22 August 2001
03/02

INITIAL ASSESSMENT REPORT

PROPOSAL P236

DEVELOPMENT OF JOINT FOOD REGULATION FOR SPORTS FOODS

EXECUTIVE SUMMARY

Sports foods are currently regulated by Standard 2.9.4 - *Formulated Supplementary Sports Foods* in Volume 2 of the *Food Standards Code* (Volume 2). Time constraints during development of Volume 2 meant that a full review of Australian and New Zealand regulations for sports foods could not be completed in time. Standard R10 in Volume 1 of the *Food Standards Code* (Volume 1) was transported into Volume 2 as Standard 2.9.4 *Formulated Supplementary Sports Foods*, as an interim measure. Proposal P236 was raised to develop joint regulations for sports foods during the transition period, which is expected to cease in December 2002.

Sports foods are currently regulated in Australia and New Zealand by a variety of regulatory options. They are: the New Zealand *Food Regulations 1984*; the New Zealand *Dietary Supplement Regulations 1985*; and Standard R10 in Volume 1. Manufacturers in both countries however, are not able to manufacturer for domestic sale to all of these regulations. This regulatory situation introduces an increased level of complexity to the impending review.

This Initial Assessment Report seeks public comment on issues relating to the regulation of sports foods in Australia and New Zealand. Several issues have been discussed including the appropriate regulatory framework and its impact, the underpinning regulatory policy, scope and definition of sports foods, and compositional and labelling requirements for sports foods. A series of related questions are posed for each issue that may assist submitters in responding to this Initial Assessment Report.

1 INTRODUCTION

On 1 July 1996, an Agreement between Australia and New Zealand (the Treaty) came into force that established a joint Australian New Zealand Food Standards System, which served to underpin the development of Volume 2 of the *Food Standards Code* (Volume 2).

Under the Treaty, during the transition period to the joint system, products sold in New Zealand and Australia could comply with either the New Zealand *Food Regulations 1984* (NZFR), (if manufactured or imported into New Zealand) or Volume 1 of the *Food Standards Code* (Volume 1) (formerly known as the Australian *Food Standards Code*) until such time as Volume 2 had been developed and became the sole set of regulations for the two countries.

Volume 2 came into effect in Australia and New Zealand in December 2000. It is expected that most of the existing national Australian and New Zealand food regulations (other than Volume 2) will be repealed towards the end of 2002.

During the current transition period, ANZFA needs to complete the development and review of several outstanding food regulation matters. These include development of joint regulations covering food-type dietary supplements (Proposal P235) and sports foods (Proposal P236), which is the subject of this Initial Assessment Report.

As part of the review process, ANZFA is seeking comment, in particular in relation to the series of boxed questions throughout this report, from all interested parties. Submissions should clearly identify relevant issues or impact(s) and provide rationale and/or supporting documentation where possible.

2 BACKGROUND

2.1 Regulatory Framework For Sports Foods

2.1.1 Australia

Prior to 1993, there were no regulations specific to any type of sports foods in Australia. In mid-1993, Standard R9 - Electrolyte Drink Bases and Electrolyte Drinks was gazetted in Volume 1.

Proposal (P92) to review the regulation of sports foods in Australia was initiated in 1993 by the then National Food Authority (NFA). It arose from concerns from enforcement agencies about the growing number of sports food products that did not comply with existing food regulations, and the widely held view, previously expressed in public submissions during assessment of the application for electrolyte drinks, that the sports food market was outstripping the pace of regulatory change. As part of this process a consultant's report (by Dr Louise Burke) was commissioned to identify important sports-related nutrients, the role of sports foods in the diets of athletes and to detail the range of products currently available on the Australian market. In 1995, the Australian Quarantine and Inspection Service became concerned about the safety of some highly fortified sports foods and raised its inspection of shipments from 5% to 10% of product entering Australia.

In 1995, the NFA held a workshop, attended by 48 participants with interests in sports foods who represented 32 organisations and industries from Australia and New Zealand and relevant regulatory bodies, to discuss issues relating to a new regulatory framework. In 1996, the work began in earnest to develop a standard for sports foods, and included establishing an Expert Advisory Panel. The resultant Standard R10 - Formulated Supplementary Sports Foods in Volume 1 was gazetted in March 1998.

During the development of Volume 2, Proposal P216 was raised in 2000 to transport Standard R10 into Standard 2.9.4 - Formulated Supplementary Sports Foods, with only minor changes consistent with the format of Volume 2. No formal review of its content was undertaken at that time, but it was fully expected that a comprehensive review would be conducted during the transition period to incorporate the standard into the Volume 2. Standard 2.9.4 is given at Attachment 1. Electrolyte drinks have remained outside of this review as they continue to be encompassed under Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks, in Volume 2 of the Code.

2.1.2 New Zealand

Under the New Zealand *Food Regulations* (1984) there is no specific regulation for sports foods, however some of these products are regulated under Regulation 237 – Special Purpose Foods. Alternatively, sports foods may comply with the New Zealand *Dietary Supplement Regulations* 1985 (NZDSR). Relevant provisions of both sets of regulations are given at Attachments 2 and 3 respectively.

Compared with the relevant Australian regulations, the New Zealand food regulations permit more nutrients and impose fewer restrictions and labelling requirements such as:

- unlimited amounts of some vitamins and minerals permitted can be added; and
- products are not required to carry specific statements regarding directions for use and advisory statements to the effect that such products are not suitable for children under the age of 15 years or for pregnant women.

2.1.3 New Zealand Dietary Supplement Regulations 1985

The NZDSR were made under the *New Zealand Food Act* 1981, and commenced in August 1985. In contrast to Australia, these regulations created a separate regulatory category for dietary supplements in addition to those for foods and medicines/therapeutic goods. These "dietary supplements" in Australia could be regarded as foods or medicines/therapeutic goods depending on the nature of the product. Many products promoted to sports people such as drinks, powders, gels and bars that are regulated under NZDSR are regarded as foods in Australia. Those products not regarded as foods, would more likely be considered as therapeutic goods and be subject to the *Therapeutic Goods Act 1989* (Commonwealth).

The NZDSR define a dietary supplement as:

> *any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food*.

2.1.3.1 New Zealand Ministry of Health Proposal

The New Zealand Ministry of Health (NZMOH) is proposing to amend parts of the NZDSR that are now considered outdated and therefore no longer necessary. These include removing the upper limit for permissions for vitamin B12; increasing the current permitted levels of folic acid; and increasing the range of permitted intense sweeteners. The NZMOH is also proposing, a slightly later stage, to amend the current definition of dietary supplements to exclude foods regulated by Volume 2. If adopted, this proposal means that most sports foods currently manufactured under the NZDSR would be required to comply with relevant provisions of Volume 2.

The NZMOH is intending to release a consultation document on the first part of the amendments to the NZDSR early in the second half of 2001. Consideration of changes to the definition of dietary supplements is expected to coincide with the work that ANZFA is undertaking on the review of dietary supplements (P235). These changes will be considered as part of the development of the standard for sports foods (P236).

Clearly such a proposal could not be fully implemented until the results of this Proposal 236 are adopted and preferably, prior to the time that Volume 2 becomes the sole food regulatory instrument in effect in Australia and New Zealand. NZMOH is currently considering the future of the NZDSR, and in particular how to regulate those products covered by the NZDSR that are not considered to be foods.

2.2 Trans Tasman Mutual Recognition

The Trans Tasman Mutual Recognition Arrangement (TTMRA) came into effect on 1 May 1998 to promote trade between Australia and New Zealand. Under TTMRA, food that can be legally sold in one country, may be lawfully imported into the other country.

The Treaty related only to 'food standards' and as such dietary supplements were not considered to be covered by the scope of the Treaty. Following the commencement of TTMRA, however, those products complying with the NZDSR and not considered to be therapeutic goods (i.e. foods) under the *Therapeutic Goods Act 1989* could be lawfully imported from New Zealand into Australia and sold. Those products considered to be therapeutic goods under the *Therapeutic Goods Act 1989* must comply with all the requirements of that Act, irrespective of compliance with any laws in New Zealand. Currently, sports foods may not be manufactured in Australia in accordance with the NZDSR for sale in Australia.

2.3 International and World Trade Organization obligations

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by COAG requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the Treaty between the Governments of Australia and New Zealand on joint 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).

2.4 International and Overseas Standards

2.4.1 Codex Alimentarius

There are currently no Codex standards specifically related to sports foods, neither are any in preparation.

2.4.2 European Commission Directive

The European Commission has prepared a Council Directive on foodstuffs intended for particular nutritional uses. The Annex to Council Directive 89/398/EEC on foodstuffs intended for particular nutritional uses, as amended by Council Directive 1999/41/EC, lists the groups of foodstuffs for which specific provisions will be laid down by specific Directives. "Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen" is one of these groups.

For the preparation of this specific directive, the Report of the Scientific Committee on Food (SCF) on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen, was adopted by the SCF on 22 June 2000 and corrected by the SCF on 28 February 2001.

The report categorises the food products intended to meet the expenditure of intense muscular effort, especially for sports men as; **carbohydrate-rich energy food products**; **carbohydrate-electrolyte solutions**; **protein and protein components**; **supplements**; including **essential nutrients** such as vitamins, minerals and essential fatty acids, and **other components**, including caffeine, creatine, carnitine, medium chain triglycerides (MCT), and branched chain amino acids (BCAA). For each category of food product, composition and specification are recommended. The executive summary of the SCF report is given at Attachment 3.

2.4.3 United States

Many of the products marketed to sports people in the US such as drinks, powders, gels and bars, are positioned under the *Dietary Supplement Health and Education Act (DSHEA)* 1994.

The term "dietary supplement" is defined in the DSHEA as:

> "*A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders.*
> *They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special*

category under the general umbrella of "foods", not drugs, and requires that every supplement be labelled a dietary supplement."

The manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The US Food and Drug Administration (FDA) is responsible for taking action against any unsafe dietary supplement product after it reaches the market. There are no regulations that limit a serving size or the amount of a nutrient in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval.

By law, manufacturers may make three types of claims for their dietary supplement products: health claims, structure/function claims, and nutrient content claims. These claims describe respectively: the link between a food substance and disease or a health-related condition; the intended benefits of using the product; or the amount of a nutrient or dietary substance in a product.

2.5 Current Market

The sports food industry is rapidly expanding in Australia and New Zealand with the market for sports foods in both countries growing considerably during the last decade. A diverse range of products is available to consumers but the composition, labelling and advertising of these products is extremely varied and a number of them do not appear to fully comply with either country's regulations. Furthermore, under the present regulatory arrangements, many sports foods that are manufactured to New Zealand regulations do not meet the composition and labelling requirements of Standard R10 in Volume 1 or Standard 2.9.4 in Volume 2.

3 OBJECTIVES & POLICY

3.1 Objectives of Development of a Joint Regulation for Sports Foods

This is the first phase of the development of a joint Australia New Zealand regulation for sports foods. This Initial Assessment Report has been prepared to encourage and facilitate public comment on those issues that need to be considered in order to create a workable regulatory framework for sports foods that meets ANZFA's objectives.

The development of all food standard(s) in or intended for Volume 2 is predicated on fulfilling ANZFA's Section 10 objectives given below.

ANZFA's statutory objectives in developing food regulatory measures and variations of food regulatory measures

(1) The objectives (in descending priority order) of the Authority in developing food regulatory measures and variations of food regulatory measures are:
   (a) the protection of public health and safety; and
   (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
   (c) the prevention of misleading or deceptive conduct.

(2) In developing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
   (a) the need for standards to be based on risk analysis using the best available scientific evidence;
   (b) the promotion of consistency between domestic and international food standards;

(c) the desirability of an efficient and internationally competitive food industry;
(d) the promotion of fair trading in food.

The development of food standard(s) are also carried out in accordance with the competition policy principles which have been adopted by the Council of Australian Governments (COAG) and the draft Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to remove unnecessary obstacles to competition and an assessment of proposed regulation on all affected sectors of the community, and can be encapsulated in the phrase 'minimum effective regulation'.

The specific objectives for this Proposal are to:

1. Protect public health and safety in relation to the consumption of sports foods, particularly by ensuring safe levels of consumption and that vulnerable non-target groups are advised against inappropriate consumption.
2. Provide information to consumers to enable them to make informed choices about the consumption of sports foods and to prevent misleading conduct.
3. Develop consistent food regulations applying to sports foods between Australia and New Zealand.

Regulatory policies that have been previously developed which are relevant to consideration of sports foods include those underpinning the following standards:

- the addition of vitamins and minerals (Standard 1.3.2), botanicals (Standard 1.4.4), additives (Standard 1.3.1) and other substances;
- novel foods (Standard 1.5.1); and; other
- relevant standards, for example the [proposed] formulated caffeinated beverages.

3.2 Policy Framework Specific to Sports Foods

At the then NFA's 1995 Sports Food workshop, a set of principles was adopted upon which the future regulatory framework for formulated supplementary sports foods was founded. Those principles relevant to a future sports food standard were:

- simple and clear regulation;
- an inclusive workable definition for sports foods;
- safety, based on an assessment of risk to target and non-target groups;
- truth in labelling;
- validation of claims; and
- provision for innovation which benefits both industry and consumers.

The main public health and safety issues related to the composition of products sold as sports foods and the inappropriate use of some products by non-sports people and children. It was noted that many sports foods carried misleading claims or exaggerated labelling claims that could misinform consumers through implicit or explicit claims. Those claims often referred to muscle building and/or enhanced performance, endurance, recovery, provision of 'instant' energy; many of them appeared to be without substantiation.
Although ANZFA's highest priority was to protect the public health and safety of consumers, the agency recognised the need to provide for innovation in the food industry while ensuring that manufacturers did not engage in conduct that could mislead consumers or constitute deception or fraud.

In 1996, as part of the development of Standard R10 - *Formulated Supplementary Sports Foods*, ANZFA suggested that the regulatory framework for sports foods should be based on scientific risk assessment and be enforceable, meaningful and credible and it endorsed the following more detailed policy principles:

- sports foods are specifically formulated to assist sports people in achieving specific nutritional or performance goals, and as such, may be permitted to contain substances not permitted in general purpose foods;
- sports foods are intended as supplements to a diet rather than for use as the sole or principal source of nutrition;
- maximum amounts of nutritive substances should be set based on scientific risk assessments, and a cautionary approach in the absence of substantive evidence. Permissions for the composition of sports foods should be sufficiently liberal to allow them to function to help to maintain or improve the nutritional status of sports people but highly fortified products should not be covered by *food* regulation. For vitamins and minerals, this policy was implemented by setting a maximum of twice the Recommended Dietary Intake (RDI) or Estimated Safe and Adequate Daily Dietary Intake (ESADDI) or less where potential for toxicological problems or undesirable nutrient-nutrient interactions existed;
- certain substantiated claims could be permitted relating to physical performance and training;
- label advice, consistent with the assessed level of risk, should be required on all products that advised the target group about appropriate levels of consumption, and warned non-target at-risk groups against consumption, which for Standard R10 was children and pregnant women; and
- a prescribed name should be required to assist enforcement agencies.

QUESTION:

- Are these policy principles appropriate to underpin the development of joint regulation? Why or why not?

4 OPTIONS FOR REGULATION

There are four options for the regulation of sports foods. These are:

Option 1: Status Quo – Retain Standard R10 in Volume 1, and Standard 2.9.4 in Volume 2 to apply in Australia and New Zealand; retain relevant provisions of NZFR and NZDSR to apply in New Zealand. Retain current TTMRA arrangements; and do not proceed with NZMOH proposal to exclude foods from the scope of NZDSR.

Option 2: Full revised regulatory provisions within Volume 2; proceed with NZMOH proposal to exclude foods from the scope of NZDSR; and ultimately repeal relevant provisions of Volume 1 and NZFR.

Option 3: As for Option 2 except that full regulation in Volume 2 is replaced by co-regulation in Volume 2 and an industry code of practice.

Option 4: No overt recognition of sports foods within Volume 2 (generic provisions for mixed foods would only apply); proceed with NZMOH proposal to exclude foods from the scope of NZDSR; and ultimately repeal relevant provisions of Volume 1 and NZFR.

4.1 Affected Parties

The parties affected by this application are: **consumers**, including the target market of adults engaging in physical activity, adults who do not participate in physical activity, and children; **sports foods industry**, including New Zealand and Australian manufacturers, exporters to Australia and New Zealand including multi-national manufacturers, and New Zealand and

Australian importers; **governments** of New Zealand, the States and Territories and the Commonwealth of Australia; and **sports consultants and advisors**.

5 IMPACT ANALYSIS

There is a keen interest in the review of the sports food standard, primarily by New Zealand manufacturers of sports food-type dietary supplements, because of the draft NZMOH proposal to exclude foods from the definition of dietary supplements, and the limitations of the current Standard 2.9.4. There are also issues around inequity of trade because Australian industry cannot compete directly with New Zealand product manufactured under NZDSR. Also a proportion of sports food products are less than fully compliant with current regulations.

Option 1: Status Quo – Retain Standard R10 in Volume 1 and Standard 2.9.4 in Volume 2 to apply in Australia and New Zealand; retain relevant provisions of NZFR and NZDSR to apply in New Zealand. Retain current TTMRA arrangements; and do not proceed with NZMOH proposal to exclude foods from the scope of NZDSR.

Australian manufacturers would be required to manufacture in accordance with Standard R10 in Volume 1 or Standard 2.9.4 in Volume 2. New Zealand manufacturers would be required to manufacture according to Volumes 1 or 2, or the relevant New Zealand provisions in either the NZFR or NZDSR. Products manufactured in other countries and imported into either Australia or New Zealand would be required to comply with the prevailing standards in either country.

Although Standard 2.9.4 in Volume 2 regulates sports foods in Australia and New Zealand, and thus theoretically achieves the objective of harmonisation of regulations, it is not the sole source of regulation and has not yet undergone joint review. As currently drafted, Standard 2.9.4 is not widely supported in New Zealand given the more liberal approach to regulation of sports foods that already exists. Harmonisation would not be truly achieved until all relevant national food regulations are repealed.

Government

Advantages
No change required to enforcement in both Australia and New Zealand.

Disadvantages
Continued discrepancy between Australia and New Zealand food (and dietary supplement) regulations pertaining to sports foods.

Consumers/Sports advisors

Advantages
Readily available and wide choice of sports foods to interested consumers in both countries.

Disadvantages
Continuation of apparent consumer confusion over the marketing of sports foods in Australia [as dietary supplements] when some products are not permitted [for manufacture] in Australia.
Continued inconsistencies in labelling provisions for food sold under different regulatory regimes.
Increasing risks to public health and safety, as the Australian market for sports foods expands, from increased popularity of product and/or consumption by non-target groups.

Partial competition for New Zealand sports foods manufactured under the NZDSR would continue potentially resulting in higher prices for these products in both countries.

Industry

Advantages
New Zealand industry advantaged over Australia's through the ability to be more innovative in both countries and internationally than Australian manufacturers.

Disadvantages
Australian industry severely disadvantaged by not being able to manufacture and directly import into Australia as broad a range of sports foods as New Zealand industry can manufacture.

Overseas industry unable to import directly into Australia as broad a range of products as available and, where they comply with NZDSR, must enter such products via New Zealand.

Option 2: Full revised regulatory provisions within Volume 2; proceed with NZMOH proposal to exclude foods from the scope of NZDSR; and ultimately repeal relevant provisions of Volume 1 and NZFR.

The provisions related to labelling and composition of sports foods within Volume 2 would be revised in order to permit manufacture and import of sports foods under food regulation in both Australia and New Zealand. Subject to future ANZFA and New Zealand government action, revised provisions in Volume 2 would ultimately replace the current provisions for sports foods in Volume 1, and NZFR.

Government

Advantages
Harmonised food standards ensuring consistency of regulatory approach between trading partners.

Disadvantages
Enforcement burden and costs to Australia arising from implementation of a revised standard expected to be small, but potentially greater in New Zealand. if the resultant revised food standard is more restrictive than NZDSR.

Consumers/Sports Advisors

Advantages
More products available to interested consumers.
Greater consistency in regulatory provisions for products sold as foods, promoting more reliable information to consumers and more effective choices by consumers.
Appropriate controls over composition and labelling requirements enhancing their confidence in the product.

Disadvantages
None.

Industry

Advantages

Australian industry is able to compete equitably with New Zealand industry.

Disadvantages
Potential for reduced market innovation in New Zealand as food standard potentially more restrictive than current New Zealand dietary supplement regulations.
Possible lower growth in exports from New Zealand when joint regulation is in effect. However, New Zealand exports might not reduce in absolute terms, because the rapidly expanding market in Australia may be able to accommodate all suppliers.

Option 3: As for Option 2 except that full regulation in Volume 2 is replaced by co-regulation in Volume 2 and an industry code of practice.

Volume 2 would be amended to address compositional requirements for sports foods, whereas labelling and related aspects would be encompassed by a voluntary code of practice within each country. Enforcement responsibilities would be shared between government and industry.

Government

Advantages
Fewer burdens than full regulation.

Disadvantages
Likelihood of continued discrepancies arising from response to code of practice, between Australia and New Zealand.
The mix of government agencies and industry bodies that manage sports foods may cause confusion, lack of clarity about the regulatory objectives and lead to diminished public health outcomes.
Limited control over labelling of imports.

Consumers/Sports advisors

Advantages
Increased range of products would be available for interested consumers.

Disadvantages
Potential for increased range of sports foods on the market whose labelling may have been subject to lower levels of scrutiny.

Industry

Advantages
Less prescriptive than the full regulation of Option 2, resulting in lower compliance costs for business.
Greater control over some aspects, such as labelling and enforcement.
Can choose not to subscribe to code of practice.

Disadvantages
Increased responsibility and costs for implementation, management and enforcement, although overall compliance costs would be less than Option 2.
Potentially greater inequalities in trading as code of practice is voluntary.
Overseas manufacturers are not bound by code of practice, although their importing agents could be.

Option 4: No overt recognition of sports foods within Volume 2 (generic provisions for mixed foods would only apply); proceed with NZMOH proposal to exclude foods from the scope of NZDSR; and ultimately repeal relevant provisions of Volume 1 and NZFR.

Under this option there would not be any overt recognition of sports foods under food law in either Australia or New Zealand. Although this is an equitable situation, it also means that sports foods would be illegal foods or perhaps therapeutic goods or medicines since the necessary permissions for addition of nutritive substances, eg vitamins, would not be given in food regulation.

Advantages
This option achieves harmonisation, but does not permit currently formulated sports foods to be legally manufactured. It therefore stifles trade except perhaps for illegal importation of sports products to fulfil demand, which may put the health of the target group at risk.

Disadvantages
This option does not achieve the objectives of the Proposal as the product would be unable to be manufactured or imported. Furthermore, amendments to, or repealing of, the NZDSR would be required.

QUESTIONS:

- Which is your preferred regulatory option for regulating sports foods and why?
- For each option, what are the potential costs and/or benefits to you as a stakeholder? Do the benefits outweigh the costs?
  - What are the costs and/or benefits for consumers in relation to accurate and meaningful information, changes to food supply in response to criteria set for claims, potential for misleading consumers etc?
  - What are the costs and/or benefits for government in relation to administration, enforcement, public health and safety etc?
  - What are the costs and/or benefits for industry in relation to compliance, reporting and trade (fair trading) etc?
  - Are there any effects on international trade, import/export levels?

  Please provide quantitative data, where possible, to support your response.

In relation to industry as a whole, if a regulatory system other than full regulation was introduced:

- To what extent would the industry be prepared to be responsible for enforcement and monitoring of, for example, a code of practice?
  - What level of resourcing (funding and human resources) of enforcement and reporting arrangements could the industry sustain?
  - What level of resourcing of monitoring and reporting arrangements could the industry sustain?

6 ISSUES AND QUESTIONS RELATED TO THE DEVELOPMENT OF A JOINT APPROACH TO REGULATION OF SPORTS FOODS

The following issues and questions relate to the option of developing of a joint Australian and New Zealand food standard for sports foods.

6.1 Purpose of regulation

The purpose statements outlined in food standards are provided to clarify the scope and

regulatory parameters of the standard. The current statement in Standard 2.9.4 states:

> *"This Standard defines and regulates the composition and labelling of foods specially formulated to assist sports people in achieving specific nutritional or performance goals. Such foods are intended as supplements to a diet rather than for use as the sole or principal source of nutrition.*
>
> *Due to the particular physiological demands of sports people, this standard provides for the addition to formulated supplementary sports foods of certain micronutrients and other ingredients, which are not permitted to be added to other foods. This means that such products are not suitable for consumption by children."*

While sports foods are formulated to assist sports people in achieving specific nutritional or performance goals, an increasing proportion of the population are consuming sports foods for other reasons. Some of these reasons include convenience, and the perception that sports foods are scientifically formulated and therefore nutritionally well-balanced and useful in weight control diets or 'healthy' diets.

Also there is a large diversity of types of 'sports people' who may consume sport food products. Sports people can range from an elite athlete to someone who undertakes casual, or moderate forms of exercise.

Current policy states that, due to the particular physiological demands of sports people, sports foods may contain certain micronutrients and other such ingredients, which are not permitted to be added to other foods. In today's society, many people take sports foods for reasons other than a physiological benefit, such as convenience. Therefore, the policy framework for sports foods may need to also consider other requirements of sports people that relate to their rationale for choosing sports foods.

The appeal of sports foods to children is becoming an increasing concern. Children often see sporting heroes as role models and this can influence copy-cat behaviour. The marketing of some sports foods causes concern also. For example, drinks that are packaged in bottles with sipper tops are very popular with children and encourage consumption of those products. For the purpose of Standard 2.9.4, children are considered as those under 15 years of age.

QUESTIONS:

- Is the purpose of a Sports Food standard appropriately encompassed by the opening paragraphs in Standard 2.9.4?
- Should sports foods be formulated for reasons beyond physiological demands? If so, what other needs or wants should be considered?
- Should a sports food standard focus solely on the needs of sports people or consider possible consumption by other groups (for example; children, people wanting convenient products in a form ready for consumption)? If so, which groups and why?
- What other key features may need to be addressed?
- Should a sports food standard control the representation of sports foods that might inappropriately make them appeal to children? How could this be achieved?

6.2 Definition of sports foods

The definitions given in food standards are provided to define the nature of the product that is regulated by a standard. The current definition in Standard 2.9.4 is:

"*Formulated supplementary sports food means a food or mixture of foods specifically formulated to assist sports people in achieving specific nutritional or performance goals.*"

This very broad definition is founded on the intent of the manufacturer to create and market a sports food targeted to (therefore implicitly effective for) sports people in enhancing physical performance. There are few compositional controls on macrocomposition. These include the permission for a sports food to consist of a single ingredient as well as a mixture of foods. This permission to consist of a single ingredient has caused some uncertainty and confusion at the food/therapeutic goods interface in Australia because some single compounds are permitted in therapeutic goods, or even subject of declarations according to section 7 of the *Therapeutic Goods Act* 1989 that deem particular products or forms of products to be therapeutic goods. For example, the Australian Therapeutic Goods Administration made a declaration under section 7 of the *Therapeutic Goods Act 1989* (Commonwealth) that goods containing isolated HMB (β-hydroxy-β-methylbutyrate) or its salts, when presented in the form of powders, tablets, capsules or pills, are to be therapeutic goods. This action therefore prohibits addition of the listed forms of HMB to formulated supplementary sports foods, when presented as powders, tablets, capsules or pills. In contrast, creatine has not been the subject of a section 7 declaration and is permitted to be added to sports foods to a maximum quantity of 3g/day. Isolated creatine or creatine salts may be considered as therapeutic goods, depending on total presentation.

QUESTION:

- What is the most appropriate definition of a sports food?

6.3 Composition of Sports Foods

Australian and New Zealand food regulations treat nutritive substances in the same way as food additives in that they require explicit permission to be added to foods.

Volume 2 has defined a 'nutritive substance' to mean:
"*a substance not normally consumed as a food and not normally used as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentially added to a food to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides*".

Depending on how nutritional purpose is interpreted, this term could cover an extensive array of biological substances.

6.3.1 Micronutrients

Standard 2.9.4 permits addition of vitamins and minerals including electrolytes, sodium and potassium, amino acids and a small range of other nutritive substances. For all of these substances, the previous approach was to impose an (indirect) control of a maximum claim or (direct) control of a maximum amount depending on the level of risk. For vitamins and minerals, the maximum claimed amounts, and where set, the maximum absolute amounts, have been based on multiples of the RDIs or ESADDIs per one-day quantity. Water-soluble vitamins are permitted to a maximum claim of twice RDI/one-day quantity, whereas fat-soluble vitamins and some minerals are permitted to a maximum claim (and amount) of one RDI/one-day quantity. The maximum amounts of added essential amino acids are based on 50% of the estimated daily requirement of each amino acid for an adult. The permissions for added non-essential amino acids are based on 20% of the amount of each amino acid which would be consumed in a typical western diet containing 100 grams of protein derived from animal and plant sources. Upper limits are prescribed for total amount of sodium and potassium equivalent to the midpoint of their respective adult RDIs.

Market surveillance in New Zealand and Australia has identified many products that contain some of these nutrients at fortification levels greater that the permissions in Standard 2.9.4. For example some sports foods presented as bars contain particularly high levels of iodine, copper, zinc, folate and vitamin B6.

6.3.2 Other Substances

Standard 2.9.4 permits addition of a small range of other biologically active substances such as L-carnitine, choline, inosine, ubiquinones, creatine and gamma-oryzinol, each to a specified maximum amount per one-day quantity. These substances, some of which are now regarded as nutritive substances, were previously a permitted addition to sports foods because of their purported ergogenic functions. Such permissions were given on the basis that the substances were used in a number of products; they occurred naturally in some foods; there was some reasonable evidence of safety (or no evidence of harm); and/or that there was some evidence for their beneficial effects.

QUESTION:

- If the definition of 'nutritive substance' is applied to this standard, is it necessary for a definition of sports foods to exclude single-ingredient foods? If so, why?

Market surveillance has indicated that other ingredients are being added to sports foods in New Zealand and Australia such as oxygen, probiotics, colostrum, caffeine, HMB, phytochemicals and many botanicals which are legally permitted under the NZDSR.

6.3.3 Caffeine

Caffeine has been shown to produce an ergogenic effect in sports people however, Standard 2.9.4 does not permit caffeine to be added to sports foods because of the stringent controls on physiological caffeine levels in sports competition. Guarana – a caffeine-containing ingredient is added to some sports foods. This practice is not prohibited under Standard 2.9.4 by the virtue of sports foods being defined as a mixture of foods. Similarly, adding kola-based beverages as an ingredient to sports foods is another means of adding caffeine to sports foods.

QUESTIONS:

- Should the definition of nutritive substances be clarified to extend beyond a potentially narrow definition of nutritional purpose for the purposes of permitting added substances to sports foods? If so, how should that purpose be described?
- Should more nutritive (and other) substances be permitted additions to sports foods? If so, what criteria should be considered (for example safety, efficacy?)
- Is there a need to reappraise ANZFA's previous approach to risk assessment, particularly in the absence of evidence?
- Are there particular botanicals used in sports foods which are not prohibited or restricted under Standard 1.4.4, but which should be specifically regulated under Standard 2.9.4?
- Are there particular botanicals or other ingredients, which are currently added to sports foods, but are prohibited under Volume 2 of the FSC (for example Standard 1.4.4) that should be readdressed? If so, what evidence can be given to support this?
- Is caffeine an appropriate ingredient in sports foods? If so, why, from what sources,

6.4 Labelling of Sports Foods

6.4.1 Generic labelling standards of particular relevance to Sports Foods

Volume 2 FSC contains many generic labelling requirements that apply to all foods. Those of particular relevance to sports foods are:

Standard 1.2.3 – Mandatory warning and advisory statements and declarations. Sub-clause 2(1) states that the label on certain products must include an advisory statement to the effect that they are either unpasteurised (2), contain phenylalanine, quinine or caffeine (2).

Standard 1.2.8 – Nutrition information requirements applies to any standard in Volume 2 FSC unless specifically exempted. This standard sets out the conditions for making nutrition claims and declaring nutrition information on food labels, including mandating a Nutrition Information Panel on most manufactured foods.

Draft Standard 1.2.7 - Health and related claims about food has been recommended for adoption to the meeting of the Australia New Zealand Food Standards Council in late July. Under the draft standard, all current prohibitions on making prophylactic and therapeutic claims are retained. However, it is proposed that certain claims could be permitted if ANZFA was satisfied that the level of evidence for the claim was convincing and the agency had recommended the specific claim and appropriate foods bearing the claim for approval. This does not apply to nutrition claims, which are permitted providing the information is supported by scientific evidence to be held by the manufacturer and the labelling is not misleading or deceptive. The current prohibition on representations in Standard 2.9.4 that "*a sports food must not include an express or implied representation that relates to any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects*" may be redundant if Standard 1.2.7 is gazetted in the future.

All of these standards, except draft Standard 1.2.7, are contained within Volume 2 posted on ANZFA's website: www.anzfa.gov.au. Draft Standard 1.2.7 is found within the P153 Inquiry Report on health claims on ANZFA's website.

6.4.2 General Labelling Requirements of Sports Foods

Standard 2.9.4 sets out labelling provisions that apply to all sports food manufactured under the Standard. These provisions aim to either protect the health of consumers, and/or provide sufficient information to enable them to make informed choices. The first category includes mandated advisory statements about: the unsuitability of sports foods for children and pregnant women; the food should be used only under medical or dietetic supervision; the food is not the sole source of nutrition; and should be used by sports people as part of their training program. The second category covers directions for use; recommended one-day quantity; ingredient information including the percentage of the claimed ingredient, and nutrition content information.

6.4.3 Particular Labelling Requirements of Specific Types of Sports Foods

Standard 2.9.4 outlines additional specific labelling permissions for particular types of sports foods providing they conform to specific compositional criteria. The selected types are: high carbohydrate supplements; protein energy supplements; and energy supplements. The labelling included additional directions for use, and a range of permitted performance-related claims that was developed on the basis of scientifically-substantiated evidence for sports foods of specific composition to assist physical performance. These claims are permitted against a broader background of prohibition on representations that relate any property of proposed use of the food to enhanced athletic performance or beneficial physiological effect.

QUESTIONS:

- Is the labelling of products with general advisory statements that warn against consumption by vulnerable groups an appropriate risk management strategy for sports foods? Should other strategies also be adopted? If so, what other strategies are needed and why?
- Are the current advisory statements that warn against consumption by children less than 15 years and pregnant and lactating women, and which apply to all sports foods, appropriate in managing risk? Are there any other sub-groups of the population that should be generally warned against consumption of sports foods?
- Should such statements, if continued, be more tailored to particular compositional criteria? If so, why?
- Are there other substances, specific to sports foods, for which advisory or warning statements may be required? If so, what are the substances, and why are such statements necessary?
- What labelling statements are considered important for consumers to enable informed choice?
- Should sports foods be exempt from Standard 1.2.7 (if adopted) that proposes to regulate performance-enhancing claims, and therefore require prior submission of scientific substantiation before being used? If so, why?
- Should sports foods be exempt from the nutrition information requirements of Standard 1.2.8? If so, why?
- Is there a need for permitted labelling statements to be underpinned by compositional criteria for particular types of sports foods such as high protein, high carbohydrate, and energy supplements? Can these products be encompassed by general permissions within the standard or more broadly in Volume 2 FSC?
- Are there are any other general labelling issues that need to be considered for sports foods?

7 CONSULTATION

7.1 External Advisory Groups

In June 2001, ANZFA held external advisory group (EAG) meetings in Wellington and Sydney to discuss issues relating to both the policy and the specifics of the regulatory requirements for sports foods. Representatives from consumer bodies, public health, government and industry attended. Most delegates indicated their interest in participating in future meetings of the EAG as the Proposal is progressed after this Report has been released for public comment. The purpose of EAG will be to provide advice to ANZFA on issues of relevance to stakeholders raised by the review of food standards currently regulating sports foods in Australia and New Zealand.

This will include consideration of:

- policy principles underpinning development of future standards;
- implications for public health and safety;
- issues of interest and concern to consumers;
- impacts on manufacturers, distributors, importers and retailers;
- implications for enforcement; and
- issues relating to harmonisation between New Zealand and Australia.

7.2 Stakeholder Forums

Stakeholder forums will be held in both Australia and New Zealand following the review of

submissions from the first round of public comment and before the preparation of the next stage of the Proposal, the Draft Assessment Report.

7.3 Release for Public Consultation

The Initial Assessment Report will be released in August 2001 with a six-week consultation period. The views of the submitters will be incorporated into the development of the Draft Assessment Report. Further public comment will be sought on the Draft Assessment report in early 2002, which will include a proposed regulatory approach.

8 CONCLUSION

This Initial Assessment Report discusses several policy and specific issues in relation to regulating sports foods and raises several questions for which ANZFA seeks public comment. Responses to this Report will be used to develop the next stage of the Proposal, including drafting an appropriate response to jointly regulate sports foods in Australia and New Zealand.

9 INVITATION FOR PUBLIC SUBMISSIONS

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

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

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

Following its draft assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry, which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Proposal P236** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND

Tel (02) 6271 2222 Fax (02) 6271 2278 Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by: **3 October 2001**.

10 ATTACHMENTS

1. Standard 2.9.4, Volume 2, Food Standards Code
2. New Zealand Food Regulation 237
3. New Zealand Dietary Supplement Regulations
4. Executive Summary of Report of the Scientific Committee on Food on Composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen

Volume 2, Food Standards Code

STANDARD 2.9.4

FORMULATED SUPPLEMENTARY SPORTS FOODS

Purpose

This Standard defines and regulates the composition and labelling of foods specially formulated to assist sports people in achieving specific nutritional or performance goals. Such foods are intended as supplements to a diet rather than for use as the sole or principal source of nutrition.

Due to the particular physiological demands of sports people, this Standard provides for the addition to formulated supplementary sports foods of certain micronutrients and other ingredients which are not permitted to be added to other foods. This means that such products are not suitable for consumption by children.

Table of Provisions

Division 1 - Formulated Supplementary Sports Foods Generally

1 Interpretation

In this Code –

formulated supplementary sports food means a food or mixture of foods specifically formulated to assist sports people in achieving specific nutritional or performance goals.

one-day quantity in relation to formulated supplementary sports food, means the amount of that food which is to be consumed in one day in accordance with directions specified in the label.

2 Composition

A formulated supplementary sports food –

(a) may contain the vitamins and minerals specified in the Table to this paragraph provided that –

(i) the vitamin or mineral is added in a form listed in the Schedule to Standard 1.1.1 or in column 2 of the Schedule to this Standard; and

(ii) the amount of the vitamin or mineral in the food does not exceed the amount, if any, specified in column 3 of the Table; and

Table to Paragraph 2(a)

Column 1		**Column 2**	**Column 3**
Micronutrient		**Maximum claimed amount per one-day quantity**	**Maximum amount per one-day quantity**
Vitamin A		375 µg	375 µg
Thiamin		2.2 mg	
Riboflavin		3.4 mg	
Niacin		20 mg	
Folate		400 µg	
Vitamin B_6		3.2 mg	
Vitamin B_{12}		4.0 µg	
Vitamin C		80 mg	
Vitamin D		2.5 µg	2.5 µg
Vitamin E		20 mg	
Biotin		50 µg	
Pantothenic acid		3.5 mg	
Calcium		1600 mg	
Chromium :	inorganic forms organic forms	100 µg 50 µg	100 µg 50 µg
Copper:	inorganic forms organic forms	1.5 mg 750 µg	1.5 mg 750 µg
Iodine		75 µg	75 µg
Iron		12 mg	
Magnesium		640 mg	
Manganese:	inorganic forms organic forms	2.5 mg 1.25 mg	
Molybdenum:	inorganic forms organic forms	125 µg 62.5 µg	
Phosphorus		1000 mg	
Selenium:	inorganic forms organic forms	52 µg 26 µg	52 µg 26 µg
Zinc		12 mg	

(b) must not contain added amino acids as such, except for those specified in the Table to this paragraph, provided that the amount of the amino acid added to the food does not exceed the amount specified in column 2 of the Table; and

Table to Paragraph 2(b)

Column 1	Column 2
Amino Acid	**Maximum amount added per one-day quantity**
Alanine	1200 mg
Arginine	1100 mg
Aspartic acid	600 mg
Cysteine	440 mg
Glutamine	1900 mg
Glutamic acid	1600 mg
Glycine	1500 mg
Histidine	420 mg
Isoleucine	350 mg
Leucine	490 mg
Lysine	420 mg
Methionine	180 mg
Ornithine	360 mg
Phenylalanine	490 mg
Proline	1100 mg
Serine	1400 mg
Taurine	60 mg
Threonine	245 mg
Tyrosine	400 mg
Tryptophan	100 mg
Valine	350 mg

(c) may contain the ingredients listed in the Table to this paragraph added as such, provided that the amount of each ingredient added does not exceed the amount specified in relation to that ingredient in column 2 of the Table; and

Table to Paragraph 2(c)

Column 1	Column 2
Ingredient	**Maximum amount added per one-day quantity**
L-carnitine	100 mg
Choline	10 mg
Inosine	10 mg
Ubiquinones	15 mg
Creatine	3 g
Gamma-oryzinol	25 mg

(d) must not contain, in a one-day quantity, more than -

(i) 70 mmol sodium; or
(ii) 95 mmol potassium.

3 Required labelling statements

(1) The label on a package of formulated supplementary sports food must include statements to the effect that -

(a) the food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet; and
(b) the food should be used in conjunction with an appropriate physical training or exercise program.

(2) The label on a package of formulated supplementary sports food must include -

(a) directions stating the recommended quantity and frequency of intake of the food; and
(b) a statement of the recommended consumption in one day; and
(c) a nutrition information panel in accordance with Standard 1.2.8.

(3) The label on a package of formulated supplementary sports food must include, the statement -

'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'.

(4) If a formulated supplementary sports food contains added phenylalanine then the label must include, the statement -

'Phenylketonurics: Contains phenylalanine'.

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

4 Ingredient claims

(1) If the label on a package of formulated supplementary sports food refers to the presence of a particular ingredient, other than -

(a) vitamins or minerals; or
(b) in a statement required elsewhere in this Code;

the label must also include a statement of the amount by weight (expressed per 100g food or as a percentage) of the ingredient in that food either -

(c) immediately after the statement referring to the presence of the ingredient; or
(d) immediately following the name of that ingredient in the statement of ingredients.

(2) Subclause (1) does not apply if the nutrition information panel lists the particular ingredient and the average quantity by weight of the ingredient in -

(a) a serving of the food; and
(b) per 100g or 100mL of the food.

5 Vitamin and mineral claims

(1) The label on a package of formulated supplementary sports food must not claim the presence of a vitamin or mineral unless -

(a) the reference is required elsewhere in this Code; or
(b) the reference is specifically permitted by this clause.

(2) The label on a package of formulated supplementary sports food may only claim the presence of a vitamin or mineral in the food if -

(a) the food contains -

(i) at least 10% of the recommended dietary intake for that vitamin or mineral in a serving of that food or, in relation to a food which requires dilution or preparation according to directions, the quantity of the food which when diluted or prepared produces a normal serving; or
(ii) at least 10% of the amount specified in column 3 of the Schedule to this Standard for that vitamin or mineral in a normal serving of that food, or in relation to a food which requires dilution or preparation according to directions, the quantity of the food which when diluted or prepared produces a normal serving; and

(b) the amount claimed does not exceed the amount specified in column 2 of the Table to paragraph 2(a); and
(c) the label on the package of the food includes a statement in accordance with clause 9 of Standard 1.3.2.

6 Prohibition on representations

Unless specific permission is given in this Part, the label on a package of formulated supplementary sports food must not include an express or implied representation that relates to any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects.

Division 2 - Particular Formulated Supplementary Sports Foods

7 High carbohydrate supplement

(1) A high carbohydrate supplement is a formulated supplementary sports food for which -

(a) not less than 90% of the energy yield of the product is derived from carbohydrate; and
(b) more than 15% of the product by weight is carbohydrate when prepared as directed.

(2) The label on a package of high carbohydrate supplement must include statements to the effect that -

(a) if used during exercise, the food should be consumed in accordance with directions, to avoid the possibility of gastro-intestinal upset; and
(b) the food must be consumed with an appropriate fluid intake.

(3) The label on a package of a high carbohydrate supplement may include statements to the effect that -

(a) the product is useful either before, during and/or after sustained strenuous exercise; and
(b) appropriate usage may assist in the provision of energy in the form of carbohydrates.

8 Protein energy supplement

(1) A protein energy supplement is a formulated supplementary sports food for which -

(a) not more than 30 % and not less than 15% of the energy yield of the product is derived from protein; and
(b) not more than 25 % of the energy yield of the product is derived from fat; and
(c) not more than 70 % of the energy yield of the product is derived from carbohydrate.

(2) The label on a package of protein energy supplement must include a statement to the effect that the food must be consumed with an appropriate fluid intake.

(3) The label on a package of protein energy supplement may include statements to the effect that -

(a) the product may assist in providing a low-bulk diet as may be required during training; and
(b) the product may assist in supplementing the diet with a high energy source as may be required during training; and
(c) usage as directed may assist in the development of muscle bulk; and
(d) the product is useful either before, during and/or after sustained strenuous exercise.

9 Energy supplement

(1) An energy supplement is a formulated supplementary sports food for which not more than 20 % of the energy yield of the product is derived from protein.

(2) The label on a package of energy supplement must include statements to the effect that -

(a) if used during exercise, the food should be consumed in accordance with directions, to avoid the possibility of gastro-intestinal upset; and
(b) the food must be consumed with an appropriate fluid intake.

(3) If more than 30% of the energy yield of the energy supplement is derived from fat, the label on the energy supplement must include a statement to the effect that the product is a high fat food and should be used for special fat loading strategies rather than everyday use.

(4) The label on a package of energy supplement may include statements to the effect that -

(a) the product may assist in supplementing the diet with an energy source as may be required during training; and

(b) the product is useful either before, during and/or after sustained strenuous exercise.

SCHEDULE

Additional permitted forms and intake amounts for vitamins and minerals in Formulated Supplementary Sports Foods and in Formulated Meal Replacements

Column 1 **Vitamin or Mineral**	**Column 2** **Permitted forms**	**Column 3** **Amount**[1]
Biotin	d-biotin	100 µg
Pantothenic acid	d-calcium pantothenate Dexpanthenol d-sodium pantothenate	7 mg
Calcium	Calcium hydroxide Calcium oxide Calcium sulphate	800 mg
Chromium	*Inorganic forms:* Chromic chloride *Organic forms:* High chromium yeast Chromium picolinate Chromium nicotinate Chromium aspartate	200 µg
Copper	*Inorganic forms:* Cupric carbonate Cupric sulphate *Organic forms:* Copper gluconate Copper-lysine complex Cupric citrate	3.0 mg
Magnesium	Magnesium citrate Magnesium hydroxide	320 mg
Manganese	*Inorganic forms:* Manganese carbonate Manganese chloride Manganese sulphate *Organic forms:* Manganese citrate	5.0 mg

SCHEDULE (continued)

Additional permitted forms and intake amounts for vitamins and minerals in Formulated Supplementary Sports Foods and in Formulated Meal Replacements

Column 1 Vitamin or Mineral	Column 2 Permitted forms	Column 3 Amount[1]
Molybdenum	*Inorganic forms:* Sodium molybdate *Organic forms:* High molybdenum yeast	250 µg
Phosphorus	Magnesium phosphate, monobasic Phosphoric acid Potassium phosphate, dibasic Potassium phosphate, tribasic Sodium phosphate, dibasic Sodium phosphate, monobasic Sodium phosphate, tribasic	1000 mg
Selenium	*Inorganic forms:* Sodium selenate Sodium selenite *Organic forms:* Selenomethionine	70 µg

[1] The amount represents the recommended dietary intake for the permitted forms of calcium, magnesium, phosphorus and selenium and the estimated safe and adequate daily dietary intake for the remaining minerals listed in column 1 of the Schedule.

ATTACHMENT 2

New Zealand *Food Regulations 1984*

237. SPECIAL PURPOSE FOODS

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

(a) A particular physical or physiological condition; or

(b) A specific disease or disorder; or

(c) Both such a condition and a disease or disorder,--

and are presented as such.

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

(3) Special purpose foods shall include the following:

(a) Foods with modified composition:

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

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

(i) Infant formula [and follow-on formula]:
(ii) Supplementary foods for infants and young children:

(c) Meal replacements:

(i) Meal replacements for weight reduction diets:
[(ii) Medical nutritional products.]

[(d) Electrolyte drinks.]

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

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

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

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

(a) Any food conditioner specified in regulation 253(2) of these regulations:

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

[[(c) Flavouring:]
(ca) Spices:]

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

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

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

[(g) Subject to subclause (7A) of this regulation, vitamins and minerals as permitted in the normal counterpart of the food in accordance with the provisions of regulation 20A of these regulations.]

[(7A) Meal replacements and electrolyte drinks may contain vitamins and minerals in accordance with the provisions of regulation 20A of these regulations.]

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

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

(b) The energy content of the food.
{ Editorial Note: Until 1/1/95 label on "special purpose food" may comply with either r237(8) & (9) as substituted by, or r237(8)-(12) as revoked by, SR 1992/262. See SR 1991/262/129 in incorporated amendments. }

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

(10) Revoked.

(11) Revoked.

(12) Revoked.

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

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

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

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

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

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

ATTACHMENT 3

1985/208

[New Zealand]DIETARY SUPPLEMENTS REGULATIONS 1985

DAVID BEATTIE, Governor-General

ORDER IN COUNCIL

At the Government Buildings at Wellington this 19th day
of August 1985

Present:

THE HON. G.W.R PALMER PRESIDING IN COUNCIL

PURSUANT to section 42 of the Food Act 1981, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

ANALYSIS

REGULATIONS

1. **Title and commencement**-(1) These regulations may be cited as the Dietary Supplements Regulations 1985.

(2) This regulation, regulation 2, and regulations 4 to 11 of these regulations shall come into force on the 1st day of September 1987.

(3) Except as provided in subclause (2) of this regulation, these regulations shall come into force on the 1st day of September 1985.

2. **Interpretation**-(1) In these regulations, unless the context otherwise requires,-

"Batch" means a quantity of dietary supplement produced under essentially the same conditions during a particular period, and usually from a particular "line" or other identifiable processing unit:

"Common name", in relation to a dietary supplement, means the name by which the dietary supplement is generally known, being a noun defined in a dictionary of the English language of authority and repute in New Zealand to mean that kind of dietary supplement; and also means any expression containing such a noun: "Container" means any box, packet, or other receptacle in which 1 or more packages of dietary supplements are, or are to be , enclosed:

"Dietary supplement" means any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food:

"Foodstuff" means-

(a) Any food for which a standard is prescribed in any of the provisions of Part II of the Food Regulations 1984, except regulations 47, 51, 52, 54, 55, 73, 76, 196, to 200, and 202 to 204, whether or not the food is permitted by the relevant standard to contain a food additive:

(b) Any other food that does not contain a food additive other than an incidental constituent:

"Incidental constituent" means any extraneous substance, toxic substance, or pesticide that is contained or present in or on any food; but does not include any preservative, antioxidant, colouring substance, artificial sweetener, flavouring substance, food conditioner, anticaking agent, gaseous packing agent, propellant, or vitamin, or any mineral:

"Ingredient" means any substance, including a food additive (other than an incidental constituent), that is-

(a) Used in the manufacture or preparation of a dietary supplement; and

(b) Present, whether in a modified form or not, in the final product:

"Principal display panel" means the part of a label that is most likely to be displayed, presented, shown, or examined, under ordinary or customary conditions of display for retail sale; and, if such likelihood is equal in respect of 2 or more panels, means every such panel:

"Printed" includes written, typewritten, engraved, lithographed, or otherwise traced or copied.

(2) In these regulations, the symbols specified in the first column of the table to this subclause shall have the meanings specified in relation to those symbols in the second column of the table.

TABLE TO SUBCLAUSE (2)

Symbol	Meaning
g	grams
mcg	micrograms
mg	milligrams
mm	millimetres
ppm	parts per million

(3) In these regulations, unless the context otherwise requires, all references to proportions (whether percentages, parts per million, or otherwise) shall be references to proportions by weight in a dietary supplement as sold.
(4) Nothing in these regulations shall prohibit the use of any symbol the style of which conforms with a specimen in the table to subclause (2) of this regulation, or with the conventional usage of metric measurements.

PART 1
GENERAL REQUIRMENTS

3. **Maximum daily doses**-(1) Every dietary supplement described as or containing minerals or vitamins specified in the first column of the table to this subclause shall be so manufactured that each daily dose (for an adult) does not contain more than the maximum specified in the second column of the table.

TABLE TO SUBCLAUSE (1)

Dietary Supplement	Maximum Daily Dose (For Adult)
Minerals:	
Copper	5mg
Iron	24mg
Selenium	150mcg
Zinc	15mg
Vitamins:	
Vitamin A or retinol	3000mcg
Niacin (and salts) or nicotinic acid (and salts)	100mg
Vitamin B_{12} or cyanocobalamin or hydroxocobalamin	50mcg
Vitamin D	25mcg
Folic acid	300mcg

(2) Every dietary supplement described as or containing any mineral, other than a mineral specified in regulation 19 (1) of these regulations, shall be so manufactured that each daily dose (for and adult) does not contain more than the maximum specified in the current edition of *Recommended Dietary Allowances*, published by the Food and Nutrition Board of the National Academy of Science and National Research Council, Washington D.C., U.S.A

4. **Dietary supplements not to be sold unless properly labelled**-No person shall sell any package or container containing any dietary supplement, or any dietary supplement contained in a package or container, if the package or container-
    (a) Does not bear a label containing all the particulars required by these regulations to be contained on a label relating to such package or container; or
    (b) Bears a label containing anything that is prohibited by these regulations from appearing on a label relating to such package or container; or
    (c) Bears a label containing any particulars that are not in the position, manner, and style required by these regulations in respect of a label relating to such package or container.

5. **General requirements for labelling of dietary supplements**-

(1)Every package and container containing a dietary supplement shall, unless otherwise provided in these regulations, bear a label that includes the following:

(a) The common name of the dietary supplement, or a description (other than the brand name of the dietary supplement) sufficient to indicate the true nature of the dietary supplement, or a description of the dietary supplement including the common names of its principal ingredients:
(b) A statement of the net weight or Volume or number of the contents of the package or container, whichever measure is appropriate for retail sale of the dietary supplement concerned:
(c) The trading name and business address of the manufacturer or seller or packer of the dietary supplement , or of the owner of the rights of manufacture, or of the principal or the agent of any of them:
(d) A consumer information panel that complies with regulation 9 of these regulations:
(e) The words “DIETARY SUPPLEMENT”:
(f) A batch number:
(g) A date mark, being an expression in one of the following forms:
    i) Use by (followed by a date); or
    ii) Not to be consumed after (followed by a date); or
    iii) Words of similar meaning (followed by a date);- the relevant date in any case being no later than 5 years after the date of manufacture:
(h) A statement of the recommended daily dosage (for an adult) both as to quantity and frequency, which shall nor exceed the maximum daily dose permitted by regulation 3 of these regulations, and, if the dietary supplement is suitable for children, the recommended daily dose for children:
(i) A warning in any case where a danger exists if an overdose is taken:
(j) The method of preparation before use (where necessary).

(2)Notwithstanding paragraphs (f) and (g) of subclause (1) of this regulation, no container containing a dietary supplement need be labelled with the batch number or with a date mark.

(3)Notwithstanding subclause (1) of this regulation, where dietary supplements are packed in blister or strip packaging, the packaging shall be labelled with-

(a) The common name; and
(b) A batch number.

(4)For rhe purposes of subclause (1) © of this regulation,-

(a) A postal address, not being a telegraphic or code address or an address at a Post Office, shall be given:

(b) The name and address of a person who is not ordinarily resident in New Zealand shall not be sufficient unless the dietary supplement is wholly manufactured and packed outside New Zealand:

(c) In the case where that trading name is of a body corporate (whether registered inside or outside New Zealand), either the name of the town in which the body corporate has its registered office or the full postal address of the premises where the dietary supplement is actually manufactured or packed by the body corporate shall be given as the address.

(5)Where a package or container of a dietary supplement is enclosed or wrapped in a transparent covering and the particulars with which that package or container is required to be labelled are clearly visible through that covering, that covering shall be exempt from the labelling requirements under these regulations.

(6)No person who has in that person's possession any package or container of a dietary supplement intended for sale by retail shall-

(a) Remove any label required by these regulations to be on the package or container;

(b) Alter, erase, obliterate, or obscure any word or statement borne on such a label in accordance with any of the requirements of these regulations.

6. **Form and manner of labelling**-(1) Every word or statement that is required by these regulations to be borne on a label shall-

(a) Be conspicuously printed and, for each statement separately required, be in uniform colour contrasting strongly with a uniform background; and

(b) Be clearly, legibly, and durably marked either on the material of the package or container or on material firmly and securely attached to the package or container; and

(c) Be presented with continuity.

(2)The lettering of every word or statement required by these regulations shall be clear, distinct, and legible with no decoration, embellishment, or distortion that could interfere with the legibility of the words.

7. **Size of letters**- (1) The lettering of every word or statement required by these regulations to appear on labels shall be-

(a) All capital letters; or

(b) All lower case letters; or

(c) Lower case letters with an initial capital letter.

(2)In every case to which paragraph (a) or paragraph (b) of subclause (1) of this regulation applies, the height of the lettering shall be uniform in every word or statement that is separately required.

(3)In every case to which paragraph © of subclause (1) of this regulation applies, the height of the lower case lettering shall be uniform in every word or statement that is separately required.

(4)Except as otherwise provided in these regulations, the lettering of any word or statement required by these regulations to appear on labels shall be not less than 1.5mm in height, except where the package or container to be labelled is so small as to prevent the use of letters of that height, in which case letters of not less than 0.75mm in height may be used.

(5)The height of the lettering for the common name or description that is required by these regulations to appear in the principal display panel of a label shall be not less than one-third of the height of the largest lettering appearing in that panel, and-

(a) Not less than one-twentieth of the height of the label, in the case of a label that is no longer than twice the width of the label; and

(b) Not less than one-thirtieth of the height of the label, in any other case.

(6)For the purposes of subclause (5) of this regulation, the height of a label is the distance between the top and bottom of all printed or pictorial information on the label.

8. **Principal display panel**-(1) The particulars that are required by paragraph (a) and paragraph (b) and paragraph (e) of regulation 5 (1) of these regulations to appear on a label shall appear in the principal display panel.

(2)Every word or statement that is required by these regulations to appear in the principal display panel of a label shall be in the lines that are generally parallel to the base on which the package or container rests as it is designed to be displayed.

(3)In the case of a cylindrical package or container, the width of the principal display panel on the cylindrical surface shall not exceed one-third of the circumference of the package or container.

9. **Consumer information panel**- (1) The following information, when required by these regulations to be on the label, shall be grouped together in one portion of the label (that portion being called the consumer information panel):

(a) The statement of ingredients, which shall show-

(i) The quantities or proportions of the claimed active ingredients in the package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units, the quantity or proportion of the claimed active ingredients in each unit; and

(ii) The inactive ingredients in the package or container, which shall be described either by their specific names or by their class names, being any of the following permitted class names:

Antioxidants
Artificial sweeteners:
Colouring or colour:
Encapsulating or flavour:
Minerals:
Preservatives:
Tabletting aids:
Vitamins:

(b)The storage instructions (where appropriate).

(2)The consumer information panel may be any part of the label, but shall-

(a) Be conspicuously placed in relation to other information included on the label; and

(b) Be clearly differentiated from all other promotional material or illustrations.

10. **Misleading statements**- (1) No printed, pictorial, or other descriptive matter appearing on or attached to or supplied or displayed with any dietary supplement shall include any comment on, reference to, or explanation of any word, statement, or label required by these regulations to be borne on any dietary supplement if that comment, reference, or explanation either directly or by implication contradicts, qualifies, or modifies that word or statement or the contents of that label.

(2)No printed, pictorial, or other descriptive matter supplied or displayed with any dietary supplement shall include any false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion of the dietary supplement or of any ingredients of the dietary supplement.

11.**Therapeutic claims**- Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:

(a) Treating or preventing disease:
(b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:
(c) Altering the shape, structure, size, or weight of the human body:
(d) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.

PART II
SPECIFIC REQUIREMENTS

12.**Tabletting aids**- (1) In these regulations "tabletting aid" means a food grade substance that is added to a dietary supplement to constitute the form in which that supplement is sold; and includes an encapsulating aid.

(2)The following tabletting aids or encapsulating aids, and any other food conditioners specified in the Food Regulations 1984*, may be added to dietary supplements:

Alginic acid and its derivatives:
Beeswax:
Bone meal (sterilised); calcium phosphate:
Carbohydrate sweeteners:
Carnauba wax:
Cellulose and its derivatives:
Coating pigments:
Enteric coatings:
Gelatin:
Gelatin capsule shells:

Lactose:
Lecithin:
Light mineral oils:
Monoglycerides, diglycerides, and triglycerides from edible oils and fats:
Montan ester wax:
Pectins:
Polyethylene glycols:
Polyvinylpyrrolidone and its derivatives:
Shellac:
Silicic acid and its salts:
Talc (sterilised):
Vegetable gums:
Vegetable oils, and hydrogenated vegetable oils:
Xanthan gum:
Zein corn protein.

13.**Preservatives**-(1) In these regulations "preservative" means any substance that, when added to a dietary supplement, has the property of arresting or impeding fermentation, putrefaction, or decomposition.
(2)Dietary supplements may contain any of the following preservatives and no others:
Benzoic acid or sodium benzoate:
Parahydroxybenzoic acid and its esters:
Sorbic acid, or its sodium, calcium, or potassium salts:
Sulphur dioxide, or sulphites calculated as sulphur dioxide.

14.**Antioxidants**-(1) In these regulations "antioxidant" means any substance that, when added to a dietary supplement, has the property of arresting or retarding oxidative rancidity.
(2)Dietary supplements may contain any of the following antioxidants and no others:
(a) Propyl gallate, dodecyl gallate, octyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and tertiary butylhdroquinone (TBHQ), where the proportion of those antioxidants, singly or in combination, does not exceed 500ppm:
(b) Ascorbyl palmitate, and ascorbyl stearate, where the proportion of those
(c) Natural tocopherols, synthetic tocopherols, citric acid, and sodium citrate:
(d) Isopropyl citrate mixture, monoglyceride citrate, and phosphoric acid, where the proportion of those antioxidants, whether singly or in combination, does nor exceed 100ppm.

15.**Colouring substances**-(1)In these regulations "colouring substance" means any substance that, when added or applied to a dietary supplement, is capable of impairing colour to that dietary supplement.
(2)Dietary supplements may contain any of the colouring substances (and, where appropriate, their aluminium lakes) specified in the table to this subclause and no others.

TABLE TO SUBCLAUSE (2)

Common Name	Index Name	Index Number
Allura Red AC	CI Food Red 17	16035
Aluminium		77000
Amaranth	CI Food Red 9	16185
Annatto extracts (bixin, norbixin)	CI Natural Orange 4	75120
Anthocyanins		40800
Beet red (betanin)		
B-carotene	CI Food Orange 5	
B-apo-8'-carotenol	CI Food Orange 6	40820
B-apo-8'-carotenoic acid, and its ethyl		40825
And methyl esters	CI Food Orange 7	
Brilliant Black PN	CI Food Black 1	28440
Brilliant Blue FCF	CI Food Blue 2	42090
Brown HT	CI Food Brown 3	20285
Canthaxanthin	CI Food Orange 8	40850
Caramel		14720
Carmoisine (azorubine)	CI Food Red 3	
Chlorophyll	CI Natural Green 3	75810
Chlorophyll copper complex		75470
Chlorophyllin copper complex,		
potassium and sodium salts		
Cochineal (carminic acid)	CI Natural Red 4	
Erythrosine	CI Food Red 14	45430
Fast Green FCF	CI Food Green 3	42053
Gold		77480
Grape skin extracts		44090
Green S	CI Food Green 4	
Indigotine (indigo carmine)	CI Food Blue 1	73015
Iron oxides and hydrated iron oxides	CI Pigment Red 101&102	77491
	CI Pigment Yellow 42&43	77495
	CI Pigment Black 11	77499
Paprika (paprika oleoresin)		16255
(capsanthin and capsorubin)		
Ponceau 4R	CI Food Red 7	
Riboflavin (lactoflavin)		75100
Riboflavin-5-phosphate		
Saffron (crocin, crocetin)	CI Natural Yellow 6 & 19	
Silver		77820
Sunset Yellow FCF	CI Food Yellow 3	15985
Tartrazine	CI Food Yellow 4	19140
Titanium dioxide		77891
Turmeric (curcumin)	CI Natural Yellow 3	75300
Xanthophylls	CI Natural Yellow 27	75135

NOTE: The index numbers specified in the third column of this table are the numbers allotted in the current edition of the Colour Index published jointly by the Society of Dyers and Colourists of the United Kingdom and the Association of Textile Chemists and Colorists of the United States of America.

16. Artificial sweeteners-(1) In these regulations "artificial sweetener" means any substance that when added to a dietary supplement, is capable of impairing sweetness to that dietary supplement, and that is not a saccharide, polyhydric alcohol, or honey.
(2)Dietary supplements may contain any of the following artificial sweeteners and no others:
Aspartame:
Saccharin and its sodium, and calcium and ammonium compounds:
Sodium cyclamate and calcium cyclamate.

17.**Flavouring substances**-(1) In these regulations "flavouring substance" means any wholesome substance that, when added or applied to a dietary supplement, is capable of imparting flavours to, or enhancing flavours in, that dietary supplement.
(2)Dietary supplements may contain any flavouring substance, except the following:
Cade oil:
Coumarin:
Nitrobenzene:
Pyroligneous acid:
Safrole and isosafrole:
Sassafras oil.

18.Vitamins-(1) The dietary supplements specified in the first column of the table to this subclause, or any compound of those supplements, and no others, may be described as vitamins, and the quantity of vitamins in those dietary supplements shall be calculated in accordance with the second column of that table.

TABLE TO SUBCLAUSE (1)

Dietary supplement described as vitamins or containing vitamins	Calculated as
Vitamin A or retinol	retinol in mcg
Vitamin B_1 or thiamine	thiamine in mg
Vitamin B_2 or riboflavin	riboflavine in mg
Niacin or nicotinic acid	niacin equivalents in mg
Pantothenic acid	pantothenic acid in mg
Vitamin B_6 or pyridoxine	pyridoxine in mg
Vitamin B_{12} or cyanocobalamin, or hydroxycobalamin	vitamin B_{12} in mcg
Vitamin C or ascorbic acid	ascorbic acid in mg
Vitamin D or calciferol	calciferol in mcg
Vitamin D or cholecalciferol	cholecalciferol in mcg
Vitamin E	vitamin E in mg
Biotin	biotin in mcg
Vitamin K	vitamin K in mcg
Vitamin K_1 or phytomenadione	vitamin K_1 in mcg
Vitamin K or menaphthone	vitamin K in mcg
Folic acid	folic acid in mcg

(2)If the quantity of vitamins in a dietary supplement is declared on a label, it shall be stated to an accuracy of not greater than 3 significant figures.
(3)There may be marked on any package or container containing a dietary supplement, described as or containing a vitamin, a statement indicating-

(a)The presence of vitamins; and

(b)The quantity, calculated in accordance with the table to subclause (1) of this regulation, of that vitamin in that package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units, the quantity of that vitamin in each unit.

19.Minerals-(1) The following dietary supplements may be described as minerals:
Calcium:
Chlorine:
Chromium:
Copper:
Fluorine
Iodine:
Iron:
Magnesium:
Manganese:
Molybdenum:
Phosphorus:
Potassium:
Selenium:
Sodium:
Zinc.

(2)If the quantity of minerals in a dietary supplement is declared on a label, it shall be stated in milligrams or micrograms to an accuracy of not greater than 3 significant figures.
(3)There may be marked on any package or container containing a dietary supplement described as or containing a mineral, a statement indicating-

(a)The presence of minerals; and

(b)The quantity of that mineral in that package or container or in each dosage unit, where the dietary supplement is divided into a number of units the quantity of that mineral in each unit.

20.Enzymes-The following enzymes may be added to dietary supplements:
Amylase and protease derived from *Aspergillus flavus oryzae* or *Aspergillus niger*:
Bromelin:
Ficin:
Invertase:
Papain:
Pectinase:
Pepsin:
Rennet and protein-coagulating enzymes:
Lactase:
Lipase.

PART III
OFFENCES and PENALTY

21.Offence**s and penalty**-(1)Every person who contravenes of fails to comply with any of the provisions of regulations 3, 4, 5(6), 13(2), 14(2), 15(2), 16(2), 17(2) and 18(1) of these regulations commits an offence against these regulations.
(2)Every person who commits an offence against these regulations is liable to a fine not exceeding $500, and, in the case of a continuing offence, to a further fine not exceeding $50 for every day on which the offence has continued.

P.G Millen,
Clerk of the Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, in a sense, fill the gap between the Food Regulation 1984 and the Medicines Regulation 1984, in that dietary supplements are not "food" or "medicine" in the ordinary sense of those words. However, they are "food" within the meaning of the Food Act 1981, and will be "related products" within the meaning of the Medicines Act 1981 if therapeutic claims are made for them.

Part I prescribes certain general requirements relating to the manufacture, labelling, and advertising of dietary supplements, and follows broadly the equivalent provisions of Part I of the Food Regulations 1984.
Part II prescribes certain specific requirements relating to food additive standards in respect of certain classes of dietary supplements.

Issued under the authority of the Regulations Act 1936.
Date of notification in *Gazette*: 22 August 1985.
These regulations are administered in the Department of Health.

THE DIETARY SUPPLEMENTS REGULATIONS 1985, AMENDMENT NO. 1

Paul Reeves, Governor-General

ORDER IN COUNCIL

At Wellington this 19th day of December 1986

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to section 42 of the Food Act 1981, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

REGULATIONS

1.Title and commencement-(1) These regulations may be cited as the Dietary Supplements Regulations 1985, Amendment No.1, and shall be read together with and deemed part of the Dietary Supplements Regulations 1985 (hereinafter referred to as the principal regulations).
(2) These regulations shall come into force on the 1st day of January 1987.

2.Commencement of principal regulations-(1)Regulation 1 of the principal regulations is hereby amended by revoking subclauses (2) and (3), and substituting the following subclauses:
"(2) Regulations 2 and 4 to 11 of these regulations shall come into force on the 1st day of September 1987."
"(3) Except as provided in subclause (2) of this regulation, these regulations shall come into force on the 1st day of January 1987."

P.G MILLEN,
Clerk of the Executive Council.

EXPLANATORY NOTE
This note is not part of the regulations, but is intended to indicate their general effect.

These regulations relate to the commencement of the principal regulations. Because of a drafting error in regulation 1(2) of those regulations, it appears that none of the provisions of the principal regulations have yet come into force.
These regulations provide that the principal regulations will come into force on 1 January 1987, except those provisions that relate to labelling. They will come into force on 1 September 1987.

Issued under the authority of the Regulations Act 1936.
Date of notifications in *Gazette*: 22 December 1986.
These regulations are administered in the Department of Health.

ATTACHMENT 4

REPORT OF THE SCIENTIFIC COMMITTEE ON FOOD ON COMPOSITION AND SPECIFICATION OF FOOD INTENDED TO MEET THE EXPENDITURE OF INTENSE MUSCULAR EFFORT, ESPECIALLY FOR SPORTSMEN

Executive Summary

Council Directive 89/398/EEC on foodstuffs intended for particular nutritional uses, as amended by Council Directive 1999/41/EC, foresees the adoption, by the Commission, of a specific directive on foodstuffs for particular nutritional uses intended to meet the expenditure of intense muscular effort and especially for sportsmen. In order to prepare this specific directive the Commission asked the Scientific Committee for Food (SCF) for advice on the nature, the essential composition where necessary, and any other specific requirements concerning the labelling and the appropriate use of such foodstuffs.

The Committee reviewed the scientific literature in the area of sport nutrition as well as a number of consensus reports that were prepared by various sport organizations and came to the conclusion that the concept of a well-balanced diet is the basic nutritional requirement for athletes. Nevertheless, taking the aspects of intense muscular exercise in consideration such as intensity, duration and frequency as well as specific constraints like time and convenience, individuals can benefit from particular foods or food ingredients beyond the recommended dietary guidelines for the general population.

As the increased energy needs of these individuals is the most apparent difference, the food intake is higher. This can lead to differences in food choice and eating pattern as well as gastro-intestinal distress. Specially adapted nutritious foods or fluids may help to solve specific problems so that an optimal nutritional balance can be reached. These beneficial effects are not only limited to athletes who are taking part in regular intense prolonged muscular exercise, but are also intended for other target groups, for example for occupational jobs with hard physical work or with extreme environmental conditions, as well as for individuals with irregular physical high intensity or fatiguing leisure activities.

In relation to these general considerations, four food categories have been identified, reviewed and where applicable, essential requirements were formulated.

- Carbohydrate-rich energy food products

Consensus has been reached about the essential role of carbohydrate intake in relation to physical performance during all types of exercise, generally lasting longer than one hour. This knowledge is based on the importance of increased body glycogen stores in liver and muscle for sustaining prolonged heavy exercise, as well as the direct relationship between the level of carbohydrate intake and the resynthesis of muscle glycogen after exhausting exercise.
Ad libitum eating during 24 h after prolonged heavy exercise may lead to an inadequate intake of energy, especially carbohydrates and consequently, a sub-optimum recovery. Therefore when athletes have only 24 h to recover from prolonged heavy exercise, optimal carbohydrate intake should be guaranteed by specific instructions regarding the timing and choice of carbohydrate intake by food and/or carbohydrate rich food products. High glycaemic index carbohydrate foods are recommended and they should provide 10g per kgbw during the 24 h recovery. The refuelling should begin immediately after the exercise bout

when athletes should consume up to 1 g/kgbw of carbohydrate and then about 0,5 g/kgbw at hourly intervals until the next meal, which should be made up of high glycaemic index carbohydrate foods.
In this respect all types of bio-available carbohydrates that increase blood glucose concentration effectively are suitable. Besides the high carbohydrate/low fat dietary guidelines, especially developed carbohydrate-rich energy food products can be of benefit in reaching an adequate carbohydrate intake

- Carbohydrate-electrolyte solutions (C.E.S.)

The two factors that have been considered to contribute most to the onset of fatigue in exercise are the depletion of the body's carbohydrate reserve and the onset of dehydration, as a consequence of the loss of water and electrolytes in sweat.
Compared to water as a control drink, a substantial body of scientific evidence supports the suggestion that during prolonged exercise drinks containing carbohydrates and electrolytes, in particular sodium, improve performance.
The optimum carbohydrate concentration in the drink depends on a number of factors, among others the need for water (hot/cold conditions) and the intensity and type of exercise (gastro-intestinal absorptive capacity, osmolality (rate of gastric emptying as well as water absorption in the small intestine), type of carbohydrate simple vs polymers). The only electrolyte added to drinks consumed during exercise that is known to confer physiological benefit is sodium. A sodium concentration of 20-50 mmol/l (460-1150 mg/l) will stimulate carbohydrate and water uptake maximally in the small intestine and will help to maintain extracellular fluid Volume. The evidence to support the inclusion of other components as essential ingredients, is not at present convincing.

- Protein and protein component

Athletes continue to believe, as did the Olympians of antiquity, that extra protein intake is essential for maximal performance. There is not much scientific evidence available to support this.
Endurance athletes have a modest increase in protein requirements and, therefore, the recommended daily intake is increased to 1.2 – 1.4 g per kgbw per day. A diet containing 10 – 11% En protein meets this modest increase, as the daily energy needs may be two to three fold higher than those of non-athletic subjects. The use of protein-carbohydrate solutions or protein-carbohydrate rich solid food products in the post-exercise period may help to rapidly re-synthesise glycogen stores that were lost during the exercise.
The protein requirement for strength athletes, who have trained for years, is not higher than 1.0 to 1.2 g per kgbw per day. Novice athletes involved in strength training programs have marginally higher protein requirement and their recommended intake is therefore increased to 1.3 to 1.5 g per kgbw per day. A diet containing 10 – 12% En protein of mixed quality may not contain enough protein to meet this temporary need if the total energy intake is relatively low. In addition there is no scientific evidence at all for further increases in protein intake with protein supplements to levels of 3 – 6 g per kgbw per day, as frequently occurs in practice. Also the use of supplements of free amino acids has no beneficial effects on the whole body and protein synthesis when compared to the use of a balanced protein in a mixed meal.

- Supplements

For micronutrients there is a scientific consensus that with an adequate dietary intake, there is no further need for additional supplementation for essential micronutrients such as minerals, trace elements and vitamins. In the case of restricted food intake, as is frequently observed in weight related sports, micronutrient intake could become marginal or deficient, which would justify supplementation. Intake of a number of minerals and vitamins such as magnesium, calcium, zinc and the anti-oxidants vitamins C, E as well as carotenoids, have been suggested to be critical in relation to physical performance. So far, scientific evidence is lacking or inconsistent in supporting recommendations for nutritional intakes beyond the accepted dietary guidelines. The upper safe levels of vitamin- and mineral intake area t present under the consideration of the SCF and have not been reviewed in this report.
Finally, a number of food components have been reviewed since they are often related to physical performance. So far, only for caffeine and creatine is there scientific data to show that they have an ergogenic effect. For caffeine, levels of 3 to 8 mg/kgbw improve short-term high intensity exercise as well as endurance performance. Creatine intake levels of 2 – 3 g per day have been shown to be effective in increasing total muscle creatine and in improving performance of a short term high intensity exercise.

The committee wishes to stress that this report is dealing with the physiological needs and appropriate uses of food and food ingredients to meet the expenditure of intense muscular effort. The safety aspects of high level of intake of certain compounds such as free amino acids are not taken into consideration. Upper safe levels of vitamin and nutrient intakes are at present under consideration of the SCF. The committee has adopted opinions on the safety of caffeine in the past (Opinion on caffeine, taurine and D-glucurono- gamma –lactone as constituents of so-called “energy” drinks, expressed on 21 January 1999). The Committee considers the safety aspects of creatine supplementation in a separate report.