	17% x ESADDI
organic	8% x ESADDI	8% x ESADDI
copper:		
inorganic	17% x ESADDI	17% x ESADDI
organic	8% x ESADDI	8% x ESADDI
selenium:		
inorganic	25% x RDI	25% x RDI
organic	13% x RDI	13% x RDI

molybdenum: inorganic organic	 17% x ESADDI 8% x ESADDI	 17% x ESADDI 8% x ESADDI

Table 3

Column 1 **Nutrient**	**Column 2** **Maximum amount per serve**	**Column 3** **Maximum claim per serve**
vitamin A	25% x RDI	25% x RDI
thiamin	No amount set	50% x RDI
riboflavin	No amount set	50% x RDI
niacin	No amount set	50% x RDI
vitamin C	No amount set	50% x RDI
vitamin D	25% x RDI	25% x RDI
calcium	No amount set	50% x RDI
phosphorus	No amount set	50% x RDI
iron	No amount set	25% x RDI
vitamin B6	No amount set	50% x RDI
vitamin B12	No amount set	50% x RDI
vitamin E	No amount set	50% x RDI
folate	No amount set	50% x RDI
zinc	No amount set	25% x RDI
iodine	50% x RDI	50% x RDI
magnesium	No amount set	25% x RDI

Table 4
Recommended Dietary Intake

Column 1 **Nutrient**	**Column 2** **1 - 3 years**	**Column 3** **4 years and over**
Vitamin A (μg)	300	700
Thiamin (mg)	0.5	1.1
Riboflavin (mg)	0.8	1.7
Niacin (mg)	5	10
Vitamin B6 (mg)	0.7	1.6
Folate (μg)	100	200
Vitamin B12 (μg)	1.0	2.0
Vitamin C (mg)	30	40
Vitamin D (μg)	5	10
Vitamin E (mg)	5	10
Vitamin K (μg)	15	80
Calcium (mg)	700	800
Phosphorus (mg)	500	1000
Magnesium (mg)	80	320
Iron (mg)	6	12
Zinc (mg)	4.5	12
Iodine (μg)	70	150
Selenium (μg)	25	70

Table 5
Estimated Safe and Adequate Daily Dietary Intake

Nutrient	4 years and over
Biotin (µg)	100
Pantothenic Acid (mg)	7.0
Copper (mg)	3.0
Manganese (mg)	5.0
Chromium (µg)	200
Molybdenum (µg)	250

Editorial Note

Permitted form of vitamin K is: phylloquinone.

Drafting Note

In the final drafting Tables 4 and 5 may be contained in the Vitamins and Minerals Standard. With the exceptions of selenium and vitamin K, all of the nutrients listed in Table 4 are currently listed in Standard A9. All of the nutrients listed in Table 5 are currently listed in Standard R10.

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

Drafting for the review of Formula Dietary Foods and Supplementary Foods is contained in a new Standard which is intended to be included in the joint Australia New Zealand Food Standards Code. This Standard is Standard 2.9.5 (Formulated meal replacements and formulated supplementary foods).

According to the proposed implementation plan for the revised Code (outlined at Item 9 of ANZFA 51, June 1998), there is no requirement to draft consequential amendments to the current Code. The proposed plan contemplates that, as an interim measure, Standards in the current Code and revised 'critical mass' Standards, that is, those Standards which need to be put in place before commodity Standards are implemented, should run in parallel. Therefore, under the plan, revised Standards or provisions would operate concurrently with, and as an alternative to, the existing Standard or provisions.

However, for indicative purposes only, those provisions in the current Code which would need to be deleted, but for the implementation plan, are included below.

Standard A1 *is varied by omitting from paragraph (19)(f)(ii)*

in Standards R4, R5, R6, R7 and R10

substituting

in Standards R5, R6, R7 and R10

Standard A9 *is varied by:-*

(1) *omitting from paragraph 1 of the Purpose -*

in Standards R5, R6, R7 and R9.

substituting -

in Standards R5, R6 and R7.*; and*

(2) *by deleting from Column 1 of the Table to clause 3*,

Formula Dietary Foods

and all corresponding entries in Columns 1, 2, 3, 4 and 5 relating to Formula Dietary Foods.

Standard T1 *is varied by deleting from the Table to Clause 3*
Food standardised in Standard R4