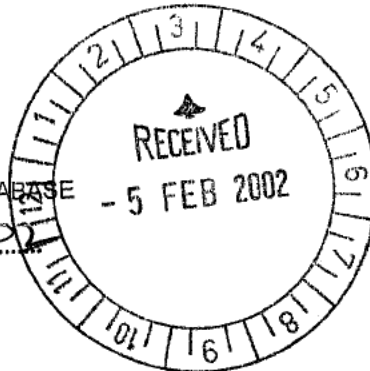




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5.12.02



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ACKNOWLEDGED

Following, please find comments on P236, prepared by ChemSkill on behalf of GNC LiveWell. This submission has also been forwarded to the CHC for consideration and sections of it may be included in their Industry Group submission. Please consider this as a separate submission prepared solely on behalf of GNC LiveWell.

Yours sincerely,

MANAGING DIRECTOR.

**Comments on The Initial Assessment  
Report of ANZFA Proposal P236 –  
Development of Joint Food Regulation  
For Sports Foods**

Prepared by [REDACTED]  
Snr Regulatory Affairs Consultant  
ChemSkill

on behalf of  
GNC LiveWell

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## **EXECUTIVE SUMMARY**

The following document tables GNC LiveWell's response to P236. This document addresses the points raised throughout P236 and gives recommendations and comments. This report strongly recommends Options 2 and 3 over 1 and 4 and provides objective reasons.

The current sports foods standard 2.9.4 is restrictive with respect to composition. In order for an effective joint code the restrictive nature of 2.9.4 must be overcome and reflect the liberal nature of the NZDSR. This is necessary to enable New Zealand manufacturers to continue to manufacture the standard of product that they are currently supplying and the Australian suppliers to be able to continue to supply the goods that are currently imported from New Zealand under the TTMRA. In addition to this, consumers have become accustomed to the products currently sold in Australia and New Zealand and if the code becomes more restrictive they will no longer have access to these products. This will result in lack of control over the consumption of sports foods as consumers will turn to purchasing goods from overseas and importing them for personal use.

Sports foods have a specific target consumer group and should be labelled accordingly. Warnings against use by pregnant and lactating women and children are appropriate. However, other warnings are not necessary provided labelling is clear in stating the intention of the product.

## **OBJECTIVES AND POLICY**

### **Are these policy principles appropriate to underpin the development of joint regulation?**

For the most part the principles set in 1996 remain valid today and can be implemented in New Zealand provided a new joint code is written and is liberal enough to cater for sports foods that are currently on the market in that country.

Sports foods require a more liberal code than general purpose foods as they are designed for a specific reason and aimed at a target group. They are not intended to be "normal" foods and provisions should be made so that they can contain ingredients that are not appropriate in foods for general consumption. In addition, allowances should be made for claims relating to specific requirements of athletes and the actions relating to sports persons of individual ingredients, providing they do not hinge on the therapeutic.

The third point regarding maximum amounts of nutritive substances is not clear. Why would highly fortified products not be considered foods? When in the same sentence it states "Permissions for the composition of sports foods should be sufficiently liberal to allow for them to function to help to maintain or improve the nutritional status of sports people..." The beginning of the sentence expresses a required liberality for this type of product, but concludes by limiting the scope and the liberal nature of the product type. It would be necessary to define "highly fortified" as any product with, for example, added vitamins is fortified.

Additionally, maximum amounts of nutritive substances should only be set if there is evidence that taking more than that amount may be detrimental to the health of the consumer. One of the ANZFA code objectives ((2)(c)) expresses the desirability of an internationally competitive food industry. Maximum allowable concentrations of nutrients based upon the Australian RDI's or ESADDI's limits international competition by those countries that do not have the same RDI's as Australia. This is especially so with products manufactured in the US.

The Therapeutic Goods Administration does not have maximum limits for vitamins, minerals and herbals unless there is a specific documented reason for a particular ingredient to have a capped maximum amount. If ANZFA were to adopt this system Australia and New Zealand would be able to compete internationally as well as protecting the consumer from taking too large an amount of potentially dangerous ingredients.

## **IMPACT ANALYSIS**

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

Options 2 and 3 are preferred over 1 and 4. The compositional allowances must be addressed, as they are currently restrictive to the demands of the consumer as well as overseas markets.

In order for a joint code to operate effectively, the restrictions of R10 and 2.9.4 will have to be overcome to encompass the liberal nature of NZDSR. If the code is restrictive with respect to composition a joint code will not be possible as the products currently imported, sold and manufactured in NZ under NZDSR will no longer be available for sale. Thus the sports foods market in both Australia and NZ will not meet the growing need of consumers of these products.

Option 3 allows self regulation over labelling – therefore promotes flexibility over Option 2 – however, the nature of regulation within the industry must be established before its feasibility can be determined. Would the code of practice in Australia and NZ be the same?

**For each option what are the potential costs and/or benefits to you as a stakeholder? Do the benefits outweigh the costs?**

### **OPTION 1**

**Advantages:** This option does not provide any additional advantage to the system that is currently in place. Companies can continue to sell products that conform to the current code for sports foods.

**Disadvantages:** This option severely limits importation of sports foods, whether from NZ or other countries. The current code is not flexible enough to cater for the rapid development of the sports food industry. The rigidity of the current code prevents Australian vendors from keeping up with new developments overseas. It also limits manufacturers in Australia from developing any new products – as they would not be able to sell them, and it inhibits Australian products from being sold globally as the restrictions in place with respect to composition put Australia at a distance behind the international market.

With separate codes for both Australia and NZ trade between the two countries is severely limited. In addition to this, currently some vendors legally import products through NZ to take advantage of the TTMRA and the NZDSR. If this option is no longer available it places Australian vendors at a severe disadvantage in the global marketplace. Vendors of sports foods take these drastic measures so that they can supply the types of product that their target consumers need.

A code that restricts the sale of product that sports people demand and that are freely available overseas is detrimental to this industry as a whole and will seriously affect sales. Serious sports persons will import their own products for personal use if they cannot access it from Australian vendors. Australian athletes must have access to the same standard of sports foods as sold overseas in order to be able to compete at an international level. If athletes are importing their sports foods it will severely limit the sales potential of vendors in the Australian market and also remove any level of control over the consumption of these products.

In addition to the above, Option 1 does not allow for comparative products pertaining to international laws and regulations. Therefore, this option does not meet with the principles set out to guide the writing of the code that is, there is no consistency between domestic and international markets.

## **OPTION 2**

Consistency of codes between Australia and NZ is necessary to improve trade between the countries. However in order for this transition to be effective the revised standard must be comparable to the NZDSR with respect to composition. Labelling changes can always be made for existing products, however if the new standard is more restrictive in respect to composition these current products may no longer be available for legal sale.

Advantages: This would depend upon the manner in which the new, joint code was written. If the new code were flexible in respect to composition such as the NZDSR, current and new products would be available for sale to consumers of sports foods in Australia. Keeping flexibility in the code with respect to composition would allow for advances in research and technology within the industry to be passed on to the consumer in superior formulations. The ability to keep up with advances overseas would be a huge advantage to the sports food industry in Australia.

Disadvantages: If the code is comparative to the current R10 and 2.9.4 the types of products sold in both Australia and New Zealand would be restricted. This would have a detrimental effect on the industry as a whole, but would have a particularly negative effect in NZ, given that the majority of their products would no longer conform to the relevant code. In addition to this, the sports food industry in Australia and NZ would be so far behind the world leaders in this field that competition would be impossible. As a consequence, this directly opposes objective (2)(c) which describes the desirability of an efficient and internationally competitive food industry.

### OPTION 3

The idea of a voluntary code of practice requires much further investigation. How would this code be enforced? How would shared enforcement between industry and government be co-ordinated? How could adherence to the code be enforced if it is a *voluntary* code?

Advantages: The advantages of Option 3 are the same as Option 2 and also include industrial control over labelling of the products, which in theory would involve less compliance costs for the company.

Disadvantages: Disadvantages of Option 3 are the same as for Option 2. The nature of labelling regulation within the industry must be established before its feasibility can be determined. Whether this proves to be an advantage or a disadvantage can only be determined after development of the procedure for regulation. For smooth trade practice between Australia and NZ the code of practice with respect to labelling would have to be the same.

Having a voluntary code of practice for labelling breaches the objectives of Proposal P236 as industry have the option not to comply to the code and as such it cannot be ensured that consumers are receiving adequate information about the product through labelling. Labelling must be sufficient enough to allow consumers to make informed choices about different foods. Informative labels should provide consumers with enough information about the product that constrictive compositional guidelines should not be necessary.

### OPTION 4

Advantages: none

Disadvantages: Incredible loss of business in both Australia and NZ with respect to the sale of sports foods. This may result in the illegal import and sale of these products as there is a definite consumer need for them. If consumers cannot obtain sports foods in Australia they will obtain them from overseas and there will be no control over their usage from within Australia.

Option 4 does not allow for any of the objectives of the proposal.



## **DEVELOPMENT OF JOINT REGULATION OF SPORTS FOODS**

**Is the purpose of a sports food standard appropriately encompassed by the opening paragraphs in Standard 2.9.4?**

The purpose of a sports food specified in Standard 2.9.4 may be deemed as appropriate, depending upon the future purpose of this code. If the code is no longer responsible for labelling, rather industry will regulate over this area, the parameters of the purpose must be altered.

The purpose specified in 2.9.4 accurately states the nature of a sports food and its intended use.

**Should sports foods be formulated for reasons beyond physiological demands?**

Sports foods should only be aimed towards sports people, specifically for physiological reasons associated with exercise. However, this should not be limited to the needs of the elite sports person, but rather should be diverse enough to also encompass the casual exerciser.

**Should a sports food standard focus solely on the needs of sports people, or consider possible consumption by other groups?**

Sports foods are designed for the purpose of assisting the nutritional demands of sports persons. This should be reflected in the standard.

Sports foods should not be sold to consumers for the sake of convenience. Consumers should be directed to the products that best suit their needs. Ultimately this is the responsibility of the retailer. In addition to this, labels of sports foods should clearly state their purpose and provide the consumer with the means to make a decision as to whether the product is suitable for them.

Sports persons should not be disadvantaged by a restrictive code, with respect to composition, to counter the possibility that a non-sports person may purchase the goods. Labelling should be clear to the consumer as to the nature of the food and the responsibility should lie with the consumer.

It is not appropriate to sell sports foods to children, under the age of 15 years and this should be stated on the label.

### **What other key features need to be addressed?**

Provisions for different categories of sports foods should be made in Volume 2. These categories should be regulated by labelling of products rather than limitations to composition. Consumers could determine which product best suited their needs quickly by choosing products from a particular category. Then more detailed information about the advantages of the composition of the different products could be obtained from individual labels.

For example:

- Body building
- Casual sports
- Cardio fitness

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

Sports foods should not be advertised to children. However, it is unlikely that the types of foods that are to be regulated by this standard would, in fact appeal to children. This standard is not to encompass the regulation of electrolyte drinks which are probably the most appealing, and affordable, to children. It is the ready-made electrolyte drinks that are sold with sipper tops that appeal to children and this type of beverage is regulated by standard 2.6.2. Powders and formulations that require preparation prior to consumption are not as appealing to children as the ready-to-drink electrolyte beverages. The powders and formulations are also quite expensive which makes them less desirable to children.

### **What is the most appropriate definition of a sports food?**

The current definition is broad enough to cover a variety of sports foods and therefore, is appropriate for the new standard.

Single ingredient foods should be included in the sports food standard unless included in Schedule 7 of the *Therapeutic Goods Act 1989*.

### **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?**

It is not necessary to exclude single ingredient foods as a sports food. The standard for composition of sports foods must be sufficiently broad to cover consumer needs, current product sales, the global market and the current NZDSR. If these factors are ignored the new standard will not be effective.

If manufacturers are inhibited in their capacity and retailers cannot sell the types of products demanded by the consumer, customers will look to overseas markets where they can freely purchase the desired goods and import them for personal use. Objective (2)(c) refers to the desirability of an efficient and internationally competitive food industry.

In order to obtain this goal it is necessary to look to international markets and the sports foods currently sold abroad and the current consumer demands.

The sports foods code that is prepared for Volume 2 should recognise the many different types of ingredients that are currently permitted under the NZDSR and as such are available to consumers in both Australia and New Zealand. Restricting the code so as to disallow these ingredients/foods would cause great upheaval in the industry for manufacturers, retailers and consumers.

If single ingredient foods are to be excluded it may force the addition of other ingredients which are not essential to the product.

**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?**

Substances permitted as ingredients in sports should include those for the purpose of physiological as well as nutritional intentions.

In addition to this the definition of a nutritive substance is vague in meaning by use of the word "normal". The definition states that a nutritive substance is "a substance not normally consumed as a food and not normally used as an ingredient of a food..." However, the policy principles for a sports food states that "[sports foods] may be permitted to contain substances not permitted in general purpose foods". This could be interpreted in such a way that it is normal for sports foods to contain abnormal ingredients and therefore, permitted to have a very wide compositional allowance.

**Should more nutritive (and other) substances be permitted additions to sports foods? If so, what criteria should be considered?**

More substances should be permitted than is currently available in standard 2.9.4 and the amounts currently permitted should also be re-evaluated. Serious evaluation of current market demands should be taken into account. If the new standard is much more restrictive with respect to composition than the NZDSR, consumers will not be able to obtain the products that they have been able to buy for years. This can only have a negative effect on the sports food market in both Australia and New Zealand. Taking current products from consumers at the end of 2002 will cause a public relations crisis within the industry and for government.

Why were these products available to us before? Are they dangerous? If they weren't dangerous before why are they now? How is industry to answer these questions from consumers?

In addition to the above, objective (2)(b) "the promotion of consistency between domestic and international food standards" should be considered. The sports foods that are allowed internationally should be reviewed for composition and considered when determining compositional allowance in Volume 2.

The safety of ingredients should be assessed, however efficacy of ingredients should not be reviewed by ANZFA unless labelling claims can be made about the action and advantages of individual ingredients. As this is not currently permissible according to the ANZFA Code, efficacy should not be a consideration. Provided ingredients are of a food grade quality and are not toxic or in any way harmful to the consumer, they should be acceptable for inclusion in a sports food.

**Is there a need to reappraise ANZFA's previous approach to risk assessment, particularly in the absence of evidence?**

The current assessment of risk is very thorough. A system that encompasses risk at all levels eg. Historical, traditional use, would be beneficial.

**Are there particular botanicals used in sports foods which are not prohibited or restricted under 1.4.4, but which should be specifically regulated under Standard 2.9.4?**

No.

**Are there particular botanicals or other ingredients, which are currently added to sports foods, but are prohibited under Volume 2 of the FSC that should be readdressed?**

No.

**Is caffeine an appropriate ingredient in sports foods? If so, why, from what sources?**

Caffeine as a performance enhancing factor is controversial. However, it has many other advantages which favour inclusion in sports foods. The ANZFA Report of the Expert Working Group on the safety aspects of dietary caffeine state that moderate level intake of caffeine can cause increased energy, alertness, motivation and concentration. This is an action that would have positive effect in a sports food. This report also states that it is not established that caffeine contributes to any cardiovascular disease or high blood pressure.

In addition to this, the report states metabolism of caffeine is similar in adults and children and there is no reason to suspect that children are more sensitive to the effects of caffeine than adults. Even though the report has found this, we do not believe it is necessary for children under the age of 15 to consume sports foods.

Dr Mark A Jenkins MD has published an article on the Rice University, (Texas USA) web site titled Caffeine and the Athlete. This article describes the advantages and disadvantages of using caffeine in the diet of an athlete. The article states that caffeine mobilises fat stores and encourages working muscles to use fat as a fuel. This delays the depletion of muscle glycogen and allows for prolonged exercise.

Allowing caffeine to be added to sports foods may be desirable to the consumer and allowing it in both the chemical form and as guarana would be preferable to industry. Consumers can make the decision whether they would like to take their sports food with or without the addition of caffeine.

**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?**

Labelling as to the product's intended consumer group and warnings against taking the product for those in vulnerable groups is sufficient advice for the consumer. There are many examples in today's society showing that there is no way of stopping people taking products that are not intended for them if they are determined to do so. This is regardless of the laws and strategies in place to stop them.

Sports foods are aimed specifically at athletes. Products sold in stores that specialise in sports foods should have sales staff that can direct the customer to the product that best suits them and to show them the relevant warnings on the label. If the customer is determined to purchase a good regardless of the warnings, they are making an informed choice. Manufacturers and industry ensure that labels are detailed as to the intent of the product in order to dissuade inappropriate consumption. Many stores refuse to sell sports foods to children, however, this does not prevent parents from buying the product for them. As previously stated, if consumers are determined to obtain a product there is no way of stopping them. Education as to the reasons why a particular food is not appropriate for a particular person may help to dissuade them from buying it, however warnings are already present on labels.

**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 about the consumption of sports foods?**

Warnings that state that the food "is not a sole source of nutrition" inform dieters that they cannot take sports foods as a meal replacement. Other than this, and the above warnings, there is no need to warn the general population about the consumption of sports foods. The reason for this is that sports foods are targeted towards a specific market and the labels indicate this.

**Should such statements, if continued, be more tailored to particular compositional criteria? If so, why?**

The current general warnings are appropriate. There is no need for individual warnings other than for guarana which should always state the equivalent amount of caffeine. Provided sports foods are targeted towards sports people there is no need for individual warnings for each ingredient.

**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?**

The capped limit of 3.5g of creatine per day is extremely low compared to the amounts currently included in many sports foods sold outside of Australia. In order to compete with the international market ANZFA must either increase the allowed maximum or preferably remove the limit all together. Scientific studies have been performed to show the effects of creatine consumption and blood chemistry and have used up to 20g creatine per day. Copies of peer reviewed journal articles will be supplied on request.

The TGA have removed the capped limit of creatine and now require the following warning: "Seek professional advice before long term use". This warning could be added to sports foods if the maximum daily intake cap was removed for creatine. The wording could be slightly altered to "Seek professional advice before using products containing creatine long term".

**What labelling statements are considered important for consumers to enable informed choice?**

It would be useful for consumers if sports foods could state their specific intended target groups, for example, weight lifters, endurance sports, casual exercise, high intensity etc etc. This type of classification would allow consumers to make a clear and well informed choice depending on the type of sport or exercise that they undertake.

Coupled with the warnings against the use of sports foods by pregnant women and children, consumers would have a clear understanding of the intended use of the product. This would also indicate to dieters that it is not a meal replacement or a sole source of food.

**Should sports foods be exempt from standard 1.2.7 (if adopted) that proposes to regulate performance-enhancing claims, and therefore require proper submission of scientific substantiation before being used? If so, why?**

Most ingredients that are used in sports foods are well established and industry and consumers alike know their effects. Scientific substantiation of ingredients should not be required to be submitted before the ingredient can be used, as this process seems to imply that the product has an action over and above its intention as a food. TGA do not require scientific substantiation for every complementary medicine that is listed, however, the sponsor is required to hold evidence and provide it for review upon request. Any ingredient that a manufacturer could possibly have a label claim for would probably also be included with the TGA's listable medicines. As the products are not therapeutic and are intended for use as foods it is not necessary to make the sorts of claims that would require substantiation by ANZFA.

**Should sports foods be exempt from the nutrition panel requirements of standard 1.2.8? If so, why?**

Nutrition information should be present on all foods without exemption. The consumers of sports foods may be particularly interested in the nutritional information and should be given every opportunity to make an informed decision as to the sports foods that they choose to purchase.

**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?**

It should be evident as to the type of sport food a particular product is by the information present in the nutrition panel. The problem with this type of classification is that a sports food may fall just outside of the criterion for a particular category. It would be of more value to the consumer for the products to be categorised as to their purpose, for example, for weight lifters, endurance sports, casual exercise, high intensity etc.

**Are there any other general labelling issues that need to be considered for sports foods?**

No.