INQUIRY REPORT

SUBJECT: P199 - FORMULATED MEAL REPLACEMENTS AND FORMULATED SUPPLEMENTARY FOODS

Executive Summary

Meal Replacements and *Supplementary Foods* have previously been regulated as two separate special purpose foods within the Australian Food Standards Code (AFSC). In reviewing these two standards it has been identified that the purpose of both products, in providing nutrition via a formulated supplement or formulated meal, could be accommodated within a single special purpose food standard.

The Authority recommends that *Formulated Meal Replacements* and *Formulated Supplementary Foods* be combined into one standard within the special purpose food category, as all product has undergone significant nutritional modification, usually in terms of nutrient enhancement, and all product need specific nutritional labelling requirements. The combination of the two standards and the need to be retained as a special purpose food was fully endorsed at Full Assessment.

The regulation of supplementary foods designed for 1-3 year old children was decided to be included under this standard, rather than under draft Standard 2.9.2 – Foods for Infants and Young Children. This approach was taken because the purpose of these products clearly aligns with this standard, rather than foods regulated under Standard 2.9.2, which are more akin to adult versions of general purpose foods.

Executive Summary from the Full Assessment Report

The preferred options for the regulation of formulated meal replacements and formulated supplementary foods proposed by the Authority at Full Assessment are stated below.

ANZFA proposes a joint standard for formulated meal replacements and formulated 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; and.
  - 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 that are required to meet a minimum content from at least 5 to at least 1, 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, B_{12}, E and folate, and magnesium, iodine and zinc.
  - set a maximum claim of 25% RDI/serve of the final food for zinc, 35% RDI/serve for vitamin A, 40% RDI/serve for magnesium, 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 vitamin D, and iodine;
  - permit 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 must not to be consumed as total diet replacements;
- removes the current prohibition on declaration of nutrient claims on supplementary foods;
- 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;
- requires nutritional information for formulated supplementary foods to be declared per serve as made up;
- does not permit comparative claims;
- requires the purpose for which each supplementary food is intended to be stated on the label;
- clarifies that a serving of meal replacement is equivalent to one meal; and
- requires that formulated supplementary food for young children, reference age appropriate RDI (i.e. 1-3 year old) for vitamin and mineral claims.
- prescribes minimum protein and energy levels/serve for formulated supplementary food for young children.

Previous Authority Consideration

Full Assessment for this proposal was completed in February 1999 and was released for public comment on 17 February 1999. The comment period closed on 31 March 1999.

Summary of New Submissions Received

Thirteen submissions were received at Inquiry. A detailed summary of submissions is in Attachment 3.

The matters and concerns raised by the respondents are considered in the following section.

Proposed Change from Full Assessment

The only changes to the preferred options identified in the Full Assessment Report are:

- That the permissions for the addition of vitamins and minerals to Formulated Supplementary Foods be on the basis of a maximum claim of 50% RDI/serve of the permitted nutrients, except for vitamin A, magnesium and zinc which are set at 35 %, 40% and 25% RDI/serve respectively;

- That the standard clarify that a serving of meal replacement is equivalent to one meal;

- That a Nutrition Information Panel (NIP) be mandatory on all Formulated Meal Replacements and Formulated Supplementary Foods even if no nutrition claim is made, and that formulated supplementary foods be required also to declare nutrition information per serve as made up;

- That the advisory statement on the label of a Formulated Meal Replacement be strengthened to state that the product *must* not be consumed as a total diet replacement.

- That any Formulated Supplementary Food for young children be required to reference RDIs for the age group 1 -3 years;

- That minimum protein (2.5g) and energy (330 kJ) levels/serve be set for Formulated Supplementary Food for young children;

- That there is a prohibition on the use of comparative claims on Formulated Meal Replacements and Formulated Supplementary Foods;

- That the contribution of natural levels of vitamins and minerals from the reconstituting liquids used in meal replacements and supplementary foods use an average vitamin or mineral value to take account for natural variation;

- That a change be made to draft standard 1.3.1 so that schedules 2, 3 and 4 of the standard are permitted additives for the purposes of products standardised by draft standard 2.9.5; and

- That the permitted forms of vitamins and minerals for draft standard 2.9.5 be cross referenced to those given in draft standard 1.3.2 – Vitamins and Minerals or 2.9.2 – Foods For Infants And Young Children.

Assessment of Issues Raised in Public Submissions at Inquiry

This paper is the next stage in the Authority's process to review the requirements for Formulated Meal Replacements and Formulated Supplementary Foods. Comments received in response to the Full Assessment Report have been considered and the issues identified and assessed in light of those comments. This paper includes amendments to the proposed draft standard (see Attachment 1).

The Authority has undertaken an inquiry into the proposal for the purpose of making recommendations to the Australia New Zealand Food Standards Council in relation to the draft Australia New Zealand Food Standards Code.

General Issues

Public submissions in response to the Full Assessment Report identified issues of concern under six major headings. These issues were:

Protein

- That protein quality criteria be required;
- That the minimum protein requirements for supplementary foods be either removed or reduced;

Vitamins and Minerals

- That maximum claims for vitamins A and D and the minerals iron and magnesium in Supplementary Foods are set at too low a level of 25% RDI/serve;
- That maximum nutrients amounts and the maximum nutrient claims in Supplementary Foods should be based on the product itself not the product as recommended for consumption;
- Provide justification for the maximum claims for vitamins and minerals set at 50% RDI/serve in Formulated Supplementary Foods consumption;
- That vitamin and mineral permissions should be segmented to allow for population groups with special needs;
- That minimum vitamin and mineral contents in Formulated Meal Replacements should not be mandatory; and
- That dietary modelling should be undertaken for all nutrients permitted in Formulated Meal Replacements and Formulated Supplementary Foods including for high consumers of the foods.

Labelling

- That a Nutrition Information Panel should be mandatory for Formulated Meal Replacements and Formulated Supplementary Foods;
- That comparative claims and the use of the words fortified and enriched be permitted on the label;
- That an editorial note should be provided to assist with the determination of serving sizes of meal replacements;
- That the strength of the current advisory statement for meal replacements is not sufficient to protect public health and safety; and
- That information should be provided on preparation and frequency of use.

General

- That the standard is too broad and there should be segmentation to allow for the differing needs of specific population groups.

Principles for special purpose foods

- That the guiding principles for special purpose foods required further consultation.

Process

- That there are issues of significance for public consultation and a round of consultation should not have been omitted.

Discussion of General Issues

1. Protein Quality Criteria

1.1 Proposed at Full Assessment

It was proposed that protein quality not be prescribed in the joint standard for Formulated Meal Replacements and Formulated Supplementary Foods.

1.2 Comments from Public Submissions

Submissions were received from 11 individuals, companies and organisations. Of these, two considered that protein quality criteria should be required.

- The **Dietitians Association of Australia (DAA)** believed that protein quality should be required as some people may use meal replacements as total diet replacements even though the standard is not proposed for total diet replacements. The **New Zealand Ministry of Health** also recommended requiring protein quality criteria for meal replacements on the basis that they may be used as the sole source of nutrition and that problems had occurred in the United States of America with Very Low Energy Diets (VLEDs) during the 1960s.

1.3 Assessment of Issues

The Authority believes that the arguments presented by the **DAA** in favour of prescribing protein quality criteria are flawed in that they aim to protect a potential public health and safety issue that is outside the scope of the standard. If products are used as total diet replacements when this is not the intention of the standard or the purpose of the product, the public cannot be protected from such inappropriate behaviour.

The reference made by the **New Zealand Ministry of Health** to deaths resulting from VLEDs is inappropriate as it refers to product that would not meet the minimum energy requirements of the proposed standard. It also refers to total diet replacements that are outside the scope of this standard.

As stated in the Full Assessment Report neither the Food Standards Code nor the New Zealand Food Regulations currently prescribe protein quality criteria. The Authority does agree however that it is very important that these products are not used as total diet replacements and recommends strengthening the proposed

advisory statement to support this.

1.4 Conclusion

There does not appear to be any reason to amend the proposal to prescribe protein quality criteria based on the evidence provided. The ANZFA believes that the health of Australians and New Zealanders is not at any risk if the regulations do not prescribe protein quality criteria for meal replacement products. The Authority does however recommend a strengthening of the advisory statement to say that products MUST NOT be used as total diet replacements. This will also help ensure that other foods will contribute to the protein intakes of consumers of meal replacements.

2. Minimum protein and energy requirements for formulated supplementary foods

2.1 Proposed at Full Assessment

It was recommended that macronutrient criteria be set for protein and energy content which are slightly greater than the nutrient density of whole milk (whole milk/200mL: 6.6g protein; 560kJ). Modified milks would easily meet these recommendations.

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

2.2 Comments from Public Submissions

Three submissions did not support having minimum protein levels set higher than that found in whole milk. **Jalna Dairy Foods Pty Ltd** and **Ronald Cossen and Associates Pty Ltd** both stated that the protein level for supplementary foods was currently set at 21.2 percent higher than whole milk and recommended that the figure be set at the same as whole milk or a suggested 3 percent higher.

Peters & Brownes Group stated that the minimum protein and energy requirements would restrict the development of new innovative products. Fruit and vegetable products would not meet this criterion.

2.3 Assessment of Issues

The definition of supplementary food states that the product is consumed to supplement a normal diet where intakes of energy and other nutrients are not sufficient to meet an individual's requirements. The Authority believes that product able to be marketed as supplementary foods should offer more in some key macronutrients than a similar unmodified food. Hence it is inappropriate to have the same energy and protein contribution for whole milk as the criterion for supplementary foods. Requiring both energy and protein criteria ensures a more significant contribution from a supplementary food.

ANZFA has proposed a less prescriptive criterion to the current standard for supplementary foods, which is based on a minimum contribution of cereals or milk powder base. Also the Authority is recommending a deregulation of the reference quantity to a normal serve size which will provide more flexibility for manufacturers.

Further consideration of drafting issues raised the need for protein and energy minimum amounts to be set for formulated supplementary foods for young children. These amounts were determined by applying the same percentage contribution of a serve of a regular formulated supplementary foods to average adult protein or energy requirements, to the average protein and energy requirements of young children, aged 1-3 years.

2.4 Conclusion

That the macronutrient criteria of:
Protein: not less than 8 g protein/serve as ready to consume.
Energy Content: not less than 550 kJ/serve as ready to consume.
be retained in the regulation of regular formulated supplementary foods.

That the macronutrient criteria of:
Protein: not less than 2.5 g protein/serve as ready to consume.
Energy Content: not less than 330 kJ/serve as ready to consume be introduced into the regulation of formulated supplementary foods for young children.

3. Maximum nutrient permissions and maximum claims in Formulated Supplementary Foods have decreased for some nutrients

3.1 Proposed at Full Assessment

It was proposed at Full Assessment to:

> *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.*

The current permissions for vitamin and mineral addition to supplementary foods ranges from maximum claims of 20 - 47% RDI per 200 ml reference quantity. Vitamin A has a maximum amount of 33 % RDI/serve and vitamin D is at 30 % RDI/per serve.

3.2 Comments from Public Submissions

There were four of the submissions that raised concern about the maximum claims of some nutrients at 25 % RDI/serve. These were **Nestle**, **Cossens, Zenica Bio Plus** and the **New Zealand Dairy Board**. This was particularly the case for nutrients that are permitted in the current regulations at higher levels per 200 ml.

These are iron (maximum claim of 42 % RDI/serve), vitamin A (maximum claim of 27% RDI/serve) and vitamin D (maximum claim of 26 % RDI/serve). The **New Zealand Dairy Board** states that there is not enough substantiation in the assessment report to decrease some maximum nutrient levels from the previous standard.

3.3 Assessment of Issues

The Authority has undertaken further modelling for vitamins A and D, iron and magnesium on the basis of permissions of 50% RDI/serve for all identified nutrients, except vitamin A in Formulated Supplementary Foods (see Appendix One). Vitamin A was modelled on a maximum claim of 35% RDI/serve. The highest potential intakes for these nutrients were estimated for the 2 - 3 year olds. The maximum intakes for this age group are:

vitamin A @ 3.3 x RDI
vitamin D @ 3.2 x RDI
iron @ 2.5 x RDI
magnesium @ 3.6 x RDI.
Note: the RDI used is the age appropriate RDI of 1-3 years.

It should be noted that for this age in particular, with a limited stomach capacity, no allowance has been made for a decrease in consumption of other foods, with an added three serves of supplementary foods/day. It is highly unlikely that small children would be consuming an additional three serves of supplementary foods - which could be an extra 1000-2000 kJ, without displacing other food in their diet. Potential nutrient intakes are likely therefore to be overestimated.

On reassessment of these levels it appears that permitting 50% RDI/serve for all nutrients in Formulated Supplementary Foods, except vitamin A, magnesium and zinc, is not placing any particular population group at risk of overconsumption.

Iron intakes are to be encouraged in most age groups but particularly in young children if they are consuming inadequate intakes of meat or do not have sufficient stores of iron at birth. At maximum intakes of 2.5 RDI/serve there does not appear to be an issue with excessive intakes of iron. Iron levels were initially proposed at 25% RDI to take account of possible iron interaction with copper and calcium. Although nutrient interactions are an issue that must be considered, iron intakes at 50 % RDI/serve do not pose a public health risk. Interactions between iron and copper appear to become an issue at intakes in excess of 50 mg/day.

Acute vitaminosis A can occur in young children who consume vitamin A in amounts greater than 200 times RDI. Chronic hypervitaminosis A has been reported in children consuming 20 times RDI of vitamin A for over four months. It has been recommended by the Committee on Dietary Allowances of the U.S National Research Council that ingestion of supplements of retinol exceeding 3000 mcg RE daily only be undertaken under medical supervision. This level is 10 times the RDI.

In the United Kingdom assessment was undertaken for all nutrients in setting the Dietary Reference Values (DRV). The guidance given on high intakes recommended that intakes of vitamin A should not exceed 1,800 ug RE for 1 - 3 years olds; 3000 ug RE for 4 -6 years olds; and 4500 ug RE for 6 -12 year olds. These upper levels all exceed the maximum nutrient intakes identified in the dietary modelling of three serves of supplementary foods in addition to the mean nutrient intake (see Appendix One).

One abstracted report, however, suggests that retinol intakes over 3000 ug/day can potentiate vitamin A toxicity in alcoholics (Worner et al, 1988) and evidence exists of a teratogenic effect of excess retinol in early pregnancy. Vitamin A supplements of 5000 IU (about 1500 ug) or less are required to be labelled with a warning statement such that taking more than 2500 IU (about 750 ug) a day during pregnancy can cause birth defects. More recently there have been reports of decreased bone mineral density in post menopausal women with chronic excess retinol intakes as low as 2 times RDI (Whiting et al, 1999).

Based on these findings, ANZFA increased the maximum claim to 35% RDI/ serve. The slightly higher amount in the proposed new standard takes account of the contribution of vitamin A from any reconstituting liquid as the permissions in the draft new standard are for product "as consumed", which for drink bases, is after being prepared with milk. This level should not pose any risk of excessive consumption for any age group and would maintain a similar contribution from vitamin A from such products as is currently permitted in the Food Standards Code.

Vitamin D toxic intakes are only likely to occur with pharmalogical doses including supplementation with fish oil. There does not appear to be any risk associated with the proposed permissions of a maximum claim of 50% RDI/serve.

The US has recently set an upper level for non-food magnesium of 65 mg for children aged 1-3 years, and 350 mg for adults. There is evidence of mild diarrhoea resulting from large oral intakes of magnesium. At permissions of 40% RDI/serve, intakes of fortificant magnesium from 3 serves a day gives 66 mg for young children and 324 ng for adults. It is therefore proposed that permissions for magnesium remain at a maximum claim of 40% RDI/serve.

3.4 Conclusion

It is concluded that the standard for Formulated Supplementary Foods be amended to have a maximum claim for all permitted nutrients of 50 % RDI/serve except for vitamin A, magnesium and zinc where the maximum permitted claim be 35%, 40%, and 25 % RDI/serve respectively.

4. That the draft standard is too broad and does not cater for the needs of particular population groups

4.1 Proposed at Full Assessment

The proposed standard was developed to meet the special dietary needs of the general population.

4.2 Comments from Public Submissions

The **New Zealand Dairy Board** stated that the standard was too broad and that the particular dietary needs of some population groups, such as pregnant and lactating women, could not be met within the current provisions. They also stated that general population RDIs were inappropriate for particular population groups. The **New Zealand Dairy Board** was particularly concerned about folate requirements in pregnancy.

4.3 Assessment of Issues

The development of the recommended upper levels of micronutrients in Formulated Supplementary Foods used sets of population specific RDIs in determining maximum nutrient permissions. These were adults and children up to and including three years of age.

The Authority acknowledges that it is essential that product aimed at young children should only be permitted to add nutrients at the levels appropriate for the age group. This is particularly the situation for children under three years of age who are more vulnerable to excess intakes of nutrients. Specific RDIs for children aged 1 - 3 years of age have been referenced in the standard and must be used for product marketed at this age group.

ANZFA acknowledges that Formulated Supplementary Foods are sources of additional nutrients in the diet and not the main source of nutrition. Hence the cut off point has been set at maximum claims at 50 %RDI/serve as ANZFA believes it inappropriate that a supplementary food supply the complete needs of given nutrients.

Although folate requirements are known to be higher for pregnant women than for the general population the critical stage for consumption of folate is pre-pregnancy and in the first twelve weeks of pregnancy. Product aimed at consumption during pregnancy is unlikely to contribute significantly to folate intakes at these critical early stages.

The fact that there will be no prescribed reference quantity and manufacturers can recommend more than one serve of a product enables manufacturers to recommend higher intakes.

4.4 Conclusion

ANZFA concluded that division of maximum nutrient permissions be continued on the basis of RDI for the general population and for children up to the age of three. If product is directed to young children of 1 - 3 years of age the vitamin and mineral additions must not exceed 50% of the RDIs for 1-3 year olds rather than the RDIs for adults.

Some of the concerns of the NZDB over maximum nutrient permissions have been addressed in recommending a modification to permit maximum claims for vitamin D, iron of 50 % RDI/serve and maximum claims for vitamin A of 35% RDI/serve and magnesium of 40% RDI/serve.

5. Dietary modelling for all nutrients in Formulated Meal Replacements

5.1 Proposed at Full Assessment

Dietary modelling was undertaken on nutrients that were proposed to be increased from current permissions in the AFSC and the NZFR. Modelling was not carried out on all nutrients particularly if no change in permissions was being proposed. The modelling was mostly carried out on Australian dietary data but New Zealand data were used where available. The modelling proposed a worst case scenario of adding the nutrient contribution from three serves of maximally fortified formulated supplementary food to a mean nutrient intake. No allowance was made for displacement of other foods in the diet. Also, more than three serves of supplementary foods per day were consumed by fewer than one percent of the population. It is therefore believed that the dietary modelling would be likely to overestimate nutrient intakes.

5.2 Comments from Public Submissions

The **New Zealand Ministry of Health** was the only submission that raised concerns about the dietary modelling. The **Ministry of Health** stated that they believed it was essential that dietary modelling was available for all of the proposed nutrient amounts in both meal replacements and supplementary foods. They stated that they were most concerned about amounts of nutrients in meal replacements and in particular vitamin A and iron where maximum claims are proposed. They also recommended that dietary modelling be undertaken on riboflavin even though the proposed level was decreased.

The **Ministry of Health** also recommended that ANZFA model on high intake consumers rather than mean intakes with the addition of a high consumption of supplementary foods (i.e. three serves /day) and that the modelling data on folate did not represent the worst case scenario.

The **Ministry of Health** were also concerned that a mean dietary intake of vitamin B12 was assumed to be the RDI as no Australian data existed and had not used available New Zealand data on vitamin B_{12} intakes.

5.3 Assessment of Issues

Modelling was only undertaken on nutrients where it was proposed that permitted levels be increased from the current standard or where the nutrients had not been previously permitted. For meal replacements this meant retaining the required 16 nutrients already permitted in the AFSC but allowing for the voluntary addition of a further eight nutrients. In the NZFR the addition of vitamins and minerals to meal replacements is on a voluntary basis although the definition of meal replacements states that it relates to products sold as a replacement for one or more meals. The NZFR already permits for the additional eight nutrients to be added to meal replacements.

On the basis of current permissions, modelling was not undertaken on the New Zealand data for meal replacements as it was not proposed to increase permissions for vitamins and minerals.

Addition of the extra eight nutrients to meal replacements took into account the recent analysis of increasing permissions of these specific nutrients within the Formulated Sports Food Standard (Standard R10) and permitted the nutrients at similar levels. Increasing permissions also took into account that these nutrients were currently permitted in the NZFR with no apparent concern for adverse effect as evidenced by no active monitoring.

Also dietary modelling on any potential changes to the intakes of Australians of these added nutrients to meal replacements could not be undertaken as there are no dietary data on current intakes of biotin, pantothenic acid, vitamin K, chromium, copper, manganese, selenium and molybdenum. Modelling on the effects on the New Zealand population was not undertaken as there were no increases in vitamin and mineral permissions being proposed.

In relation to the Ministry's concern about the lack of modelling for vitamin A and iron in meal replacements in setting a maximum claim, the Authority notes that the current NZFR does not specify maximum nutrient levels for meal replacements. The requirements of the proposed standard are more restrictive than the current NZFR. In addition, concern about possible impact on industry of having maximum claims for vitamin A and iron in meal replacement products were not raised by any of the industry groups.

Regarding the recommendation to model for high intake consumers, it was assumed that this referred to high consumers of supplementary foods. People consuming more than three serves of supplementary foods per day comprise fewer than one percent of the population, according to the Australian National Nutrition Survey,

1995. If modelling was undertaken on this group, the baseline data would represent only a very small number of people.
ANZFA recommended that a much more realistic picture could be obtained by adding the nutrient contribution from a high consumption of maximally fortified supplementary foods (i.e. three serves/day) to mean nutrient intakes. No account was taken for the displacement of other foods in the diet that the addition of supplementary foods might affect hence the results are likely to be an overestimation of potential intakes.

With respect to dietary modelling undertaken on folate, the Authority modelled on a scenario representing present levels of folate fortification and not the theoretical maximal fortification of fortified breads and supplementary foods as well as other fortified foods. If ANZFA were to model maximal fortification, the maximum folic acid intake would be 1145 ug folic acid/day not 1417 as stated in the paper of the **Ministry of Health.** The level of 1417 ug refers to the total intake of food folate and folic acid yet it is only the folic acid that is used in the upper safe intake cut off point. The Authority reiterates that the worst case scenario modelling is highly unrealistic. Such a value was determined assuming that all breakfast cereals, breads and fruit juices are fortified with folate. It also assumes that such products are fortified with the maximum permitted amounts of folate. To date, after three years of permissions for fortification of certain foods with folic acid, no permitted category of foods has become fully folate fortified. What the modelling does confirm though, is that young males are the most likely population group to consume higher levels of folate but that based on current dietary habits, these levels of consumption do not give rise for any concern.

Dietary modelling was not undertaken for riboflavin in Supplementary Foods as the recommendation was to permit addition of riboflavin at 50% RDI/serve as consumed rather than the current permissions of 47% RDI/amount made up to a 200 mL reference quantity. The current regulation enables a supplemented milk drink base made up with milk to provide 75% RDI/serve. Although this is an effective reduction in the permissions for the addition of riboflavin, concerns about a decrease in the maximum permission for riboflavin were not raised as an issue in the public consultation process. As dietary modelling is being used to address potential excess of nutrient intakes, it was not seen as appropriate to model on riboflavin. This same approach was taken for all other nutrients for which there was no proposed increase in permitted levels.

The **Ministry of Health** raised concern that modelling had been undertaken on an assumed intake of vitamin B_{12} of 1 x RDI/day as there were no Australian consumption data. However there were New Zealand consumption data and these data should have been used. The ANZFA acknowledges this oversight and agrees that New Zealand data should have been used. On remodelling vitamin B_{12}, a mean intake has been estimated at 3.3ug /day (NZ data) rather than the assumed intake of 2 ug/day (i.e. 1 x RDI). The potential intake of vitamin B_{12} for high consumers of Formulated Supplementary Foods is thus increased to 6 ug/day (3 x RDI). The

original figure in the Full Assessment report was 2.5 x RDI. This result does not affect the final recommendation of ANZFA to permit 50% RDI/serve of vitamin B_{12} to be added to Formulated Supplementary Foods.

It should also be noted that in the recently established USA Dietary Reference Values, a tolerable upper intake was not set due to no known adverse effects of vitamin B_{12}

The **Ministry of Health** also pointed out that a reference had been omitted from the Full Assessment report in relation to dietary modelling. The reference to be included should have been:

Wilson NC, Allen JB, Russell DG and Herbison P. 1993. Nutrient Analysis II of 24 Hour Diet Recall Using 1992 DSIR Database. Report no 93 - 26, LINZ Activity and Health Research Unit, Dunedin, New Zealand: University of Otago.

5.4 Conclusion

The Authority believes that adequate dietary modelling was undertaken in the development of the standard for Formulated Meal Replacements and Formulated Supplementary Foods and does not believe it is necessary to extend the modelling on the basis of comments provided. A minor modification on the modelling of vitamin B_{12} was undertaken but this does not affect the final recommendations.

6. Mandatory addition of some vitamins and minerals for meal replacements

6.1 Proposed at Full Assessment

It was proposed that Meal replacements contain at least 25% of the RDI of each of 16 micronutrients and that voluntary addition of a further eight be permitted.

6.2 Comments from Public Submissions

The **Ministry of Health (NZ)** raised concerns about mandatory addition of any nutrients to meal replacement products. They stated that the NZFR allowed for nutrients to be added to meal replacements on a voluntary basis and requiring mandatory addition of these 16 nutrients would pose significant reformulation costs on industry.

Neways International (Australia) PTY Ltd also raised concerns that ANZFA was imposing new mandatory provisions for meal replacements.

6.3 Assessment of Issues

ANZFA surveyed products currently on the Australian and New Zealand market and could not find any meal replacement products that are not already meeting the proposed mandatory vitamin and mineral proposal.

Justification for the mandatory addition of the 16 micronutrients is based on the special purpose of meal replacements in replacing possibly one or two meals per day. It was therefore proposed that a significant amount of key essential nutrients may need to be supplied by these products. Decisions as to the range of essential nutrients to be prescribed for formulated meal replacements were made according to those nutrients for which an Australian RDI had been established. As New Zealand has also adopted these same RDIs except for selenium, they would be considered essential for the New Zealand population as well. Selenium is the only nutrient with an RDI that does not have a 25% RDI/serve mandatory requirement in the proposed standard. There are, however, permissions to add selenium if so desired.

The approach of mandatory addition of certain essential vitamins and minerals is also consistent with the Codex position. Codex state in the standard for *Formula Foods for the use in Weight Control Diets* that for formula foods represented as a replacement for a single meal, the amounts of vitamins and minerals shall provide a minimum of 33% or 25% RDI depending on whether the recommended number of servings per day is three or four respectively. The Authority has recommended that the same essential vitamins and minerals must be present in meal replacement products at levels of at least 25% RDI/serve, where a serve is equivalent to one meal.

ANZFA believes that the current NZFR requirement of complete voluntary addition of all micronutrients to meal replacements allows for potentially inadequate product on the market and that the special purpose of a meal replacement product must mean that a minimum of essential nutrition is provided in replacing one or more meals. The concern of the **Ministry of Health** about mandatory addition of vitamins and minerals is inconsistent with their recommendation on protein quality.

In relation to the concerns of **Neways,** it is noted that the proposed standard for Formulated Meal Replacements requires minimum content of the same nutrients that are currently required to be present in meal replacement products under Standard R4 (Formula Dietary Foods).

6.4 Conclusion

It is proposed to retain the current recommendation of a minimum requirement for meal replacements to contain at least 25% RDI/serve for the 16 micronutrients stated in the draft standard and that a further eight micronutrients be permitted on a voluntary basis. The requirements therefore remain unchanged from current Australian regulations.

7. Nutrient permissions based on product as recommended to be consumed

7.1 Proposed at Full Assessment

The setting of maximum nutrient levels be based on product as recommended to be made up and consumed and not necessarily as sold.

7.2 Comments from Public Submissions

Nestle was concerned with the new approach for composition being based on product as recommended to be consumed rather than product as sold. They stated that such a position adds an uncontrollable factor due to natural variation and complicates the enforcement of these products. Such a change to the standard would require a significant change to the recipe of some key products without there being any problem with the current nutrient profile.

7.3 Assessment of Issues

On assessment of the issues ANZFA identified that with the increase of maximum claim permission of vitamin A to 35 % RDI/serve, magnesium to 40% RDI/serve, vitamin D and iron to a maximum claim of 50% RDI/serve, there would appear to be no need to reformulate product with respect to those nutrients. With these proposed modifications, the requirement for nutrient composition to be based on product 'as consumed' could be retained. This would ensure that product, particularly supplementary foods, retained some key macronutrient contribution to the diet as well as micronutrient contribution.

Concerns about natural variation in product, such as seasonal variation of nutrients in milk, is being addressed by the provision to enable nutrient contribution naturally present in the product be considered as an average value. This would take account of any seasonal or other natural variation in nutrient content. It should be noted that many manufacturers are already providing compositional information on the label of supplementary foods for product as recommended for consumption.

7.4 Conclusion

ANZFA proposes to retain the compositional criteria for Formulated Meal Replacements and Formulated Supplementary Foods on the basis of product 'as consumed' rather than as sold .

8. Serving Sizes

8.1 Proposed at Full Assessment

It was proposed at Full Assessment that serving sizes and/or reference quantities not be prescribed in the standard. It was however proposed that for formulated meal replacements a serve be a one meal serve and for formulated supplementary foods a serve be determined by the manufacturer. However the requirement for minimum protein and energy per serve of supplementary food would help ensure that realistic serve sizes were recommended.

8.2 Comments from Public Submissions

Most submissions were fully supportive of a manufacturer determined serve size. The **Ministry of Health (NZ)** recommended that it should be noted in the standard that a serving size for a meal replacement should be sufficient to replace one meal.

8.3 Assessment of Issues

As it was the intention of the draft standard that a serving of a meal replacement be equivalent to one meal ANZFA supports the Ministry of Health's recommendation to include a note that a serving of meal replacement product is equivalent to one meal.

8.4 Conclusion

That the standard state one serving of meal replacement is equivalent to one meal.

9 Inappropriate use of meal replacements

9.1 Proposed at Full Assessment

It was recommended at Full Assessment that formulated meal replacement products not be permitted to be marketed as total diet replacements and that product be required to carry an advisory statement to that effect.

9.2 Comments from Public Submissions

The **Ministry of Health (NZ)** was concerned that there may be some population groups that would still use the product inappropriately as a total diet replacement.

9.3 Assessment of Issues

The Authority does not believe that there is any more appropriate action to take other than provide the consumer with information that the product is not a total diet replacement. However the Authority recommends that the statement should be strengthened to state that the product MUST NOT be used as a total diet replacement.

9.4 Conclusion

It is proposed to strengthen the advisory statement on formulated meal replacements to the effect that they must not be used as total diet replacements.

10. Statement of the purpose of the food

10.1 Proposed at Full Assessment

It was proposed at Full Assessment that Formulated Supplementary Foods 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. Such a statement has been permitted in the previous standard for Supplementary Foods (Standard R9) but not required.

10.2 Comments from Public Submissions

Nestle were concerned that requiring that product state its role in supplementing an inadequate diet may not be appropriate. Many such products are used for every day consumption. They also stated that the diet may not be necessarily inadequate but the consumer may choose to boost it with either energy or micronutrients. Also there are no concerns for consumers that may be consuming these products that are eating a nutritionally adequate diet.

10.3 Assessment of Issues

ANZFA has considered this issue and believes that a statement on the role of the product in *supplementing a normal diet* should be maintained. The draft standard makes reference to the potential role of supplementary foods in a normal diet that **may** have inadequate nutrient intakes. The Authority believes that such a statement caters for product that may be used to provide just a nutrient boost even though overall diet may not be inadequate but also differentiates Formulated Supplementary Foods from similar product not considered special purpose foods.

10.4 Conclusion

It is concluded that a statement still be required on the label of formulated supplementary foods as to the role of the product in supplementing a normal diet.

11 Nutrition Information Panel

11.1 Proposed at Full Assessment

It was proposed at Full Assessment that a Nutrition Information Panel (NIP) not be mandated as it would be required to be provided if a nutrition claim was made. Because of the nature of the products it was envisaged that all products would be likely to provide a NIP as they were likely to make a nutrition claim.

11.2 Comments from Public Submissions

The **Victorian Food Safety Council** and the **Ministry of Health (NZ)** both support mandatory provision of NIPs on Formulated Meal Replacements and Formulated Supplementary Foods.

11.3 Assessment of Issues

The ANZFA fully agrees with the need to provide nutritional information on these special purpose products. It did not believe that it was necessary to mandate a NIP as it believed that such information would be being provided anyway. However the ANZFA supports the requirements for a mandatory NIP if there are groups concerned that such information may not be provided on all products. Consistency with the review of Nutrition Labelling (P167) will require declaration of energy, fat, protein, carbohydrate, sodium and any claimed nutrients in all NIPs as if a nutrition claim was made. This will only come into effect when a label does not make a nutrient claim.

11.4 Conclusion

It is concluded that a NIP is required to be provided on the labels of all Formulated Meal Replacements and Formulated Supplementary Foods as if a nutrition claim was made.

12 That information should be provided on the label of the product with instructions for preparation and frequency of use

12.1 Proposed at Full Assessment

It was proposed at Full Assessment that directions for use not be required for Formulated Meal Replacements and Formulated Supplementary Foods as is consistent with the current requirements for these products in Standard R4 and Standard R9.

12.2 Comments from Public Submissions

The **Victorian Food Safety Council** stated that these products may cause harm if misused or prepared at an incorrect concentration and that information regarding preparation, use and recommended frequency of use should be provided.

12.3 Assessment of Issues

ANZFA does not agree that such information should be mandated. Most manufacturers are providing this information already even though it is not required in the current standard. Nutrition information for meal replacements is based on a serve of one meal hence manufacturers will provide a description of a one meal serve.

For supplementary foods, the nutrient permissions are for product 'as consumed' so information will need to be provided on the recommended preparation for consumption.

For consumers to know how to use these products, manufacturers will need to provide information on directions for preparation and use. ANZFA believes that it is not necessary to prescribe this requirement.

12.4 Conclusion

That directions for preparation and use of the product not be required as part of the standard.

13 That the principles underlying special purpose foods required further consultation.

13.1 Proposed at Full Assessment

The Authority outlined some general principles for special purpose foods at the beginning of the Full Assessment paper to provide the reader with some context in which to view the paper on Formulated Meal Replacements and Formulated Supplementary Foods. As P199 was one of the first special purpose foods to be reviewed it was envisaged that the general principles would be revisited in an ongoing manner as further special purpose foods were reviewed.

13.2 Comments from Public Submissions

The **Ministry of Health** recommended further consultation on the policy principles of special purpose foods.

13.3 Assessment of Issues

The Authority had not proposed that the policy principles for special purpose foods were part of the consultation on P199 but rather they provided some context for the discussions on P199. As special purpose foods had not been previously defined in the FSC but were currently included in the NZFR, it was believed that some defining characteristics for special purpose foods was required.

13.4 Conclusion

The Authority concludes that the principles for special purpose foods will continue to be revised and refined within the Authority as the review of the FSC continues and in particular as more special purpose foods are reviewed.

Comments on Draft Standard

Comments on the draft standard have been identified in the 13 points raised previously and modified as seen appropriate.

Proposed Change from Full Assessment Resulting from this Inquiry

In the main, submissions raised issues that required further clarification and explanation or requested consideration of specific issues.

Modifications have been made to the drafting to accommodate some of the concerns that appear justified on reassessment of the issues. These include:

- an increase in permission for vitamins A, D, magnesium and iron in Formulated Supplementary Foods;
- clarification of a serving of Meal Replacements is equivalent to one meal;
- mandating a Nutrition Information Panel (NIP) on all Formulated Meal Replacements, and Formulated Supplementary Foods;
- strengthening the advisory statement on Formulated Meal Replacements;
- Formulated Supplementary Foods for young children be required to label vitamin and mineral claims by referencing RDIs prescribed for 1-3 year olds, and that a minimum protein and energy content/serve be prescribed;
- drafting modifications to capture appropriate clauses from the generic standard for the addition of vitamins and minerals to food – including claims, permitted forms and the appropriate use of minimum and average values for nutrient content claims.

There are no other changes to the recommendations made at Full Assessment for this proposal.

Proposed Changes to Regulation Impact Statement Resulting from this Inquiry

The regulation impact statement has been revised for the Inquiry report.

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community, which includes the consumers, food industry and governments in both countries. The regulation 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.

Problem

Meal replacements and supplementary foods are both categories of food that have specific nutrition composition requirements and specific labelling requirements necessary of the protection of public health and safety.

Background and Issues

Formulated meal replacements and formulated supplementary foods were originally regulated as two separate standards within the special purpose food standards. There are however sufficient similarities in relation to purpose of the product and specific nutrition composition and labelling to combine the two into one standard. There have been some differences in permissions for the addition of vitamins and minerals to meal and supplementary foods between the AFSC and the NZFR. Dietary modelling has been used to determine appropriate nutrient contents of both product types.

Objective

To develop a standard for meal replacements and supplementary foods that ensures the protection of public health and safety while allowing for innovation within the industry.

Identification of Affected Parties

Governments - Australia and New Zealand

Industry - manufacturers of formulated meal replacements and formulated supplementary foods in Australia and New Zealand.

Consumers -purchasers formulated meal replacements and formulated supplementary foods in both Australia and New Zealand.

Public Health/nutrition - Health professionals with an interest in weight loss, weight gain and diet supplementation.

Consultation

Public consultation at Full Assessment has been undertaken as well as input through the expertise of an external expert team including health and industry experts.

Impact Analysis

OPTION 1:

Retain the status quo as much as possible with minimum changes to enable harmonisation of existing provisions within the AFSC and the NZFR;

AFFECTED PARTY	COSTS	BENEFITS
CONSUMERS/ HEALTH PROFESSIONALS	• Consumers may potentially have access to a less diverse product range. • High enforcement costs from prescriptive standard may be passed on to consumer. • High production costs of strict compositional and labelling requirements may be passed on to consumers.	• Will continue to provide consumers with a product. Public health is firmly protected in Australia because of the stringent limits on composition.
INDUSTRY	• Prescriptive standards may mean higher production costs. • Manufacturers complying with NZFR or AFSC may have higher costs due modifications required to formulations to enable harmonisation. • Manufacturers will be limited in the development of new product due to prescriptive approach.	• Potential changes to composition and labelling are minimal especially for manufacturers following the AFSC.
GOVERNMENT	• Difficult to justify restrictive standard in an environment of minimum effective regulation.	• Government will incur the usual costs of regulation.

OPTION 2:

Develop joint provisions for formulated meal replacements and formulated supplementary foods in line with the Australia New Zealand Food Authority Act 1991.

AFFECTED PARTY	COSTS	BENEFITS
CONSUMERS/ HEALTH PROFESSIONALS	• May be some initial cost increases if industry decide to reformulate some products.	• May be reduced costs due to less prescriptive standards; • May be increased range of products due to less prescriptive standards.
INDUSTRY	• May be some initial costs to industry if decision to reformulate. • some costs to industry associated with labelling changes.	• Potentially lower production costs due to less prescriptive standards. • Innovation in the development of meal replacements and supplementary foods may be improved due to less compositional and labelling criteria.
GOVERNMENT	• No significant costs.	• Public health and safety is still assured but requirements are met with less prescriptive regulation. • Enforcement of product under one standard will reduce enforcement costs. • Reduced prescription of composition and labelling will reduce enforcement costs.

OPTION 3:

Have no specific regulation for meal replacements and supplementary foods with industry code of practice for composition and labelling.

AFFECTED PARTY	COSTS	BENEFITS
CONSUMERS/ HEALTH PROFESSIONALS	• Potential for public health and safety concern if nutrient composition is not adhered to. • Potential for both inadequate and excess nutrient intakes of more concern to certain groups such as young children.	• Increased range of products may appear on the market.
INDUSTRY	• May be costs to industry if compositional and labelling of current product is changed. • Potential for unethical industry groups to damage industry with production of inappropriate product. • Cost for industry of developing and monitoring Codes of Practice or guidelines.	• Minimal boundaries on product development; • Less requirements for labelling of product.
GOVERNMENT	• No significant costs unless involved in the development of the Codes of Practice or guidelines. • Potential health costs of inappropriate product.	• Less regulation and enforcement costs.

Conclusions and Recommended Option

There appears to be little advantage in option 1 as it provides minimal benefits to industry or consumers and the prescriptive nature of the regulation disadvantages most groups.

Option 3 does not provide protection of public health and safety and would not be consistent with the principles of the development of the FSC.

Option 2, where the regulation of meal replacements and supplementary foods provides the most benefits to most groups. It is also the option most consistent with the international obligations of minimal effective regulation. The stakeholders most likely to be affected by option 2 are the consumer and the industry.

The Authority's option 2 is recommended.

Conclusions

Given the changes made to the assessment of this matter since Full Assessment, it is concluded that :

The Authority proposes a joint standard for formulated meal replacements and formulated 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; and.
    - 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 that are required to meet a minimum content from at least 5 to at least 1, 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, B_{12}, E and folate, and magnesium, iodine and zinc.
  - set a maximum claim of 25% RDI/serve of the final food for zinc, 35% RDI/serve for vitamin A, 40% RDI/serve for magnesium, 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 vitamin D, and iodine; and
  - permit 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 must not to be consumed as total diet replacements;
- removes the current prohibition on declaration of nutrient claims on supplementary foods;
- 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;
- requires nutritional information for formulated supplementary foods to be declared per serve as made up;
- does not permit comparative claims;
- requires the purpose for which each supplementary food is intended to be stated on the label;
- clarifies that a serving of meal replacement is equivalent to one meal; and
- requires that formulated supplementary food for young children, reference age appropriate RDI (i.e. 1-3 year old) for vitamin and mineral claims.
- prescribes minimum protein and energy levels/serve for formulated supplementary food for young children.

The commencement date for the new joint standard will either be the date of gazettal, or 6 months after gazettal.

REGULATION IMPACT

ANZFA has undertaken a regulation impact assessment process which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the Code is necessary, cost effective and of benefit to both producers and consumers.

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 Council of Australian Governments (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 significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter was notified to the WTO as an SPS matter because of the lack of international standard for supplementary foods, and the nature of the compositional parameters prescribed in the standard to protect public health and safety.

APPENDIX 1

Dietary Modelling

This re-modelling of potential maximum nutrient intakes in supplementary foods has allowed for a maximum claim of 50% RDI/serve for all nutrients permitted in Formulated Supplementary Foods except for vitamin A, magnesium and zinc where a maximum claim level of 35%, 40% and 25% RDI/serve respectively has been modelled. Dietary intake modelling has been recarried out on potential intakes of vitamin A, vitamin D, iron, and magnesium. These nutrients were modelled based on a permission of 25% RDI in the previous Full Assessment report. Intakes reflect an RDI for vitamin A of 750 ug (not 700 ug as inadvertently given in the full assessment report).

The modelling has allowed for three servings of maximally fortified supplementary foods in addition to the nutrient intakes from a regular diet (mean intakes). There has been no allowance made for displacement of other nutrients in the diet because of added supplementary foods. It should also be noted that an additional three servings of supplementary foods is over and above any supplementary foods that are in the base data from the National Nutrition Survey - Australia. For these reasons it is emphasised that the dietary modelling will overestimate for all nutrients.

Nutrient Intakes from mean nutrient intake plus three serves Formulated Supplementary Foods (based on 50% RDI/serve for vitamin D and iron, 35% RDI/serve for vitamin A, 40% RDI/serve for magnesium, and 25% RDI/serve for zinc)

AGE (years)

Nutrient	2 - 3	4 - 7	8 - 11	12 - 15	16 - 18	19 +
Vit A (ug)	988	1359	1541	2178	2057	2125
Vit D (ug)		32.5	32.5	32.5	32.5	32.5
Iron (mg)	15.5	23.8	26.5	34	36	34
Zinc (mg)	8.8	12.5	14.5	21.8	23.8	23.8
Magnesium (mg)	292	604	644	675	710	721

Contribution of Nutrients /day in terms of age specific RDI

AGE (years)

	2 - 3	4 - 7	8 - 11	12 - 15	16 - 18	19 +
Vit A (ug)	3.3	1.8	2.0	2.9	2.7	2.8
Vit D (ug)		3.2	3.2	3.2	3.2	3.2
Iron (mg)	2.5	2.2	2.8	3	2.8	3
Zinc (mg)	1.9	1.0	1.2	1.8	2.0	2.0
Magnesium (mg)	3.6	5.5	3.8	2.7	2.4	2.3

ATTACHMENT 1

DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

Standard 2.9.5

Formulated meal replacements and formulated supplementary foods

Purpose

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

In addition, this Standard sets out the compositional and labelling requirements for formulated supplementary foods for young children, aged one to three years.

Table of Provisions

Division 1 – Interpretation

Clauses

1 Interpretation

In this Standard-

average quantity means, in relation to a nutrient in a food, the quantity determined from one or more of the following:

(a) the manufacturer's analysis of the food;
(b) calculation from the actual or average quantity of nutrients in the ingredients used; or
(c) calculation from generally accepted data.

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 vitamins and minerals may not be adequate to meet an individual's requirements.

formulated supplementary food for young children means a formulated supplementary food for children aged one to three years.

RDI means the Recommended Dietary Intakes of vitamins and minerals –

(a) set out in the Schedule to Standard 1.3.2; and
(b) in the case of formulated supplementary foods for young children, those set out in Standard 2.9.2.

ESADDI means the Estimated Safe and Adequate Daily Dietary Intakes of vitamins and minerals set out in the Schedule to Standard 1.3.2.

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, and in the case of a formulated meal replacement is equivalent to one meal.

permitted form means the form of vitamin or mineral specified in Column 2 of the Schedule to Standard 1.3.2.

Division 2

Formulated meal replacements

2 Compositional requirements for formulated meal replacements

(1) Formulated meal replacements must contain in a serve no less than -

(a) 12 g protein;
(b) 850 kJ; and
(c) 25 per cent of the RDI of each of those vitamins and minerals listed in column 1 of Table 1 in the Schedule in this Standard.

(2) A formulated meal replacement may have added to it the vitamins and minerals listed in -

(a) column 1 of Table 1 in the Schedule, provided the total amount of each vitamin or mineral in a serve does not exceed the amount, where specified, set out in relation to that vitamin or mineral in column 2 of Table 1; and

(b) column 1 of Table 2 in the Schedule, provided the total amount of each vitamin or mineral in a serve does not exceed the amount, where specified, set out in relation to that vitamin or mineral in column 2 of Table 2.

(3) Vitamins and minerals added to formulated meal replacements must be in the permitted form.

3 Labelling of formulated meal replacements

(1) The label on a formulated meal replacement must include a nutrition information panel in accordance with Standard 1.2.8 as if a nutrition claim had been made.

(2) A claim as to the presence in a formulated meal replacement of a vitamin or mineral listed in column 1 of Table 1 or Table 2 in the Schedule in this Standard may be made on the label of a formulated meal replacement, provided that -

(a) no less than 10 per cent of the RDI or ESADDI of that vitamin or mineral is present in a serve of the food; and
(b) the claimed amount of the vitamin or mineral in a serve does not exceed the amount in relation to that vitamin or mineral set out in column 3 of Table 1 or Table 2.

(3) A claim as to the presence of a vitamin or mineral in a formulated supplementary food is calculated by summing -

(a) the average quantity of the vitamin or mineral naturally occurring in the formulated meal replacement; and/or
(b) the minimum quantity of the added vitamin or mineral in the formulated meal replacement.

(4) ‘Formulated meal replacement’ is a prescribed name.

(5) The label on a formulated meal replacement must include words to the effect that the product must not be used as a total diet replacement.

Division 3

Formulated supplementary foods

4 Compositional requirements for formulated supplementary foods

(1) Formulated supplementary foods must contain in a serve no less than -

(a) 8 g protein;
(b) 550 kJ; and
(c) 20 per cent of the RDI of no less than one of those vitamins or minerals listed in column 1 of Table 3 in the Schedule in this Standard, provided the total amount of each vitamin or mineral in a serve does not exceed the amount, where specified, set out in relation to that vitamin or mineral in column 4 of Table 3.

(2) The vitamins or minerals listed in column 1 of Table 3 in the Schedule to this Standard may be added to a formulated supplementary food, provided the total amount of each vitamin or mineral in a serve does not exceed the amount, where specified, set out in relation to that vitamin or mineral in column 4 of Table 3.

(3) Vitamins and minerals added to formulated supplementary foods must be in the permitted form.

5 Labelling of formulated supplementary foods

(1) The label on a formulated supplementary food must include -

(a) a nutrition information panel in accordance with clause 4 of Standard 1.2.8 as if the label contained a nutrition claim; and
(b) where the food is to be made up according to the manufacturer's directions, an additional column in the right hand side of the nutrition information panel, specifying in the same manner as that set forth in the panel, particulars in relation to the food as made up.

(2) A claim as to the presence in a formulated supplementary food of one or more of those vitamins or minerals listed in column 1 of Table 3 in the Schedule in this Standard may be made on the label of a formulated supplementary food provided that -

(a) no less than 10 per cent of the RDI of the vitamin or mineral listed in column 1 of Table 3 is present in a serve of the food; and
(b) the claimed amount of the vitamin or mineral in a serve of the food does not exceed the amount set out in relation to that vitamin or mineral in column 5 of Table 3.

(3) A claim as to the presence of a vitamin or mineral in a formulated supplementary food is calculated by summing -

(a) the average quantity of the vitamin or mineral naturally occurring in the formulated supplementary food; and/or
(b) the minimum quantity of the added vitamin or mineral in the formulated supplementary food.

(4) The label on 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.

(5) 'Formulated supplementary food' is a prescribed name.

Division 4

Formulated supplementary foods for young children

6 Compositional requirements for formulated supplementary foods for young children

(1) Formulated supplementary foods for young children must contain in a serve no less than -

(a) 2.5 g protein;
(b) 330 kJ; and
(c) 20 per cent of the RDI of no less than one of those vitamins or minerals listed in column 1 of Table 3 in the Schedule in this Standard, provided the total amount of each vitamin or mineral in a serve does not exceed the amount, where specified, set out in relation to that vitamin or mineral in column 2 of Table 3.

(2) The vitamins or minerals listed in column 1 of Table 3 in the Schedule in this Standard may be added to a formulated supplementary food for young children, provided the total amount of each vitamin or mineral in a serve does not exceed the amount, where specified, set out in relation to that vitamin or mineral in column 2 of Table 3.

(3) Vitamins and minerals added to formulated supplementary foods for young children must be in the permitted form.

7 Labelling of formulated supplementary foods for young children

(1) The label on a formulated supplementary food for young children must include -

(a) a nutrition information panel in accordance with clause 4 of Standard 1.2.8 as if the label contained a nutrition claim; and
(b) where the food is to be made up according to the manufacturer's directions, an additional column in the right hand side of the nutrition information panel, specifying in the same manner as that set forth in the panel, particulars in relation to the food as made up.

(2) A claim as to the presence in a formulated supplementary food for young children of one or more of those vitamins or minerals listed in column 1 of Table 3 in the Schedule to this Standard may be made on the label of a formulated supplementary food provided that -

(a) no less than 10 per cent of the RDI of the vitamin or mineral listed in column 1 of Table 3 is present in a serve of the food; and
(b) the claimed amount of the vitamin or mineral in a serve of the food does not exceed the amount set out in relation to that vitamin or mineral in column 3 of Table 3.

(3) A claim as to the presence of a vitamin or mineral in a formulated supplementary food for young children is calculated by summing -

(a) the average quantity of the vitamin or mineral naturally occurring in a serve the formulated supplementary food; and/or
(b) the minimum quantity of the added vitamin or mineral in the formulated supplementary food.

(4) The label on or attached to a formulated supplementary food for young children 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.

(5) 'Formulated supplementary food for young children' is a prescribed name.

SCHEDULE

Table 1

Formulated meal replacements

Column 1 Vitamins and minerals	**Column 2 Maximum amount per one-meal serve (proportion RDI)**	**Column 3 Maximum claim per one-meal serve (proportion RDI)**
Vitamin A	300 µg (40%)	300 µg (40%)
Thiamin	No amount set	0.55 mg (50%)
Riboflavin	No amount set	0.85 mg (50%)
Niacin	No amount set	5.0 mg (50%)
Vitamin B6	No amount set	0.8 mg (50%)
Folate	No amount set	100 µg (50%)
Vitamin B12	No amount set	1.0 µg (50%)
Vitamin C	No amount set	20 mg (50%)
Vitamin D	5.0 µg (50%)	5.0 µg (50%)
Vitamin E	No amount set	5.0 mg (50%)
Zinc	No amount set	4.8 mg (40%)
Iron	No amount set	4.8 mg (40%)
Iodine	75 µg (50%)	75 µg (50%)
Magnesium	No amount set	160 mg (50%)
Calcium	No amount set	400 mg (50%)
Phosphorus	No amount set	500 mg (50%)

SCHEDULE (CONTINUED)

Table 2

Formulated meal replacements

Column 1 **Vitamins and minerals**	**Column 2** **Maximum amount per one-meal serve (proportion RDI unless stated otherwise)**	**Column 3** **Maximum claim per one-meal serve (proportion ESADDI unless stated otherwise)**
Biotin	No amount set	17 µg (17%)
Pantothenic acid	No amount set	1.3 mg (17%)
Chromium:		
inorganic	34 µg (17%)	34 µg (17%)
organic	16 µg (8%)	16 µg (8%)
Manganese:		
inorganic	0.85 mg (17%)	0.85 mg (17%)
organic	0.4 mg (8%)	0.4 mg(8%)
Copper:		
inorganic	0.50 mg (17%)	0.50 mg(17%)
organic	0.24 mg (8%)	0.24 mg (8%)
Vitamin K	No amount set	40 µg (50%)
Selenium:		
inorganic	17.5 µg (25% RDI)	17.5 µg (25% RDI)
organic	9 µg (13% RDI)	9 µg (13% RDI)
Molybdenum:		
inorganic	42.5 µg (17%)	42.5 µg (17%)
organic	20 µg (8%)	20 µg (8%)

SCHEDULE (CONTINUED)

Table 3

Formulated supplementary foods and formulated supplementary foods young children

Column 1 Vitamins and minerals	Column 2 Maximum amount per serve (young children) (proportion RDI)	Column 3 Maximum claim per serve (young children) (proportion RDI)	Column 4 Maximum amount per serve (adults) (proportion RDI)	Column 5 Maximum claim per serve (adults) (proportion RDI)
Vitamin A	135 µg (45%)	105 µg (35%)	340 µg (45%)	265 µg (35%)
Thiamin	No amount set	0.25 mg (50%)	No amount set	0.55 mg (50%)
Riboflavin	No amount set	0.4 mg (50%)	No amount set	0.85 mg (50%)
Niacin	No amount set	2.5 mg (50%)	No amount set	5.0 mg (50%)
Vitamin B6	No amount set	0.35 mg (50%)	No amount set	0.8 mg (50%)
Folate	No amount set	50 µg (50%)	No amount set	100 µg (50%)
Vitamin B12	No amount set	0.5 µg (50%)	No amount set	1.0 µg (50%)
Vitamin C	No amount set	15 mg (50%)	No amount set	20 mg (50%)
Vitamin D	2.5 µg (50%)	2.5 µg (50%)	5.0 µg (50%)	5.0 µg (50%)
Vitamin E	No amount set	2.5 µg (50%)	No amount set	5.0 µg (50%)
Zinc	No amount set	1.1 mg (25%)	No amount set	3.0 mg (25%)
Iron	No amount set	3.0 mg (50%)	No amount set	6.0 mg (50%)
Iodine	35 µg (50%)	35 µg (50%)	75 µg (50%)	75 µg (50%)
Magnesium	No amount set	32 mg (40%)	No amount set	130 mg (40%)
Calcium	No amount set	350 mg (50%)	No amount set	400 mg (50%)
Phosphorus	No amount set	250 mg (50%)	No amount set	500 mg(50%)

ATTACHMENT 2

DRAFT VARIATIONS TO THE FOOD STANDARDS CODE

Standard 1.3.1

Food Additives

Purpose

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food. Food additives are distinguishable from processing aids (see Standard 1.3.3) and vitamins and minerals added to food for nutritional purposes (see Standard 1.3.2).

This standard regulates the use of food additives in the production and processing of food. A food additive may only be added to food where expressly permitted in this standard. Additives can only be added to food in order to achieve an identified technological function according to Good Manufacturing Practice.

Standard 1.3.4 prescribes standards for the identity and purity of food additives.

Table of Provisions

Clauses

1 Definitions

In this standard -

technological function means a function set out in Schedule 5.

maximum permitted level means the maximum amount of additive which may be present in the food as set out in relation to that food in Schedule 1.

processed food means food which has undergone any treatment resulting in a substantial change in the original state of the food.

Editorial note:

This definition of 'processed food' is used to determine some additive permissions.

Processes such as dividing, parting, severing, boning, mincing, skinning, paring, peeling, grinding, cutting, cleaning, trimming, deep-freezing or freezing, milling or husking, packing or unpacking are not considered to result in a substantial change to the original state of the food.

flavourings mean concentrated preparations which are added to foods to impart taste and/or odour, which are used in small amounts and are not intended to be consumed alone, but do not include herbs, spices and substances which have an exclusively sweet, sour or salt taste.

2 General prohibition on the use of additives

Unless expressly permitted in this Standard, food additives must not be added to food.

3 Permitted use of additives

The additives listed by name or number in Schedules 1,2,3 and 4 may be added to a food or class of food to perform technological functions provided that:

(a) the use complies with any restrictions on use listed in Schedule 1; and
(b) the proportion of the additive does not exceed the maximum level necessary to achieve one or more technological functions under conditions of Good Manufacturing Practice (GMP).

Editorial Note

The Codex Alimentarius Commission Procedural Manual sets out the following relevant criteria for use in assessing compliance with Good Manufacturing Practice:

(a) the quantity of additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;
(b) the quantity of the additive that becomes a component of food as a result of its use in the manufacture, processing or packaging of a food and which is not intended to accomplish any physical, or other

technical effect in the finished food itself, is reduced to the extent reasonably possible; and

(c) the additive is prepared and handled in the same way as a food ingredient.

The manner in which a food is intended to be presented (eg. by the use of such quality descriptors as natural, pure, traditional etc) may affect the type and level of food additives that could be used in accordance with GMP. Similarly, the type and level of food additives used may affect the way in which a food may be presented.

4 Requirements for use of intense sweeteners

Save where otherwise expressly stated in Schedule 1 and not withstanding any specific level specified in a Schedule to this Standard, intense sweeteners may only be added to food in an amount necessary to replace the sweetness normally provided by sugars or as a flavour enhancer.

Editorial Note:

In general, the use of intense sweeteners is limited to:

1. foods meeting the definition of 'reduced joule' or 'low joule';
2. "no added sugars" food e.g. artificially sweetened canned fruit without added sugar; or
3. specific foods in which the use of the sweetener is in addition to sugar rather than as an alternative e.g. chewing gum, brewed soft drink (these foods are listed in Schedule 1 on a case-by-case basis).

Conditions relating to the use of reduced/low joule and no added sugar claims can be found in Standard 1.2.8 or in ANZFA's Code of Practice on Nutrient Claims in Food Labels and in Advertisements (Commonwealth of Australia, AGPS 1995).

5 Maximum permitted levels of additives

(1) Where a maximum level for an additive in a food is prescribed, unless otherwise stated, the level refers to the maximum amount which may be present in the food as sold or, where there are directions for preparation, when prepared for consumption according to label directions.

(2) For the purposes of this Standard:

annatto and annatto extracts shall be calculated as bixin.

benzoic acid and its salts shall be calculated as benzoic acid.

cyclamate and its salts shall be calculated as cyclohexyl-sulphamic acid.

propionic acid and its salts shall be calculated as propionic acid.

saccharin and its calcium and sodium salts shall be calculated as saccharin.

sorbic acid and its salts shall be calculated as sorbic acid.

sulphur dioxide, sulphites including bisulphites and metabisulphites shall be calculated as sulphur dioxide.

6 Additives performing the same function

(1) Where two or more additives may be added to a food for the purpose of achieving the same technological function, those additives may be used singly or in combination.

(2) Where two or more additives are used in combination to achieve the same technological function, the sum of the fractions obtained by dividing the amount of each food additive used by the maximum amount permitted for that food additive must not exceed 1.

Example

A food can have a maximum amount of 40 mg/kg of preservative X or 20 mg/kg of preservative Y. Some of the permitted combinations of the two preservatives are:

Preservative X	Fraction for Preservative X	Preservative Y	Fraction for Preservative Y	Sum of Fractions
40 mg/kg	1	nil	0	1
30 mg/kg	0.75	5 mg/kg	0.25	1
20 mg/kg	0.5	10 mg/kg	0.5	1
10 mg/kg	0.25	15 mg/kg	0.75	1
nil	0	20 mg/kg	1	1

7 Carry-over of additives

Other than by direct addition, an additive may be present in any food as a result of carry-over from an ingredient, provided that the level of the additive in the final food is no greater than would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice.

Editorial Notes

In clause 7, the ingredient can itself be a food additive.

The additive must be permitted to be present in the ingredient and must not be present in any greater quantity than permitted.

8 Food for use in preparation of another food

A food intended for use in the preparation of another food may contain any or all of the additives in a quantity permitted in the final food.

9 The addition of a garnish to food

The addition of a garnish to a food does not render that food a mixed food for the purposes of this Standard.

> **Editorial Note**
> Examples of the addition of a garnish to a food include lemon slice to fish or pepper to steak to make pepper steak.

10 Colours and their aluminium and calcium lakes

A reference to a colour listed in Schedules 1, 3 and 4 of this Standard includes a reference to the aluminium and calcium lakes prepared from that colour.

11 Permitted synthetic flavourings

Permitted synthetic flavourings, for the purposes of this Standard, are those synthetic flavourings listed in at least one of the following publications:

(1) *Food Technology, A Publication of the Institute of Food Technologists*, Generally Recognised as Safe (GRAS) lists of flavouring substances published by the Flavor and Extract Manufacturers' Association of the United States from 1960 to October 1998;

(2) *Flavouring Substances and Natural Sources of Flavourings*, 4th Edition, Volume 1, Chemically-defined flavouring substances, Council of Europe, 1992;

(3) United States *Code of Federal Regulations*, 1996, 21 CFR Part 172.515.

> **Editorial Note:**
> The Flavour and Fragrance Association of Australia and New Zealand (FFAANZ) has prepared a list of permitted synthetic flavourings in the three publications for ease of reference. This list is available from FFAANZ or from the Australia New Zealand Food Authority.

12 Restricted substances in food

(1) In this clause -

(a) **food** means either a food or class of foods listed in unbolded type in column 1 of the Table to this clause;

(b) **maximum permitted concentration** (MPC) means the maximum level of a substance listed in bolded type in column 1 of the Table to this clause permitted to be present in a food, expressed in milligrams of the substance per kilogram of the food (mg/kg).

(2) The maximum permitted concentration for a substance listed in bolded type in column 1 of the Table to this clause in a food, is listed in column 2 of the Table to this clause.

TABLE to clause 12

COLUMN 1	COLUMN 2
Caffeine	

See drafting note below	
Coumarin	
Alcoholic beverages	10
All other foods	2
Quassine	
Alcoholic beverages	50
All other foods	5
Quinine (total alkaloids from Cinchona, calculated as quinine)	
Alcoholic beverages	300
Tonic drinks, bitter drinks and quinine drinks	100
All other foods	0.1

Drafting Note:

Permitted foods under the caffeine heading will be considered by a separate proposal which is yet to be assigned a number.

Schedule 5 Technological functions which may be performed by food additives

Functional class *sub-classes*	**Definition**
Acidity regulator acid, alkali, base, buffer, buffering agent, pH adjusting agent	alters or controls the acidity or alkalinity of a food
Anti-caking agent anti-caking agent, anti-stick agent, drying agent, dusting powder	reduces the tendency of individual food particles to adhere or improves flow characteristics
Antioxidant antioxidant, antioxidant synergist	retards or prevents the oxidative deterioration of a food
Bulking agent bulking agent, filler	contributes to the volume of a food without contributing significantly to its available energy
Colouring	adds or restores colour to foods
Colour fixative colour fixative, colour stabiliser	stabilises, retains or intensifies an existing colour of a food
Emulsifier emulsifier, Emulsifying salt, plasticiser, dispersing agent, surface active agent, surfactant, wetting agent	facilitates the formation or maintenance of an emulsion between two or more immiscible phases
Firming agent	contributes to firmness of food or interact with gelling agents to produce or strengthen a gel
Flavour enhancer flavour enhancer, flavour modifier, tenderiser	enhances the existing taste and/or odour of a food
Flavouring (excluding herbs and spices and intense sweeteners)	see definition in clause 1

Foaming agent whipping agent, aerating agent	facilitates the formation of a homogeneous dispersion of a gaseous phase in a liquid or solid food
Gelling agent	modifies food texture through gel formation
Glazing agent coating, sealing agent, polish	imparts a coating to the external surface of a food
Humectant moisture/water retention agent, wetting agent	retards moisture loss from food or promotes the dissolution of a solid in an aqueous medium
Intense sweetener	replaces the sweetness normally provided by sugars in foods without contributing significantly to their available energy
Preservative anti-microbial preservative, anti-mycotic agent, bacteriophage control agent, chemosterilant, disinfection agent	retards or prevents the deterioration of a food by micro organisms
Propellant	gas, other than air, which expels a food from a container
Raising agent	liberates gas and thereby increase the volume of a food
Sequestrant	forms chemical complexes with metallic ions
Stabiliser binder, firming agent, water binding agent, foam stabiliser	maintains the homogeneous dispersion of two or more immiscible substances in a food
Thickener thickening agent, texturiser, bodying agent	increases the viscosity of a food

Schedule 1 to Standard 1.3.1

13 FOODS INTENDED FOR PARTICULAR DIETARY USES[1]

13.1 Infant formulae and follow-on formulae

Additives in Schedules 2,3&4 must not be present in foods in this category unless expressly permitted below

- Additives permitted in FSC Standard R7

13.2 Weaning foods

Additives in Schedules 2,3&4 must not be present in foods in this category unless expressly permitted below

- Additives permitted in FSC Standards R5 and R6

13.3 Formulated Meal Replacements and Formulated Supplementary Foods

Additives in Schedules 2, 3 & 4 other than cyclamate and saccharin

13.4 Formulated Supplementary Sports Foods*

123	Amaranth	300	mg/kg

[1]References to Standards R3, R5, R6, and R7 will be replaced with a list of permitted additives once the appropriate standards have been reviewed.

	160b	Anatto extracts	100	mg/kg

13.4.1 Solid Formulated Supplementary Sports Foods

Propionic acids or its salts	2000	mg/kg
Sorbic acid or its salts	1000	mg/kg
Sulphur dioxide	200	mg/kg

13.4.2 Liquid Formulated Supplementary Sports Foods

Benzoic acid or its salts	400	mg/kg
Sorbic acid or its salts	400	mg/kg
sulphur dioxide	115	mg/kg

13.5 Supplementary foods for dietetic uses

Additives in Schedules 2, 3 & 4 must not be present in foods in this category unless expressly permitted below

- Additives permitted in FSC Standard R3

ATTACHMENT 3

STATEMENT OF REASONS - DRAFT

PROPOSAL P199 - FORMULATED MEAL REPLACEMENTS AND FORMULATED SUPPLEMENTARY FOODS

FOR RECOMMENDING A VARIATION TO DRAFT STANDARD 2.9.5 - FORMULATED MEAL REPLACEMENTS AND FORMULATED SUPPLEMENTARY FOODS - IN THE DRAFT JOINT AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

The Australia New Zealand Food Authority has before it a proposal for a draft standard to regulate the composition and labelling of formulated meal replacements and formulated supplementary foods.

The Australia New Zealand Food Authority recommends adoption of the draft standard, as amended, for the following reasons:

- to ensure that the composition requirements support and enable formulated meal replacements and formulated supplementary foods to meet the special dietary purpose for which they are intended with the minimum of effective regulation;

- to ensure protection of public health and safety through appropriate control of the composition and labelling of formulated meal replacements and formulated supplementary foods;

- to clarify some ambiguities and correct some anomalies in the present provisions; and

- to reduce the amount of mandatory information required on labels by the existing provisions.

The drafting prepared after Full Assessment is amended for the following reasons:

- reassessment of the appropriate permissions for vitamins and minerals in formulated supplementary foods resulted in modifications to the permitted levels of some vitamins and minerals;

- concerns raised at Full Assessment about the advisory statement resulted in a strengthening of the wording of the original statement;

- ambiguity in relation to the serving size for meal replacements resulted in clarification of a serving being equivalent to one meal;

- ambiguity in relation to the tables in the draft standard resulted in additional headings on the tables;

- concerns that NIPs were not mandated;

- the prohibition on comparative claims of these products with that of any other food;

- concerns that product directed at young children should use age appropriate RDIs, and that minimum protein and energy levels should be set.

The commencement date for the new joint standard will be the date of gazettal or 6 months after gazettal.

REGULATION IMPACT

The Authority has undertaken a regulation impact assessment process which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the Code is necessary, cost effective and of benefit to both producers and consumers.

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 Council of Australian Governments (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).

This matter was notified to the WTO as an SPS matter because of the lack of international standard for supplementary foods, and the nature of the compositional parameters prescribed in the standard to protect public health and safety.

DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

(DRAFTING WILL BE INSERTED HERE)

ATTACHMENT 4

SUMMARY OF SUBMISSIONS
P199

There were a total of 13 submissions received on the consultation of Formulated Meal replacements and Formulated Supplementary Foods (P199). They are summarised as follows:

1 Australasian Soft Drink Association Limited

Fully supported the recommendations outlined in P199.

2 Dietitians Association of Australia

General agreement for the proposed joint standard for formulated meal replacements and formulated supplementary foods.

- Disagreed with the recommendation not to require protein quality criteria. The justification given was that some consumers may use them as total meal replacements even though that is not their intended use. DAA recommended either requiring protein quality criteria or recommending how many meals may be replaced in order to achieve adequate high protein quality.

3 Jalna Dairy Foods Pty Ltd

General support for the proposed joint standard for formulated meal replacements and formulated supplementary foods.

- Recommend reviewing the minimum protein content in Supplementary Foods to be set at whole milk figures. If this is considered inadvisable the protein should be set slightly higher at about three percent higher 6.8g/200ml.

4 Health Department of Western Australia

General agreement for the proposed joint standard for formulated meal replacements and formulated supplementary foods.

- The Committee does not agree with the setting a maximum concentration for copper in formulated meal replacements and formulated supplementary foods as this is inconsistent with the risk analysis of copper conducted in the review of Standard A12.

The review of Standard A 12 (Metals and Contaminants in Food) addressed contamination levels of metals naturally in foods whereas the review of Formulated meal replacements and formulated supplementary foods is dealing with added levels of the nutrients including copper. The Authority will therefore retain the maximum amounts and maximum claims for copper.

5 Food Technology Association of Victoria

Fully supported the proposed joint standard for formulated meal replacements and formulated supplementary foods.

6 Ronald Cossens and Associates Pty Ltd

Generally supports the proposed joint standard for formulated meal replacements and formulated supplementary foods.

Issues of concern include:

Macronutrient Composition Criteria for Supplementary Foods

- Currently minimum protein is 21.2 percent higher than whole milk. It is proposed that the energy content and protein figures be set at the whole milk figures. If this is considered inadvisable the protein should be set slightly higher at about three percent higher 6.8g/200ml.

- Rationale on the basis that not only energy and protein are likely to be need e to be supplemented. If benchmark is whole milk, why should levels of energy and protein be higher?

Vitamin and mineral composition of supplementary foods

- Question the basis for proposed minimum content of vitamins and minerals at 20 percent?

- Question basis for maximum claims at 25 percent RDI/serve for vitamins A, D and iron, magnesium and zinc and the 50 percent for other vitamins and minerals?

Potential health claims

- Current Standard R9 includes a prohibition:
  claims or pictorial representations that indicate that a food standardised in this part of the standard enhances performance are prohibited. Does P199 delete this prohibition?

The performance claims previously permitted in Standard R9 were related to the electrolyte component of the standard. Electrolyte drinks are not part of the proposed draft standard Formulated meal replacements and formulated supplementary foods. Performance claims, as with all therapeutic claims, are not expressly permitted in the draft standard.

7 New Zealand Dairy Board

Raised a number of issues concerning proposal P199.

- The standard was too general. They restated the revised definition of a special purpose food and recommended that there be some segmentation to allow for the differing nutritional needs of specific target groups.

- Conservative models have been used to determine upper limits of vitamins and minerals and are not adequate to meet the special dietary needs of some groups such as pregnant and breastfeeding women.

- Conservative maximum levels of some vitamins and minerals. Especially folate where current recommendations are for women to consume at least 400ug one month prior to pregnancy and for the first three months of pregnancy.

- There is not enough substantiation to set the maximum claim limits of vitamin A and D without some further segmentation of children and adult nutrient requirements.

- There is not enough substantiation in the assessment to decrease some maximum nutrient levels from the previous standards - i.e. vitamin A and D have been reduced from a maximum claim of 33% RDI and 30% RDI to 25% RDI for both.

- NZDB describe an export product for pregnant women that exceeds the maximum claimed amounts for vitamins A, D, calcium, folate and iron. They, in particular, question the justification for maximum claims for iron, zinc and magnesium being at lower levels to account for potential nutrient interaction with calcium and copper. The NZDB claim that the calcium/ iron interactions are not well substantiated in that diets high in dairy products failed to show any significant nutritional effects on iron status.

8 Neways International (Australia) Pty Ltd

Believe that P199 is an attempt by the Authority to dictate standards of nutrient intake for consumers.

- Additional compositional and quality aspects are being introduced in the

revised standard. Neways believed that the mandatory addition of folate to meal replacements was new and that folate addition to foods was currently not permitted.

- Requiring mandatory addition of vitamins and minerals to meal replacements is in conflict with the aim of simple, non-prescriptive standards. Such requirements are quality parameters. These requirements should be replaced with guidelines on levels of vitamins and minerals but minimum and maximum levels should not be imposed. Neway recommends that all vitamin and mineral addition be voluntary and guidelines be provided on typical vitamin and mineral profiles.

- Specific per serve protein and energy limitations is more restrictive than current standards. This does not seem appropriate for products that are not total diet replacements

9 Ministry of Health (NZ)

Raised a number of issues concerning proposal P199:

- Recommended more consultation on the general principles of special purpose foods;

- Recommended dietary modelling for each of the proposed nutrient levels although no potential issues of concern were identified. Dietary modelling was recommended for nutrients currently permitted in the NZFR with no maximum levels;

- Dietary modelling was recommended on high consumers of supplementary foods (less than one percent of the population consume more than 3 serves of supplementary foods per day). Dietary modelling on the high consumers population group (13 people out of 1677) would not provide an accurate picture due to small numbers.

- That nutrition information panels be made mandatory for both meal replacements and supplementary foods;

- That justification is provided for minimum nutrient contributions to meal replacements;

- That ANZFA address the issue of people who may inappropriately use meal replacements;

- An editorial note should be provided on serving sizes;

- Justification for increasing permissions for vitamin and mineral permissions in

supplementary foods;

- Questions the decision of having no protein quality criteria if very low calorie diets are consumed;

- Recommended re-evaluation of decision to omit round of public consultation.

10 Nestle Australia Ltd

Raised a number of issues concerning proposal P199:

- Believed an error in judgement had been made in initiating the section 36 and omitting a round of public consultation;

- Agree with the minimum nutrient content recommendations;

- Believe that the setting of maximum nutrient content should be based on the product itself and not and not as its recommended to consume composition;

- Agree with the proposed definitions but recommend that the reference quantity/serve be for the product itself and not necessarily as consumed;

- Agree with the macronutrient composition criteria;

- Support recommendations for prescribed names;

- Concern with the requirement to state the purpose of the food such that it is to supplement an inadequate diet. Consumers of supplementary foods may not necessarily be having inadequate diets.

- Support the removal of linking nutritional claims to the description of the role of the food;

- The major concern lies with the micronutrient composition being based on as consumed product rather than as sold. This is very difficult for product recommended to be made with milk due to the variability of the composition of milk- dependent on season, climate, and geography. Directions for consumption are often advisory only;

- Concern that the levels of vitamin A have been decreased without any justifiable public health and safety concern;

- A figure inaccuracy for the RDI for vitamin A.

11 Peters and Brownes Group

The submitters believed that P199 suffered from structure and with being considered separately a broader category of functional foods. Concern was expressed about the development of a novel food standard and its interface with P199, dietary supplements and whether novel foods and functional foods were synonymous.

Specific recommendations on P199 included:

- That the purpose of the standard should not only state foods regulated in the standard but foods not regulated in the standard such as total diet replacements;

- The term claim needs to be defined in the standard;

- Do not support the minimum protein and energy requirements for supplementary foods and believe that this inhibits innovation. The omission of macronutrient criteria does not pose and health risk or deceive the consumer if adequate labelling is provided;

- Support the move to require only one nutrient at least at 20 % RDI as new nutrient criteria;

- Support all vitamins and minerals from A9 be permitted in supplementary foods but questions why vitamin K and selenium are not permitted. Also question why other nutrients permitted in meal replacements - biotin, pantothenic acid, chromium, manganese, copper, selenium and molybdenum are not permitted in supplementary foods;

- Why is maximum amount set at 50% RDI when other countries allow 100% RDI? Why are there no maximum amounts for vitamin E, zinc, magnesium and iron?

- Would like to be able to use comparative claims. Also would like to use the terms fortified and enriched and believe they offer consumers useful information. Recommend excluding formulated meal replacements and formulated supplementary foods from clause 5(1)b and 5(1)c of Standard A9.

12 Victorian Food Safety Council

The Victorian Food Safety Council were generally supportive of the proposal but raised two areas of concern:

- Support a mandatory Nutrition Information Panel;

- Information should be provided on the preparation of use and frequency of use.

13 Zenica Bio Plus

Zenica Bio Plus were concerned about the proposed permitted levels and maximum claims for iron to formulated supplementary foods. They stated that the proposed maximum claim of 25 % RDI per serve were too low. Their justification was that the level of 25% RDI was set on the basis of nutrient interactions with iron if levels were too high but that these interactions were dependent on the form that the iron was in.

Zenica Bio Plus state that the iron additive *Biofer*, which is ferrous sulphate and vitamin C in a phospholipid membrane, protects the ferrous sulphate from interacting with the food components.

Zenica Bio Plus recommend the maximum claimed amounts of iron in formulated supplementary foods should be consistent with other nutrients in the proposed standard for formulated supplementary foods.