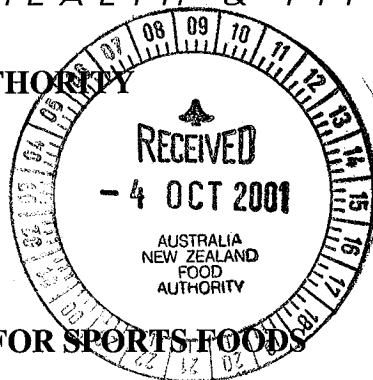


ACKNOWLEDGED

**ENTERED IN
DATABASE**

NUTRA·LIFE
HEALTH & FITNESS

**TO: AUSTRALIAN AND NEW ZEALAND FOOD AUTHORITY
ANZFA
P.O. 10-559
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**SUBMISSION IN RESPECT TO
PROPOSAL P236**

DEVELOPMENT OF JOINT FOOD REGULATIONS FOR SPORTS FOODS

Introduction:

The increasing concerns and restrictions on the use of illegal substances within sports and by sportspeople as a means of improving performance has meant much greater emphasis is now placed on training and diet as a means to achieving, higher, faster, further, heavier etc results.

This has been reflected in the burgeoning growth of specialised nutritional supplement products, used by serious athletes in particular but other sportspeople as well, as part of their diet, and are intended to help them achieve their specific nutritional or performance goals.

In fact, some sports nutritional products are used not only for their value in achieving performance objectives but because of their convenience as well.

These specialised products can be regarded as 'foods' in that they form part of the 'diet', but in our opinion they do not entirely fit the general definition of foods, and any attempt to develop specific standards is likely to limit their availability and usefulness to the very sportspeople they are designed to assist.

Sports nutritionals are used for a specific purpose, require specific labelling and may contain ingredients not normally found (or permitted) in 'normal foods'.

In some cases they will not be suitable for consumption by children or other sectors of the community. In these situations, labels may need to carry warnings and/or specific dosage/usage details.

It is clear from a review of the products currently available on the market in New Zealand and Australia that very few products comply with the current standard (R10 or Standard 2.9.4) in terms of ingredients, formats or labelling. However, most would meet the NZ Dietary Supplements market Regulations.

This suggests that the current Australian standard does not meet the demands of the market.

The current standards are extremely limited and as an example makes no mention of sports bar products which are an increasing segment of the market, and in New Zealand, these products would have to be sold as Dietary Supplements under the Dietary Supplements Regulations 1985, which in view of the proposals for Trans Tasman Harmonisation may be repealed.

As manufacturers we believe that part of the problem of non-compliance is because the current standard is far too prescriptive and takes little or no account of the realities of the market place, and the demands of the consumers of these products, who are driven by a desire to succeed and who

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want to benefit from the increasing research that shows these special dietary supplements can materially affect their desired outcomes, and essentially pose no risk when used as directed.

Unless this issue is addressed, we believe sportspeople will look to outside sources for products many of which may not have the hygiene and other safety controls in place imposed on New Zealand and Australian manufacturers.

More importantly perhaps, in their quest for increased performance, some athletes will turn to illegal substances, and bring themselves and their sport into disrepute.

In terms of its prescriptiveness, the current standard in Division 2 attempts to define several items, including 'High Carbohydrate Supplement', 'Protein Energy Supplement' and 'Energy Supplement'.

In fact these definitions bear little relationship to those products currently on the market, and that have been used by sportspeople and others for many years, with no apparent problems.

Adherence to these standards would certainly alienate manufacturers and consumers alike, and the current review of products on the market confirms the products on the market that might be covered by 'classifications', lie well outside the restrictive levels proposed by these regulations, yet are meeting consumers demands, and have not produced any apparent problems.

Recommendations:

Presently, in terms of the impact analysis we support the recommendations outlined in Option 1, to retain the status quo and retain Standard R10 in Volume 1 and Standard 2.94 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.

However, we believe it is essential to broaden the scope of the regulations to encompass both the current and future technologies in order to avoid the tedious and counter-productive processes associated with establishing new standards. Research in the field of sports nutritionals is moving at an accelerating rate, and with the advent of the immediacy of electronic media, and product through the internet, sportspeople and their coaches expect to have immediate access to new advances in formulations and format.

Sports Nutritionals - Definition

We believe that sports 'foods' are more correctly defined 'Sports Nutritionals', and more akin to dietary supplements since they are not intended as the sole source of nutrition.

We submit, a more appropriate definition that 'formulated sports foods', would be "Sports Nutritional Products", as suggested below;

Sports Nutritionals are those specially formulated products intended to supplement the diet of athletes and sports people.

They are specifically labelled as to their purpose and use and are not intended as the sole source of nutrition.

They will be labelled with appropriate warnings, where there is an established risk produced by overuse or use by a specific group (such as children or pregnant women).

They may be in powder, liquid or solid food form and contain combinations of any of the following;

Carbohydrates, protein, lipids, amino acids, vitamins, mineral salts, foodstuffs, synthetic nutrients and herbals, intended to supplement the diet of sportspeople.

They may also include approved colours, processing aids (including preservatives, antioxidants etc) flavourings, artificial sweeteners and any other agents that might be found or allowed in foods for human consumption.

NOTE: This will specifically exclude products presented in a traditional pharmaceutical form, such as tablets and capsules.

There should be no specific standard for Energy Supplements, Protein Energy Supplements or High Carbohydrate Supplements, since the market will decide what they interpret as representing these items.

The permitted levels of ingredients should not exceed the 'Maximum Daily Dose', for those substances where an MDD has been established.

There should be a 'negative' list that defines the ingredients that cannot be used in Sports Nutritionals, and this list would include prohibited herbs as defined by the TGA list.

Any ingredient approved for use in a dietary supplement or a Listable Medicine should be allowed in a sports nutritional product, provided the total daily intake does not exceed the total daily intake defined in any regulation relating to that ingredient that permits its general sale.

Other ingredients should be permitted up to their MDD.

In the case of any ingredient where there is an established risk, but is considered to be an important ingredient in the sports nutritional product concerned, then the total daily intake shall not exceed 35% of the Lowest level at which adverse affects were observed. (LOAEL)

Items on the GRAS list can be included in Sports Nutritional Products.

In cases where there is the possibility of risk associated with excess usage of ingredients, the total number of serves per pack would provide additional safety checks.

QUESTIONS & ANSWERS:

The body of Proposal P236 requests our input on a variety of questions.

1. ,Which is your preferred regulatory option for regulating sports foods and why?

Option 1 subject to variations which would eventually result in a Sports Nutritional Products standard without the prescriptiveness of R10 or 2.9.4, and allow for the inclusion of other forms of sports nutritional products, but not include those in an established pharmaceutical forms such as tablets or capsules.

This would allow for the rapid accession of new technology and avoid the necessity for New Zealand and Australian athletes to seek product from offshore sources by direct import and the internet.

2. For Each Option what are the potential costs/and or benefits to you as a stakeholder?

Currently we export to some 25 countries, and we need to take account of their individual requirements in respect to ingredients and labelling etc. The establishment of a single framework of legislation for Australia and New Zealand would mean common labelling and formulations between both countries, but in order to meet the market as it stands, and to allow for the changing environment in sports nutritional products, the current prescriptive elements of the standard would need to be repealed.

We live in an age where access to information has become immediate through electronic and other means is greater than at any time in mankind's history.

Whilst there will always be those who seek to mislead, both New Zealand and Australia have legislation and severe penalties related to false claims and advertising. The proof is always in the pudding and those products that do not perform to the consumer's expectation do not survive.

Public health and safety is as much a concern for responsible manufacturers as it is for governments and regulators. Harming one's customers is a sure way to fail! Yet in the many years sports nutritional products have been available in both New Zealand and Australia, we have received no information to indicate that there have been problems or that users have suffered ill-effects or been placed at risk.

Industry has a responsibility to comply with the laws and regulations and compliance simply represents a cost of doing business. However, we believe that regulation should be confined to the achievement of agreed objectives, and we perceive these to be health and safety in regard to sports nutritional products in terms of the development of a standard to cover them.

We see the benefits of a co-regulatory arrangement between the regulators and industry with a high level of self-policing within industry and the establishment of a code of practice which requires the support of all manufacturers of these products, covering quality, Good Manufacturing Practice, and truth in advertising.

Currently, many manufacturers, importers or distributors are members of an industry body and this could be made mandatory for those who wish to produce or market such products.

In the case of sports nutritional products that include high levels of dairy-sourced materials, manufacturers such as ourselves are licensed by MAF, and subject to regular HACCP audits and have extensive environmental testing programmes and quality control systems that ensure the quality and safety of our products.

Export of some sports nutritional products is subject to certification and other documentation from government departments and authorities to confirm the source of materials and other quality and safety issues.

There is a significant cost for aspect of compliance and some manufacturers have also made substantial investments in plant and personnel to guarantee the quality of their products.

3. Is the Purpose of the Sports Food Standard appropriately encompassed by the opening paragraphs in Standard 2.9.4.

We believe that in the context of what ANZFA perceives as the purpose and use by sports people of these foods, then it does encompass the purpose of the standard.

4. Should sports foods be formulated for reasons beyond physiological demands. If so what other needs or wants should be considered.

Without a definition of 'physiological demands', it is difficult to answer this question. However, there are a number of aspects that relate to the use of these products, including convenience of use, and preferences related to taste and other factors.

The very existence of these products acknowledges that sportspeople who are asking more of their bodies than the more sedentary sectors of the community, have a higher physiological demand. It would create a major problem for industry if it were deemed necessary to segment the market for these products by defining specific target products designed only for cyclists, or triathletes or marathon runners, body builders, kayakers, sprinters, footballers, netballers etc.

It would also confuse the users of these products as well.

No such segmentation has been generally applied to other food products, except in regard to age groupings where different nutritional requirements have been established.

5. Should a sports foods standard focus solely on the needs of sportspeople 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?

By definition these products are designed for and intended for use by sportspeople, for the purpose defined.

There are many convenience foods available for use by people and groups who do not fit the definition of 'athlete' or 'sportsperson', making it unnecessary for products classified as 'sports nutritionals' to cater for other groups.

6. What Other Key features may need to be addressed?

Labelling in particular is particularly important and the intended use should be clear to the consumer.

Because of the ingredients used in sports nutritionals, many of which will not be present in commonly available foods, full details of the ingredients and the amount present, together with the recommended daily use, along with any advisory statements or warnings, and an approximate nutritional analysis must be shown on the labelling.

7. Should a sports food standard control the representation of sports foods that might inappropriately make them appeal to children. How could this be achieved?

These products are not intended for use by children and a statement to this effect could be included on the label, as currently required by the present standard.

However, we recommend that the current age limit of 15 years be abolished, and that the statement simply says;

NOT SUITABLE FOR CHILDREN,

If preferred **'WITHOUT PROFESSIONAL ADVICE'** could be added.

Product representations, illustrations etc, should be limited to sportspeople and avoid references to a family situation or children, unless the product is considered suitable for family use.

8. What is the most appropriate definition of a sports food?

The term 'Sports Nutritional Product' more accurately describes the type of product since many products used by sportspeople to supplement their diet do not necessarily fit the accepted definition of 'food', and yet are not in a pharmaceutical format or considered to be low-risk (listable) medicines.

9. Other Substances.

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?

No, because by definition, a single nutritive substance would be used by sports people for the same purpose as more complex combinations. However, single nutrients should only be available in a food format such as a powder.

In most cases, the synergistic effects of multiple nutrients would be preferred by sportspeople.

However there will be instances when extra amounts of a specific nutrient such as whey protein isolate will be required by the consumer to supplement the diet and the availability of this material should not be adversely affected by any definition or regulation simply because it is a 'single nutritive substance'.

10. 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?

Yes. Substances such as L-Carnitine, Creatine Monohydrate, Hydroxy Methyl Butyrate (HMB) and Ribose, Keto-isocaproate and others are used to by athletes to supplement their diets.

Their nutritional purpose represents a link in a biochemical chain rather than a source of energy provided from traditional food elements such as carbohydrates, lipids and proteins.

In defining the purpose for these nutritive substance there is research to justify their inclusion in the diet.. e.g Creatine monohydrate plays an important role in the ATP energy shuttle.

L-Carnitine and its salts are primary transporters of long chain fatty acids across the mitochondrial membranes.

Ribose is a precursor to the formation of nucleotides and through adenosine to ATP.

General Comments:

Safety Primary Concern – Where There Is An Established Risk

Safety should be the primary concern covering the inclusion of any substance to sports foods.

It is important to remember however that in the main, these products will be used mostly by healthy and fit people who see the inclusion of these items in the diet as a means to improve their physical response rather than to treat some medical condition.

There are now several risk assessment models in use within industry, and experience to date has not produced real evidence that these products or the substances now considered important additions to them, have created health problems, or pose any real risk, when used sensibly and in line with the manufacturer's recommendation. While it is agreed that there may be instances where some individuals may use Sports nutritional products to excess, labelling and appropriate warnings can be included. In the final analysis however we cannot legislate against those determined to abuse any product, without interfering in their rights to behave idiotically..

The Role Of Botanicals In Sports Nutritionals

Botanicals that are not included in the prohibited list or controlled by various poisons regulations should be available for inclusion in sports nutritionals for which an appropriate use can be claimed. This would include, guarana, siberian and korean ginsengs etc and others that have a beneficial effect on stamina and other functions.

Manufacturers would need to take care to ensure that the inclusion of these substances would not contravene any sporting body's code of practice or adversely impinge on an athlete's right to compete.

Caffeine is an appropriate ingredient in certain sports foods, and is already available in coffee, tea and other foods. Its presence in sports nutritionals either as caffeine or from guarana (*Paullinia cupana*) would require the amount present to be stated on the label. This would give the consumer clear indication of the amount they were consuming in the product.

Conclusions:

Sports nutritionals are those products used by athletes and sportspeople, to supplement their normal diet with nutrients and other compounds designed to help them achieve their physical and nutritional goals.

Because sportspeople have greater physiological demands than other more sedentary sectors of the community, their needs for certain nutrients may not be met from their normal diet.

Apart from the physiological constraints, the pressure and desire to succeed often makes it difficult for serious athletes to eat properly due to training schedules or the need to maintain a job while training or competing.

There is increasing evidence that the use of carefully formulated sports nutritional products to supplement the diet, have a significant role to play in aiding athletes to meet their physical and nutritional goals.

Products that meet the current needs of the market do not appear to fit the present or proposed standards, and it is clear that few of those currently available and used by sportspeople, comply with either R10 or 2.4.9. as written.

The prescriptive nature of the regulations, especially in regard to the permitted substances or the amounts of them that can be added, is out of step with market demand and availability.

It is also clear from the decade and a half of experience with the New Zealand Dietary Supplements Regulations, that there has been no significant health risk to the public at large and athletes in particular in respect of the availability of products that do not comply with either R10 or 2.4.9.

On the basis of risk analysis and the huge amount of these products sold around the world, there appears no justifiable reason for maintaining a prescriptive standard that has been more honoured in the breach than almost any regulation affecting the availability of any group of product consumed by the public.

Whilst we endorse Option One we see this only as a stopgap to maintain products already available and in wide use, as a preliminary to reworking the whole issue of sports nutritional products.

For that reason we recommend that a working party be quickly established, to produce regulations covering Sports Nutritionals, that takes account of market forces, avoids over-prescriptiveness and allows for a simple means of change, against the current tedious and lengthy process required for even a minor change to a food standard.

A decision to include Sports Nutritionals under 'Functional Foods' or a special 'Dietary Supplements' category' would benefit manufacturers who want to provide appropriate products for sportspeople and allow consumers of these products to benefit from new technology, and avoid the need for consumers to obtain these products by mail order, which under the current regulatory framework appears their only option.

We also endorse a co-regulatory approach, that includes industry and incorporates a code of practice designed to safeguard our consumers while permitting the benefits of new technology and research to be available to our athletes who compete both at home and abroad for the honour of their country and the glory of their sport.

This Submission is made on behalf of:
Nutra-Life Health & Fitness (NZ) Ltd
Auckland, New Zealand.

1st October 2001

Contact Person:

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