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22nd October 2001
ACKNOWLEDGED
ENTERED IN DATABASE

Re : Submission on P236

Please find attached our submission on P236 – Sports Foods.

We appreciate your willingness to extend the deadline on this submission and look forward to further consultation in review of this document.

Regulatory Co-Ordinator.

October 2001

Submission on ANZFA - P236 Proposal

INTRODUCTION

As our association represents a number of significant NZ Importers, we are more than a little concerned that this area of " Sports Foods" is and may continue to be, out of step with other major trading partners and in particular USA.

For the purposes of this submission we have therefore concentrated on comparing the various regulations firstly between Australia and NZ, and secondly with those of the USA.

We believe that any such regulations should be risk based and in line with historical evidence/facts. As such it is very easy to create a set of regulations to provide safety net after safety net, when in reality history shows this to be totally unnecessary.

Therefore we have broken our submission up into two parts - Part 1 will address the issues and questions as requested in your " Initial Assessment Report" and Part 2 will offer another point of view.

PART 1

Question 1 - " Are these policy principles appropriate to underpin the development of joint regulation? Why or why not?"

Looking at the six points listed we would generally agree except for the principle three whereby the level of nutrients is set at a maximum of twice the RDI - Again based on science and risk analysis, there is no substantiation for this limitation - If these products are to be of benefit to sports people the level of nutrients **must** be considerably higher - Levels should only be limited where scientific evidence identifies the need for same.

While also on this question of principles, we take exception to the preamble under 3.2, where it is stated " the agency recognised the need to provide for innovation in the food industry.....". This in turn raises the question - Does ANZFA consider the existing Standard 2.9.4 to be innovative?

We suggest the simple answer is no way - Given that if one compares this standard to both the NZDS and the US DSHEA, its content in comparison could only be described as draconian, far too restrictive, but certainly not innovative.

Question 2 - " Which is your preferred regulatory option for regulating sports foods and why?"

We would select Option 1, with the proviso that the existing standard 2.9.4 be completely revisited.

From a NZ perspective we are convinced the average NZ sports consumer would not want to lose any further freedom of choice when selecting Dietary Supplements

to aid their sports performance - In fact we are aware that already a significant portion of these people are sourcing product, currently unavailable in NZ, direct from the USA, to ensure they obtain maximum advantage from "natural" products without using drugs.

In addition we see no value in separating sports foods from the Dietary Supplement category, as all products whether in powder, liquid, tablet or capsule form are designed to achieve exactly the same results and are amply covered under the DSR heading, whether for general or sports use.

Further we believe if Australia is not prepared to drastically loosen their regulations to accomodate the rest of the world, they will in effect create trade barriers with major trading partners, as well as create a significant black market trade for those serious sports people who want supplements that work.

Question 3 - "For each option, what are the potential costs and/or benefits to you as a stakeholder".

As regards costs/benefits, we believe these are five fold -

(a) Firstly the consumer will be able to purchase effective supplements within their own country, thereby reducing the need for a black market trade.

(b) Secondly the least complex the regulations the easier it would be to regulate - One just has to look at the American system to see this.

(c) Thirdly, the compliance costs could be kept to a minimum, irrespective of co-regulation or otherwise - This in turn would assist in keeping costs down to the consumer.

(d) Fourthly, if too much restriction is introduced many importers will not be able to survive and a significant number of small companies providing hundreds of important jobs will be lost.

(e) Finally, as indicated earlier there will be detrimental effects on international trade.

Question 4 - "To what extent would the industry be prepared to be responsible for enforcement and monitoring of, for example, a code of practice?"

The NZ Health Industry for a long time now has always maintained a policy of self regulation - One only has to check with Medsafe as to the number of complaints they get from competing companies.

The NZ Industry through, for example, the NNFA has offered to implement a register of NZ Manufacturers and Importers and to not only police irregularities, but also to co-ordinate and assist with regulators over any issue affecting our industry. - This offer has been put on the table as recently as the TTH talks, but unfortunately this has never been pursued by any regulator.

We firmly believe that very significant cost savings could be achieved to both this code as well as others if a formal co-regulation policy was implemented.

Question 5 - " Is the purpose of a Sports Food standard appropriately encompassed by the paragraphs in Standard 2.9.4?

Yes, but with the comment that in reference to not being suitable for children, the sentence be modified to " may not be suitable for children under 15 years of age". Depending on your definition of children, there may certainly be situations where young persons, perhaps in the 13-15 year age group who are seriously into a particular sport, could well benefit from supplementing their diet with some form of sports supplementation.

Question 6 - " Should sports foods be formulated for reasons beyond physiological demands? If so, what other needs or wants should be considered?"

We believe this question requires further clarification as to your definition of physiological demands. While it is acknowledged that most people wanting to take a sports food is doing so for a specific purpose, there are occasions when others would take these products for convenience.

Question 7 - " 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?"

No, we believe if you choose to have this separate category of sports foods, one has to assume they will be used primarily for one purpose only and therefore there should not be a need to complicate the matter further.

Question 8 - " What other key features may need to be addressed?

(i) Labelling - We believe the existing labelling requirements is completely unnecessary, if not totally confusing. With the existing standard one would either need an oversized label or a magnifying glass. Such instructions should be limited to Nutritional Facts and Directions For Use - Warnings should only be applied when absolutely necessary (ie pregnancy etc)

(ii) Levels of allowable nutrients - As stated earlier in this submission, the limits on various nutrients within this standard is completely out of line with other recognised codes and needs to be totally readdressed to line up with codes such as the American DSHEA regulations.

(iii) Particular Formulated Supplementary Sports Foods - Given the vast array of Sports supplements on the world market and given that many of these have more than one purpose (ie Creatine - aids energy and assists in increasing muscle mass), there is no need to require a further category breakdown on the label - Clearly a simple statement of use would suffice.

Question 9 -" Should a sports food standard control the representation of sports foods that might inappropriately make them appeal to children? How could this be achieved?

No again unnecessary - Where products contain proven risks to children (ie proven toxic levels of a particular nutrient) then a warning should be included. However,

where supplements that contain nutrients that have no proven adverse problems with children, it is completely unnecessary to require any sort of warning.

Question 10 - " What is the most appropriate definition of a sports food?"

We suggest the words " sports foods" are inaccurate as regards the purpose of use
- A better description surely would be Sports Supplements or Sports Nutritional Products.

A suggested definition could be - *"Formulated sports supplements means a substance or mixture of substances specifically formulated to assist sports people in achieving specific nutritional or performance goals."*

Question 11 - " 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 single nutrients are designed as sports supplements, just the same as combinations are.

Question 12 - " 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 - Basically any substance or combination of substances which have a proven history of safe use in the area of sports supplementation should be permitted

Question 13 - " Should more nutritive (and other) substances be permitted additions to sports foods? If so, what criteria should be considered (for example safety, efficacy?)"

Generally our answer would be yes, with the proviso that safety has always got to be the main criteria - Therefore by applying a scientifically based risk analysis approach to any substance one could clearly determine as to whether a substance or substances can be included in any formulated product.

In addition we are concerned at the restriction on certain forms of a substance. For example, in the case of Creatine, why should the regulations limit its use under this code to powders or liquids only? - What is wrong with capsules or tablets? In fact from a safety viewpoint, surely as these forms are put up in a more accurate measured dose than say powder, the dose requirement is in fact more accurate, and therefore less likely to be abused.

Question 14 - " Is there a need to reappraise ANZFA's previous approach to risk assessment, particularly in the absence of evidence?"

Very definitely yes! - Again we would refer you to the DSHEA model from the USA, where the only real issue is safety.
Why restrict substances when there is no proven cause for concern?

Question 15 - " 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?"

No - Again the same principles as outlined in 13 & 14 should apply.

Question 16 - " 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?"

No - For the same reasons as outlined in 13 & 14.

Question 17 - " Is caffeine an appropriate ingredient in sports foods? If so, why, from what sources?"

Yes - Unless you regulate against Tea, Coffee etc. Substances such as Cayenne and Green Tea added to sports supplements can provide additional energy to some individuals, in a similar manner to drinking a cup of coffee or tea.

Question 18 - " 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?"

Yes to the first part & No to the second part - One can not regulate for idiots!

Question 19 - " 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?"

Yes to the first part and no to the second part - Sports products are no different to other dietary supplements, therefore additional warnings should only apply to specific substances that again through scientific risk analysis have shown a need.

Question 20 - " Should such statements, if continued, be more tailored to particular compositional criteria? If so, why?"

No!

Question 21 - " 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?"

Refer to part two of our answer under question 19.

Question 22 - " What labelling statements are considered important for consumers to enable informed choice?"

- (a) - Nutritional Facts
- (b) - What is the product designed to do &
- (c) - Any safety warnings deemed appropriate through scientific risk assessment.

Question 23 - " 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?"

Yes - On the basis that products should have already been approved by a scientific risk analysis method and labels should contain a simple statement of designed use.

Question 24 - " Should sports foods be exempt from the nutrition information requirements of Standard 1.2.8? If so, why?"

Yes - As explained above.

Question 25 - " 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?"

No - Again please refer to comments as per our answer to question # 22.

Question 26 - " Are there any other general labelling issues that need to be considered for sports foods?"

No - It needs to be kept simple and in line with regulations of other trading partners as already explained.

PART 2.

Our members, most of whom import Dietary Supplements/Sports Foods from the USA, would like to respectfully suggest to ANZFA that the current standard/approach is significantly out of step with the American DSHEA, and in

order to facilitate ease of use, ease of trade, ease of regulation and more importantly freedom of choice to all sports consumers, serious consideration should be given to adopting the DSHEA principles, rather than "re inventing the wheel".

To elaborate, the system used in the USA (as explained on pages 5 & 6 of your proposal document) works extremely well, is simple, is cost effective, is certainly not heavy handed in regulation(as is the case in Australia), clearly revolves around co-regulation and still "there are no dead bodies"!!

Further like the NZ DSR, they clearly make no distinction between sports food and Dietary supplements and again we can find no evidence of any disadvantage to consumers.

By comparison the Australian sports consumer is extremely disadvantaged as they have only limited access to overseas sports products and the longer this continues the worse off they will be, surely leading to an influx of " banned product".

Therefore going back to the principles of the need for Standard such as 2.9.4, one must ask the question, is there a REAL need to regulate separately and so restrictively for Sports supplementation, when in effect no REAL risk exists!

Our association, indeed the NZ Industry, is unanimously agreed that regulation of Dietary Supplements (inclusive of Sports products) should be based solely on a scientific risk analysis basis, and again facts show that our products are at the very low end of the risk scale, and therefore any regulation of our industry should reflect this and not be regulated along the pharmaceutical line, which certainly appears to be the principle behind current regulations.

Finally our members are extremely concerned that if the outdated protection principle currently offered to all Australian manufacturers is also forced upon the NZ Industry via stricter regulation, a significant number of companies will certainly " go to the wall", leading to many lost jobs and a significant loss of choice to NZ consumers.

CONCLUSION

INPA is convinced that irrespective of which option ANZFA may choose, sports products associated with our industry, must not be overregulated for the sake of regulation.

Commonsense, science and risk based assessment must prevail and all democratic countries of the western world ~~should ensure that~~ rather than build trade barriers a consistent set of regulations should apply in all countries.

Further consumers should be encouraged to use " natural" sports products, by giving them as wide a choice of products as available, rather than be too restrictive, thereby encouraging the more competitive sports person to achieve their goals without the use of pharmaceutical drugs.

Thank you for the opportunity to present our views.

Collated on behalf of INPA members by


INPA Regulatory C-Ordinator.