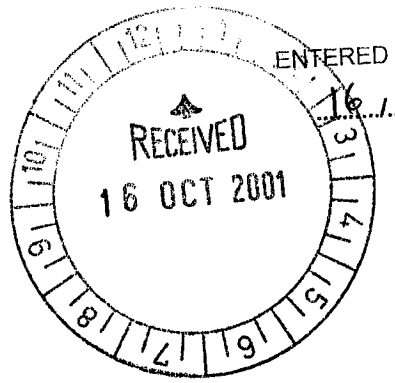
AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION



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Project Manager- Proposal P236
Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre, ACT 2610
AUSTRALIA

ACKNOWLEDGED

16 October 2001

Dear Sir/Madam

RE: ANZFA Proposal P236: Development of Joint Regulation for Sports Foods

We wish to thank the Australia New Zealand Food Authority for the opportunity for the Australian Self Medication Industry (ASMI) to respond on the above proposal.

ASMI is the peak organisations in our sector and provide both advocacy and representation for the full spectrum of the non-prescription consumer healthcare products including both over the-counter-medicines, complementary medicines.

Our interest derives from the proximity of these products to the food/therapeutic good interface, and that certain broad principles relevant to the formulation rationale, safety and presentation of certain low risk therapeutic goods may find application within this proposal.

Serious athletes, "weekend" sport people, people undertaking moderate/casual forms of exercise and those engaged in physical labour are all increasingly using sports foods within their diet. It is essential that ANZFA consider these utilization of sports foods by these demographics when developing the standard.

The regulatory framework that encompasses sports foods should also accommodate innovation and technological advances in ingredients and presentation. It should also take into account the existing variety of sports foods, some of which may not completely comply with the current food standards, but have been used by Australian and New Zealand consumers without deleterious effects, providing that no unreasonable health claims have made in relation to the product or its ingredients.

Sport foods are consumed for their real and perceived benefit to sports performance and nutritional goals, as well as for their convenient presentations. Any standard needs to recognise the need for all claims and

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benefits to be evidence based to avoid unsubstantiated benefits being communicated to the consumer.

A variety of representations need to be catered for in any new standard to accommodate innovation as the current standard does not accommodate newer presentations such as bars.

Although "Electrolyte Drinks" remain outside the review it is our view that they should be included in the new standard for Sports Foods so as to align with European Commission Directives. However, the interface between electrolyte based sports foods and electrolyte products which are therapeutic goods and medical foods need to be clarified to ensure that inappropriate claims are not made.

Objectives and Policy

While we support the stated objectives and the policy, we would urge that in addition to the listed policy principles under 3.2 a further principle be included:

- The standard be sufficiently broad to accommodate changing nutritionally based knowledge

The principles identified in 1995 NFA Sports Food Workshop are still significantly relevant.

Products should be labelled as to their purpose of use with a clear indication that that are not intended as the sole source of nutrition, as well as indicating that the product is not suitable for particular non-target at-risk groups.

Options for Regulation

Recommendations:

Industry would welcome revisions to the current standards, Option 1, the retention of the status quo is not favoured.

Presently, in terms of the impact analysis we support Option 2.

This option appears to be a reasonable way forward, offering the opportunity to revise the current standard. The scope of the regulation should encompass both current and future technologies. This should result in a less prescriptive standard and narrow the current differences between the New Zealand and Australian Standards, providing a level playing field and consistency between the two countries.

Whilst developing the standard international regulation should also be considered so as not to disadvantage Australian and New Zealand industries

in the global export market due to unique or inappropriately set standards or requirements.

Another major issue is the policy and priority setting by State Health authorities to enforce compliance of non-compliant products in the market place. Because of the number of standards that these products can be manufactured to and imported into Australia legally, checking for compliance is challenging.

A uniform standard will benefit the public by offering products that are consistent in the labelling and information supplied.

Option 3 is less attractive as compliance via an industry code of practice could only be enforced on members of the participating industry associations. This would provide the opportunity for non-compliant non-members to gain an advantage. Although enforcement responsibilities could be shared between government and industry under similar current models operating in the therapeutic goods environment, therapeutic goods are also subject to a Registration/Listing process that acts as a deterrent to products that do not comply with required standards.

Option 4 has little support as it would result in some illegal foods to be declared as therapeutic goods under Section 7 of the Therapeutic Goods Act, 1989. These products would be regulated whilst the illegal foods would continue to remain in the market place unless each of the State Health authorities had the resources to perform adequate surveillance to achieve uniform action against non-compliance.

Also NZDSR would need to be repealed, otherwise product from NZ could still be legally supplied.

While a product may fulfill the requirements of the standard, concerns may be raised of potential real safety issue with children consuming sports foods despite warning labels, because of representation and promotion. This issue may be able to be addressed through other means such as a voluntary code of marketing conduct, as is the case with the promotion of Infant Formula foods.

When establishing a definition of children it is important to be consistent with definitions in other acts/regulations. The criteria for choosing particular age restrictions needs to be clarified. If there is concern because of the physical, physiological or metabolic development than this may need to be identified as a specific warning either with or instead of a blanket childrens warning.

Issues and Questions Related To The Development of a Joint Approach To Regulation of Sports Foods.

Purpose of Regulation

Consumers who participate in casual moderate exercise may not be the ideal descriptor for a "Sports person". "Athletes" are not the only consumers of Sports Foods, hence it should be considered whether a more representative name for this class of foods is appropriate to cater for those who require physiological replenishment from any form of exercise.

It is important that these types of foods should not be formulated beyond what is required to satisfy physiological demand. It is therefore inappropriate to add substances for purposes unrelated to those which the proposed standard is proposing to regulate, and that are not normally derived from diet.

Definitions of Sports Food

Given the points raised with regards to the actual consumer market of sports foods, an appropriate definition might be "Formulated supplementary sports food means a food or mixture of foods specifically formulated to assist the achievement of specific or performance goals and recovery from physical exertion"

Composition of Sports Foods

Foods for nutritional purposes that contribute to meeting the physiological demands of exercise should be permitted to include additional substances not currently specified within the existing standard providing that they are safe and efficacious, and the claims and statements regarding nutritional effect do not contravene the definition of nutrition claim described in the outcome reports from P153- Health and Related Claims in Food, and provided they are substances normally found in the diet with a nutritional role..

Anything that is formulated and presented with either the implicit or explicit inference that the product performs a function by virtue of containing that ingredient, for which there is no clear nutritive purpose, then this needs to be restricted.

This is particularly true for those ingredients, such as botanicals, that are used within therapeutic goods close to the food/therapeutic goods interface. There are already instances of non-caffeinated "energy drinks" (ie Professor Heads Smart Drinks, distributed by Berri Limited) from New Zealand being marketed in Australia containing St John Wort, Passion Flower, Bilberry, Catnip, Gingko Biloba, Ginseng and making therapeutic claims that should be restricted to

therapeutic goods ie "supports brain function in the areas of cerebral blood flow, circulation and oxygenation" or "a precursor to the neuro-transmitters noradrenalin and dopamine, and beneficial for mood".

ASMI are opposed to the accommodation of such products within the proposed standard.

Labelling of Sports Foods

We believe it is appropriate to label products with general advisory statements that warn against consumption by vulnerable groups as an appropriate risk management strategy for sports food, provided that there is an actual risk presented to that demographic from the consumption of that particular food due to its composition. It would not otherwise be appropriate to apply these warnings to all sports foods.

Consumers should also be made aware of the content of constituents of concern ie caffeine content from mixed food sources such as guarana.

Other principles

The development of this standard, in parallel with other recent standards and proposals such as Proposal P153- Health and Related Claims in Food, and A394- Formulated Caffeinated Beverages highlights the ongoing need for a complaints mechanism to deal with advertising set up in Commonwealth model legislation, to be effected by the States and Territory government, with timely, effective and enforceable sanctions being established, consistent with those for therapeutic goods, which could include

- the withdrawal of misrepresentative claims from products
- pecuniary penalties in cases of non-compliance with principles and benchmarks/framework criteria.

There needs to be consistency in warning statements on foods for particular ingredients which require warning statements when presented as a therapeutic good and taken at similar dosage levels, particularly in products such as sports foods.

We trust our comments have been of use. Should you wish to discuss any of the points raised in further detail please do not hesitate to contact me on [redacted] or by email [redacted]

Yours sincerely

[redacted]

Regulatory and Technical Manager