Submission On Initial Assessment Report Proposal P236

DEVELOPMENT OF JOINT FOOD REGULATION FOR SPORTS FOODS

National Nutritional Foods Association of New Zealand

Contact:
[redacted]

Executive Summary

1) The National Nutritional Foods Association of New Zealand welcomes the review of regulations for sports foods and asks that it be undertaken openly and is evidence based..
2) We believe that it provides ANZFA with the opportunity to develop standards that are commensurate with international best practice and focus on safety rather than restricting consumers' access to foods of their choice through imposition of philosophically drive food standards as presently exist.
3) In an increasingly globalised market, it is important that ANZFA takes this opportunity to harmonise trans-Tasman regulation rather than simply Australianise it. There is no place for the UAF[1] in modern regulatory practice.
4) The NNFA agrees with ANZFA's statement in the introduction to P236 regarding the complexity of the current regulatory environment. We believe that the opportunity exists for evidence-based regulation based on good regulatory practice and international best practice to be introduced New Zealand and Australia to ensure that public health regulation is evidence-based rather than the current philosophically based.
5) The NNFA proposes that regulations be designed to make a valid contribution to public health, rather than simply reflecting philosophical value-driven paradigms of regulators and advisors in an attempt to restrict consumer access to perfectly safe product.
6) Given the lack of evidence of the public being at risk as a result of New Zealand's less restrictive regulatory environment, and given the Agreement between Australia and New Zealand for the least restrictive regulation required to protect public health, it seems logical and in accord with good regulatory practice for New Zealand's existing regulation to provide the basis for review rather than Australia's unique regulation.
7) The NNFA is concerned that RDAs which were developed to protect populations from insufficient intake of nutrients might continue to be used unscientifically to manage potential excessive intake.
8) In the past it was believed that vitamins and mineral intake above RDA levels were not necessary to maintain wellbeing. This is still a commonly held belief that is antithesis to the definition and use of RDAs. The RDA was developed during World War II as a means of ensuring that USA troops received enough food intake to prevent classical deficiency diseases, without wasting food which was in short supply and required massive logistical support to get it to front lines.
9) RDAs were set as a MINIMUM intake for 97.5% of a given population to prevent illness.
10) A great deal of scientific evidence accrued over the ensuing decades demonstrates quite clearly that there are a great number of benefits from consuming more than RDA levels for many nutrients such as the vitamins folic acid and B12. I fact, the arbitrary nature of RDAs is evident in the fact that the RDA for folic acid was 400 ug

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[1] Unique Australian Factor

up until the late 1980's, it was then reduced to 200 ug, and has recently been reinstated at 400 ug. In essence, the RDA was established as a minimum safe level – it has never had anything to do with safety concerns at higher levels.

11) In the absence of a scientific framework multiples of RDA have been inappropriately used as a defacto risk management tool; there is no scientific basis for such use.

12) The NNFA advocates the development of generic food standards to which specific food standards refer. For example, it is incongruent with good regulatory practice for sports food standards to have arbitrary nutrient limits defined, when there are limits defined in a large number of other food standards. This means that there is a great deal of redundancy, and reluctance on the part of regulators to change anomalies for fear of creating further anomalies. If there were a generic standard for nutrients limits then it only as to be changed once.

13) Both Australia and New Zealand subscribe to the 'least restrictive regulation required to do the job' principle. On that basis, there is no basis for Australia's present restrictive regulations regarding sports foods. International best practice clearly mandates a regulatory environment more akin to New Zealand's than Australia's.

14) As such, the NNFA suggests that a government/industry working group be established to consider the many issues raised in this submission and that given the evidence demonstrating that **there is no market failure in terms of safety** regulations be developed commensurate with international best practice and good regulatory practice.

15) Even if there were market failure, the above good regulatory practice guidelines would suggest that the magnitude of the problem using appropriate indicators based on economic, social and environmental impacts would determine that any problem is minor and therefore is unlikely to require government intervention, but could be dealt with by codes of practice and education.

16) It is the NNFA's contention that:

    a) the current sport food standard is far more restrictive than that required for the protection of the public health and safety,

    b) the current sport food standard prevents manufacturers from providing adequate information relating to food to enable consumers to make informed choices (ie they can have more nutrient in the food than allowed to claim on the label) thereby preventing consumers from making informed choices,

    c) this regulatory requirement therefore encourages misleading or deceptive conduct, rather than preventing it, .

17) It is also the NNFA's contention that the current sports food standard:

    a) Is not based on risk analysis as required by law, nor is it based on the best available scientific evidence;

    b) Does not promote consistency between domestic and international food standards as it introduces a Unique Australian Factor which is not commensurate with either good regulatory practice, nor the spirit of harmonization.

    c) Hinders, rather than enhances an efficient and internationally competitive food industry as it imposes extra compliance costs due to reformulation and special

Australian labeling requirement;

d) Does not promote fair trading in food as it imposes arbitrary formulation and labeling requirements that are not commensurate with good regulatory practices.

18) The NNFA agrees with the New Zealand Business Compliance Cost review which cautioned about the imposition of unnecessary compliance costs on New Zealand industry as a consequence of trans-Tasman Harmonisation. Harmonisation should be exactly that – not Australianisation.

19) There is no room in good regulatory practice for regulation unique to a particular country being imposed on another country in the name of harmonization, especially when there is no evidence of public health issues, nor is evidence based risk analysis used to drive the regulation.

1) Multiples of the RDA have been used by some regulators to establish maximum levels of nutrients in foodstuffs. As mentioned, they were never designed to do that. In fact, there is no relationship between deficiency safety concerns and excess safety concerns.

2) The science clearly demonstrates that there is no one-size-fits-all formula for determining upper safe levels.

3) RDAs have never had any relationship to toxicity of the nutrient.

4) Modern regulatory practices now use evidence-based risk analysis on a nutrient-by-nutrient basis. This review gives ANZFA the opportunity to adopt modern regulatory practices and as such is very welcome.

5) Apart from a handful of nutrients, the current sports food standard is not, in fact, a risk based approach at all. For those nutrients where there are restrictions on allowable amounts per day, there is now excellent science that proves that the current restrictions are excessive thereby denying consumers the opportunity to maximize their nutrition.

6) There is a growing body of science that demonstrates the extra needs of sports people and devotees of fitness programmes.

7) Table 1. Lists the current restrictions on vitamins and minerals. Biotin, Folate, Niacin, Pantothenic acid, Riboflavin, Thiamin, Vitamin B12, Vitamin B6, Vitamin C, Vitamin E, Iron, Magnesium, Manganese, Molybdenum, Phosphorus, and Zinc have restriction placed only on what can be claimed on the label – there are no restrictions on the actual concentrations of the food. The NNFA can not find any evidence that this practice occurs elsewhere

This raises several issues...

8) **Compliance costs**: In practice, all that this does is impose extra costs on manufacturers who, in order to conform to these arbitrary limits need to relabel their product without changing the formulation. Clearly, this does not protect the wellbeing of consumers, and in theory, has the potential to harm them as they may well be consuming more nutrient than they are aware of.

9) **Fair Trading Law**: Technically, ANZFA is encouraging manufacturers to disregard fair trading law. If manufacturers are limited as to what they can say on the label in terms of quantity of nutrient, but are able to actually have higher levels of ingredient in the product, then consumers are denied their right to know what they are consuming; clearly ANZFA's present standard is encouraging deception which is supposed to be one of the major issues ANZFA is meant to be preventing.

10) **Evidence Based Regulation**: The NNFA is firmly of the view that the safety of consumers should be regulated using evidence-based regulation commensurate with good regulatory practice. Analysis of sports foods around the world in countries where there are no arbitrary restrictions can find no evidence of manufacturers including unsafe levels of vitamins and minerals in their products. In other words the market has self regulated. We can find no evidence of harm due to excessive consumption of vitamins and minerals.

11) This means that for these nutrients, the Council of Australian Government's Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies leads one to the conclusion that it is

unlikely that government intervention is required (See figure 1)

12) Quite simply, **there is no market failure in terms of safety** – there might be failure in terms of non-compliance with current regulations, but as ANZFA's own research has shown; that is a reflection of the fact that the current regulations in both Australia and New Zealand are simply out of step with the evidence regarding safety, are out of step with international best practice, and are not enforced by regulators, all of which point toward to need for the regulations to be amended accordingly. This is acknowledged by the fact that ANZFA is now reviewing the standard.

Table 1

Column 1 **Micronutrient**	**Column 2** **Maximum claimed amount** per one-day quantity	**Column 3** **Maximum amount** per one-day quantity
Biotin	50 µg	
Folate	400 µg	
Niacin	20 mg	
Pantothenic acid	3.5 mg	
Riboflavin	3.4 mg	
Thiamin	2.2 mg	
Vitamin B12	4.0 µg	
Vitamin B6	3.2 mg	
Vitamin C	80 mg	
Vitamin E	20 mg	
Vitamin D	2.5 µg	2.5 µg
Vitamin A	375 µg	375 µg
Calcium	1600 mg	
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	
Zinc	12 mg	
Copper: inorganic forms organic forms	1.5 mg 750 µg	1.5 mg 750 µg
Chromium: inorganic forms organic forms	100 µg 50 µg	100 µg 50 µg
Selenium: inorganic forms organic forms	52 µg 26 µg	52 µg 26 µg
Iodine	75 µg	75 µg

13) Even if there were market failure, the above good regulatory practice guidelines would suggest that the magnitude of the problem using appropriate indicators based on economic, social and environmental impacts would determine that any problem is minor and therefore is unlikely to require government intervention, but could be dealt with by codes of practice and education.

14) The NNFA is fully cognizant of the difficulty some dietetic and medical advisors might

have regarding perceived risks associated with sports foods and supplements, but the evidence, as outlined, does not support such concerns. Clearly the fact that labeling restrictions are in place for many of these nutrients, but not ingredient limits, highlights the fact that the current regulations are philosophically based, not evidence based as required by good regulatory practice.

15) Six vitamins and minerals (see table II) have restrictions on the amount of ingredient allowed on a per day basis. The NNFA has concerns about these also, as again, evidence from countries where there are no regulatory restrictions suggests that there is no market failure in terms of safety.

16) An analysis of various risk analyses undertaken by competent authorities and industry bodies alike reveals that there are no legitimate safety concerns in terms of formulation – the market quite clearly is self-regulating to ensure that consumers can not only make informed choices, but also make safe choices.

17) As a rule, consumers learn very quickly what is safe and what is not. Of course, there will always be the exception, but regulations have never been able to prevent that – in fact if regulation is too restrictive it only forces consumers determined to access such product to source from less safe/controlled suppliers. The rapid rise of cross border Internet trade is testimony to that.

Table 2

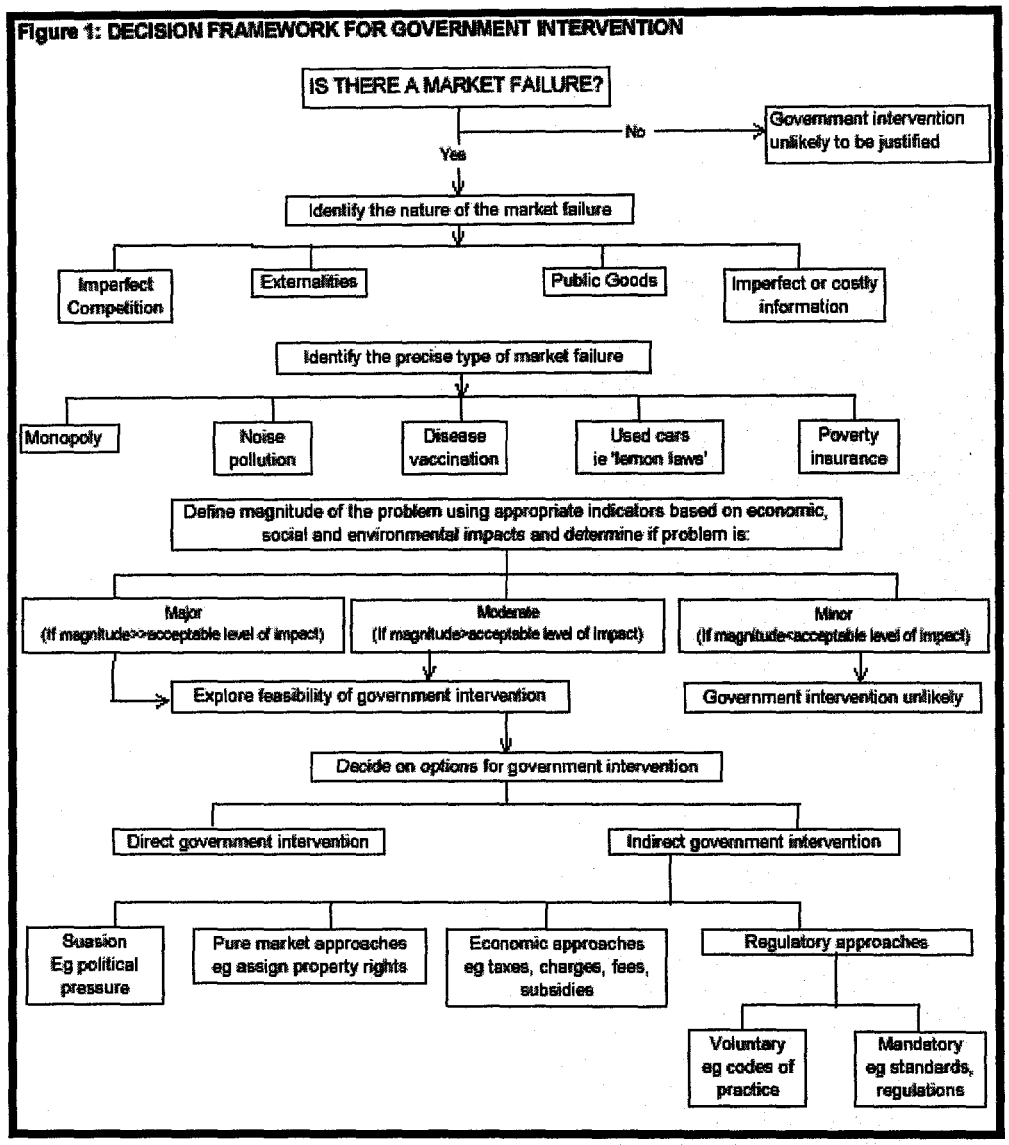
Vitamin D	2.5 µg	2.5 µg
Vitamin A	375 µg	375 µg
Copper: inorganic forms organic forms	1.5 mg 750 µg	1.5 mg 750 µg
Chromium: inorganic forms organic forms	100 µg 50 µg	100 µg 50 µg
Selenium: inorganic forms organic forms	52 µg 26 µg	52 µg 26 µg
Iodine	75 µg	75 µg

18) The "No Observed Adverse Effect Level" (NOAEL) is the greatest concentration or amount of a substance, found by experiment or observation, which demonstrates no detectable adverse alteration of morphology, functional capacity, growth, development or life span of the target organism under defined conditions of exposure.

19) The Lowest Observed Adverse Effect Level (LOAEL) is the lowest concentration or amount of a substance, found by experiment or observation, to cause significant adverse alterations of morphology, functional capacity, growth, development or life span of target organisms.

20) The "Tolerable Intake" (TI) or "Upper Safe Level" (USL) is an estimate of the intake of a substance that over a lifetime is without appreciable health risk (WHO, 1994). The establishment of the USL as the basis for risk management decision-making is now considered best practice by modern regulatory authorities.

Figure 1: Decision framework for Government intervention



21) The USA National Academy of Sciences and the European Food Standards Committee are both undertaking extensive reviews of all nutrients at present. Industry has already been using such a regime since 1998 when Hathcock[2],[3] and Shrimpton[4],[5] undertook independent reviews and reached similar outcomes.

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[2] Hathcock, J.N., (1993) Safety Limits for Nutrient Intakes: Concepts and Data Requirements. Nutrition Reviews, 51, 278-285.

[3] Hathcock, J.N (1996). Safety limits for Nutrients. J Nutr. 126: 2386S -2398S

[4] Shrimpton, D.H (1995). Essential Nutrients in Supplements - European Federation of Associations of Health Product Manufacturers.

22) The NAS and EU reviews have in most cases confirmed Hathcock and Shrimpton's results. Due to the fact that they have more recent science, they have in some cases set USL at higher levels. In the case of Niacin, for example, they have determined 'flushing' as a measure of harm and set relatively low levels, whereas 'flushing' can not possibly be considered harmful.

23) In the case of vitamin B6, a non-scientific study by proponents of hormone replacement therapy has been used to establish an unreasonably low USL in the UK and Australia.

24) Examples of Upper Safe levels

Table 3

Nutrient	Current Australian Sports Food Standard claimed Limit	US National Academy of SCience	WHO	EU Scientific Committee for Food	IPSC	UK Expert Vitamin & Mineral Committee
Copper *	1.5 ug	10 mg/day	12 mg/day for men 10 mg/day for women.	10-35 mg/day	10 mg/day	**
Vitamin D	2.5 ug	50 ug/day > 1yo, 25ug/day < 1 yo				
Selenium	26 ug	400 ug	400 ug	300 ug		
Iodine	75 ug	1,100 ug				500-1,000 ug/day
Zinc	12 mg	40 mg/day				

25) Table III demonstrates the very conservative nature of Australia's current regulations regarding the denial of consumers' free access to sports foods containing safe levels of nutrients.

* There is no scientific evidence to validate more severe restrictions on the use of organic as opposed to inorganic copper ingredients. In fact the WHO has concluded that an intake of up to 10 mg/day organic copper from food is not associated with adverse effects.

** The UK Expert Vitamin & Mineral Committee concluded that more than 99% of those prone to Wilson's disease would normally have been diagnosed by the time they were exposed to sports foods. EVM/99/19/P

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[5] Shrimpton, D.H., (1997). Vitamins and Minerals. A Scientific Evaluation of the Range of Safe Intakes. European Federation of Health Product Manufacturers.

The UK FSC concluded that idiopathic childhood cirrhosis has been linked to feeding with milk which has been boiled and stored in copper vessels; however, even with this condition, there appears to be a genetic component, and some children exposed to high concentrations of copper in milk do not go on to develop symptoms of toxicity. Although it has been postulated that young infants are more sensitive to excess copper than normal adults, as mechanisms of biliary excretion and transport are not fully developed at birth, there is no direct evidence in humans or other mammals that newborns are more susceptible to hepatic damage from copper ingestion. EVM/99/19/P

26) For infants, (0-1 year) they identified a NOAEL of 45 ug for **vitamin D**, and applied an uncertainty factor of 1.8 to derive an upper safe level of 25ug.

27) Restrictions of 2.5 ug for vitamin D are therefore not consistent with an evidence based risk analysis approach to regulating foods, especially given the balanced nutrient composition of the vast majority of sports foods. None identified during the preparation of this submission approach the USL.

28) Therefore, on the basis of good regulatory practice, there is no market failure, so therefore there is no justification for arbitrary regulatory limits.

29) The UK FS EVM committee note that Nevé (1995) reviewed data on the effect of different forms of **selenium** on indicators of tissue selenium levels. It was concluded that inorganic forms of selenium increased blood selenium levels more rapidly and to a greater extent than organic forms, quickly reaching a plateau. In contrast, selenomethionine supplementation caused blood selenium levels to increase steadily without reaching a plateau; the results of supplementation with selenium-rich yeast were more variable. The response of erythrocyte selenium to changing selenium status tended to be slower than that of plasma selenium, partly due to slower kinetics but also reflecting the time taken to synthesise erythrocytes. However, no significant differences were apparent in the response of plasma or red cell GPX activity to the different forms of selenium. Platelet GPX activity was more sensitive to the chemical form of the selenium and was saturated at lower plasma selenium levels when selenite or selenate was used than when organic forms were used as supplements.

30) Therefore, it seems that ANZFA lower threshold for organic selenium is inconsistent with the scientific evidence and would in fact discourage the use of what appear to be safer forms of selenium ingredients.

31) In the 1991 Dietary Reference Value report, the Committee on the Medical Aspects of Food Policy (COMA) gave brief guidance on high intakes of selenium. The COMA panel agreed that 450 mg Se/day was the maximum safe intake of selenium from all sources. This corresponds to 6 mg/kg bw/day for a 75 kg male.

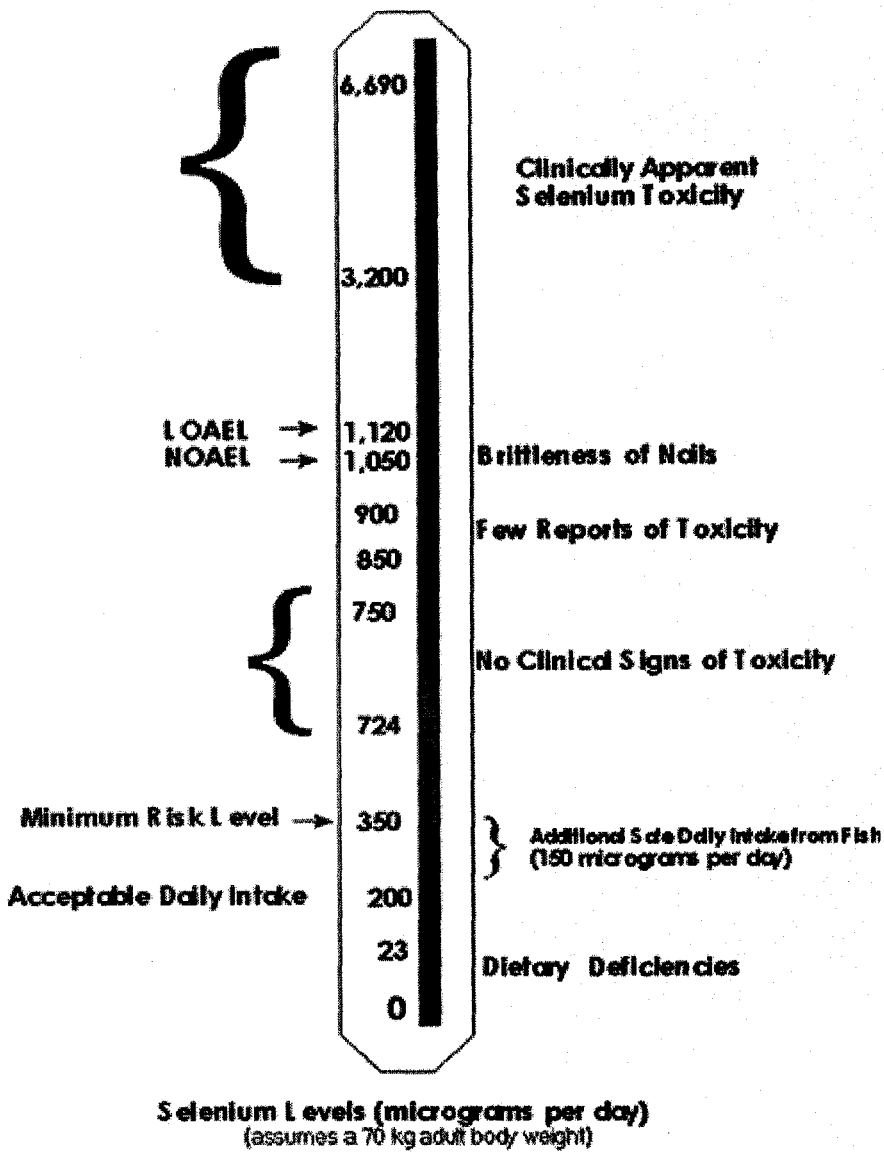
32) The Nordic Project Group (1995) considered an intake of 4-□mg Se/kg bw/day to be safe and tolerable. For a 70 kg adult the acceptable dose of 4-5 mg Se/kg bw/day was equivalent to an intake of 280-350 mg Se/day.

33) The United States Environmental Protection Agency (US EPA, 1994) used the Reference Dose (RfD) method to establish a maximum safe level for selenium of 5 mg Se/kg bw/day. (350 ug) (See Figure 2). Interestingly, the EPA concluded that it is important to note that the MRL based on the Chinese study may be conservative because only dietary exposure was considered and it has been suggested that inhalation exposure to selenium in smoke was significant.

34) The UK EVMS concluded that there were no concerns regarding the purity of

selenium in dietary supplement products have been identified.

Figure 2[6]



35) The 1991 report "Dietary Supplements and Health Foods - Report of the Working Group ("The Denner Report") was produced by the UK Department of Health and the Ministry of Agriculture, Fisheries and Food. In this, it was proposed that for isolated or highly purified products such as vitamin and mineral supplements, only one tenth of an identified "undesirable" dose should be present in dietary supplements as a daily dose. For selenium it was noted that adverse effects had been observed at intake

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[6] Center for Disease Control,
http://www.atsdr.cdc.gov/HAC/pha/marshall/mar_p4.html#figure2

levels of 1000 mg/day and this was considered to be the undesirable dose. The maximum level for selenium supplements would therefore be 100 mg/day.

36) Since then risk analysis methodology has moved on. The establishment of NOAEL levels, the increased certainty regarding toxicity and the disparity between deficiency associated risks (eg cancer, muscle pain, cardiomyopathy, enlargement of the heart, increased red blood cell fragility, and pancreatic degeneration) and toxicity associated risks (brittle fingernails, garlic breath and reversible neural effects) has meant that this level has now been set at 400 ug total intake. Industry worldwide has established upper selenium supplement levels of 200 ug.

37) The UAF[7] which results in supplement limits restricted to 26 ug is not commensurate with modern science nor with good regulatory practice. It has no scientific basis which means that it is contra to ANZFA's legal obligation to

38) Health food manufacturers recommended a maximum level for longterm supplementation of 200 mg Se/day (Hathcock, 1996, Shrimpton, 1994 and 1997).

39) The European Commission SCF/CS/Nut/Upplev/25 Final 28 November 2000 derived an UL of 300 mg Se/day was derived for adults. This value covers selenium intake from all sources of food, including supplements.

40) There is no evidence of any sports food approaching such levels in self-regulated markets.

41) Therefore, on the basis of good regulatory practice, there is no market failure, so therefore there is no justification for arbitrary regulatory limits.

42) In 1991, the joint MAFF/Department of Health Working Group identified 1g/day as an undesirable dose of **chromium** (III) and recommended that intake should not exceed 1/10 th of that (MAFF/DH 1991). This means that they set an upper safe level of 1,000,000/10 ug, or 100,000 ug per day which is quite clearly beyond the realms of any requirement for regulation when even food supplement supplier restrict dosage to less than 1% of that.

43) Clearly, there is no need to arbitrarily set limits on chromium levels in foods – self regulation more than satisfies any public health concerns.

44) The National Academy of Sciences found no evidence of any adverse effects due to excessive intake of chromium (III) from either food or dietary supplements.

45) The NHNES (III) determined that the 95th percentile for chromium from supplementation was 100 ug for men and 127 ug for women – both well within the upper safe level of 100,000 ug as mentioned above. Clearly, there is no need to regulate the maximum limits for chromium as presently occurs.

46) Therefore, on the basis of good regulatory practice, there is no market failure, so therefore there is no justification for arbitrary regulatory limits.

47) In the USA and many other countries, 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. With few exceptions, such is the case in New Zealand. There is no evidence of market failure in either country. Any safety issues primarily relate to values derived opinions and to

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[7] Unique Australian Factor

a very few individuals stretching boundaries to the limit; where genuine safety concerns exist, there is ample regulation under food law to deal with such practice. It is illegal to sell unsafe food – period.

48) Indeed, 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.

49) In its discussion, ANZFA correctly notes that 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. ANZFA then states, "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."

50) ANZFA's own research has clearly demonstrated that a vast proportion of Australian made sports foods do not comply with the requirements of Standard R10 in Volume 1 or Standard 2.9.4 in Volume 2. No public health issues have been identified as a result which suggests that current regulations are not only out of step with the market place, but if enforced would remove a considerable number of perfectly safe and nutritious product from the market and restrict consumer choice – this means that ANZFA's current food code relating to sports foods is not commensurate with good science, and if enforced, would be an effective barrier to trade.

51) Therefore, on the basis of good regulatory practice, there is no market failure, so therefore there is no justification for arbitrary regulatory limits as presently exists.

Statutory obligations

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

a) The objectives (in descending priority order) of the Authority in developing food regulatory measures and variations of food regulatory measures are:

i) the protection of public health and safety; and

ii) the provision of adequate information relating to food to enable consumers to make informed choices; and

iii) the prevention of misleading or deceptive conduct.

b) In developing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:

i) the need for standards to be based on risk analysis using the best available scientific evidence;

ii) the promotion of consistency between domestic and international food standards;

iii) the desirability of an efficient and internationally competitive food industry;

iv) the promotion of fair trading in food.

53) It is the NNFA's contention that:

a) the current sport food standard is far more restrictive than that required for the protection of the public health and safety,

b) the current sport food standard prevents manufacturers from providing adequate information relating to food to enable consumers to make informed choices (ie they can have more nutrient in the food than allowed to claim on the label) thereby preventing consumers from making informed choices,

c) this regulatory requirement therefore encourages misleading or deceptive conduct, rather than preventing it, .

54) It is also the NNFA's contention that the current sports food standard:

a) Is not based on risk analysis as required by law, nor is it based on the best available scientific evidence;

b) Does not promote consistency between domestic and international food standards as it introduces a Unique Australian Factor which is not commensurate with either good regulatory practice, nor the spirit of harmonization.

c) Hinders, rather than enhances an efficient and internationally competitive food industry as it imposes extra compliance costs due to reformulation and special Australian labeling requirement;

d) Does not promote fair trading in food as it imposes arbitrary formulation and labeling requirements that are not commensurate with good regulatory practices.

55) The NNFA agrees with the New Zealand Business Compliance Cost review which cautioned about the imposition of unnecessary compliance costs on New Zealand industry as a consequence of trans-Tasman Harmonisation. Harmonisation should be exactly that – not Australianisation.

56) There is no room in good regulatory practice for regulation unique to a particular country being imposed on another country in the name of harmonization, especially when there is no evidence of public health issues, nor is evidence based risk analysis used to drive the regulation.

Specific questions

Objectives of Development of a Joint Regulation for Sports Foods

Policy Framework Specific to Sports Foods

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

57) The NNFA endorses a regulatory framework for sports foods that is based on scientific risk assessment and is enforceable, meaningful and credible. The current food standards clearly do not align with the above.

- **ANZFA says**, 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;
    - The NNFA believes that food law should operate on a negative list basis, not a positive list that very often is not evidence based. We agree with the statement that sports foods are specifically formulated to assist sports people in achieving specific nutritional or performance goals,
    - In a globalised world, there is no place for a Unique Australian Factor regulatory system.
- **ANZFA says**, sports foods are intended as supplements to a diet rather than for use as the sole or principal source of nutrition;
    - The NNFA does not accept this view of sports nutrition. Rather we see sports foods in the same light as any other food – they simply add to the range of food that consumers are able to choose to eat. As such, we believe that sports foods are better viewed a 'serving option' rather than a supplement or food substitute. The fact that they are targeted towards sports/fitness minded consumers is no different from products targeted toward any other market segment.
    - If ANZFA is to continue to caution against food supplements on the basis that some people might use them as a sole or principal source of nutrition then they must take the same view for any food. Some people eat muesli, or even grapefruit as their primary source of nutrition for periods of time – that is their choice. It is argued that many children consume a predominantly potato chip and Coke diet – ANZFA does not require special labeling warning about the folly of such a diet which is much more likely to be longer term.
- **ANZFA says**, maximum amounts of nutritive substances should be set based on scientific risk assessments, and a cautionary approach in the absence of substantive evidence.
    - The NNFA belives that there should be a generic food standard for upper safe amounts of nutritional substances.
    - As outlined in this submission, many of ANZFA's current maximum claimable amounts and even allowable amounts are not based on evidence but are philosophically driven. This is unacceptable in a modern regulatory environment.
    - A cautionary approach in the absence of evidence must have a large dose of commonsense applied to it if it is to be rationally applied. If ANZFA were to apply a similar approach to its assessments of GE foods then the sport nutrition industry would have no fear of such an approach

as clearly there is vastly more scientific evidence relating to the safety of sports foods than there is regarding the safety of GE foods. If ANZFA were to continue to apply the 'cautionary' approach shown towards the establishment of allowable limits for many nutrients such as B12 and selenium, then it would have grave concerns regarding the objectivity of its regulatory system.

- **ANZFA says**, 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;
    - Rather than a 'permission based' regulatory system, the composition of sports foods should be restricted only when there are legitimate safety/public health concerns.
    - Many markets are self-regulated and have no significant public health problems. Prohibition never worked, and internet trading will ensure that desperate consumers can always get what they want and in doing so increase their exposure to harm as such markets are more likely to
    - It is unscientific to use RDI or ESADI to establish upper safe levels. They were never designed for such use. They are in fact MINIMUM levels of intake required for a given population and relate to nutrient deficiency. There is zero relationship between RDI and toxicity and are incompatible with good regulatory practice.
- **ANZFA says**, certain substantiated claims could be permitted relating to physical performance and training;
    - The NNFA is of the view that fair trading law should apply to all claims,
    - Present application of evidence to derive regulator determined 'substantiated claims' prevents honest claims from being made. This in turn prevents consumers to make informed choices which is anathema to good regulatory practice as well as ANZFA's legislative mandate.
- **ANZFA says**, 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;
    - Sports foods are no different than any other food in that consumers have a wide range of product to choose from and do so of their own free and hopefully informed choice.
    - There are no warnings that chips, are not good for children, or even that alcohol is no good for pregnant women. There is no scientific evidence to even suggest that women consume inappropriate amounts of sports foods.
    - Warning labels should be kept for genuine occasions, otherwise they will lose their impact.
- a prescribed name should be required to assist enforcement agencies.
    - To assist enforcement agencies do what? The current sports foods regulations are clearly not enforced with no negative impact on public

health. So long as ingredients are listed on the label, why should manufacturers be required to use linguo specifically for the benefit of regulators?

OPTIONS FOR REGULATION

58) ANZFA suggests that there are four options for the regulation of sports foods. These being:

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.

- The Ministry of Health has informed the NNFA that stated NZMOH proposal is not going to be actioned. On that basis, the status quo is not a bad option for New Zealand only supply companies, but clearly is not favoured by companies that supply to Australia.

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.

- As the NZMOH proposal is not on the agenda, this option is not valid either.

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.

- If the proposed revision of the sports food standard was undertaken on a risk based basis, then clearly a code pf practice would be a viable regulatory option.

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.

- Again, given the fact that the NZMOH have no intension of proceeding with the proposal, this is not a valid option as proposed.
- The NNFA would suggest a fifth option for ANZFA's consideration

OPTION 5: That ANZFA establish a joint working party with Australian and New Zealand industry to establish a pragmatic sports food standard that enables suppliers to provide safe and honestly labelled product to discerning consumers in such a way that consumers can make informed choices.

59) ANZFA needs to be reminded that compliance costs are significant to industry. Its own research has shown that there are no evidence-based significant public health issues concerning sports foods, and that very little product conforms to the present regulation in both countries. ANZFA has failed to demonstrate that there is a public health concern which means that it has failed to establish the need for specific sports food regulation.

Purpose of regulation

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."

60) The NNFA agrees with ANZFA's comment that many people who consume sports foods are not in fact sports people – simply health conscious folk who want to get/stay fit and healthy.

61) The vast majority of these folk eat sensibly and are not impressed or influenced by philosophical statements mandated on foods.

62) Extremists can never be regulated for.

63) Many sports foods are simply serving substitutes and are consumed as a part of a balanced diet. The need for the current statement is no more logical than a similar statement would be required for any food.

64) The fact that the addition of many nutrients to other foods is prohibited is philosophically driven, not based on evidence of public health concerns nor evidence based risk assessment as required by law.

65) The arbitrary linking of suitability of consumption of sports foods by children to a regulator defined use has no rational basis and is inconsistent with other food standards.

66) **ANZFA says**, The appeal of sports foods to children is becoming an increasing concern. The NNFA asks,

- What is this concern?
- Who is concerned?
- How does this concern compare to the increasing concern about the number of children who consume a 'chip & Coke' diet?
- What evidence does ANZFA have that there is in fact a public health issue regarding sports foods?
- Has ANZFA undertaken a risk analysis regarding these alleged public health concerns?

67) **ANZFA says**, Children often see sporting heroes as role models and this can influence copy-cat behaviour. The NNFA asks,

- If our sporting heroes are good citizens, is this a problem? Or even undesirable?
- If this is of concern, then why doesn't ANZFA ban Michael Jordan adverts for Colas?
- What evidence does ANZFA have that this is causing a public health issue?

68) **ANZFA says**, 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. The NNFA asks,

- This is a very values driven statement. Is there any evidence that there is a public health issue? If so, then sipper tops should be banned or regulated, not sports foods.

69) **ANZFA says**, For the purpose of Standard 2.9.4, children are considered as those under 15 years of age. The NNFA asks,

- Is this definition scientifically based?
- Is it relevant?
- Regulators need to ensure that food standards are not philosophically driven if the standard is to be taken seriously by consumers or industry.

70) **ANZFA asks**, Is the purpose of a Sports Food standard appropriately encompassed by the opening paragraphs in Standard 2.9.4? The NNFA asks,

- Is a definition of the purpose of a food is irrelevant in the market place?

71) **ANZFA asks**, Should sports foods be formulated for reasons beyond physiological demands? If so, what other needs or wants should be considered?

- Again, this is a marketing issue and has nothing to do with the safety of a product.

72) **ANZFA asks**, 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?

- Does a potato chip standard focus on the needs of any one group?
- Does it consider the possible consumption by 'other groups?'
- The use of a food will never be determined or controlled by the standard under which it is manufactured. Most people would never have heard of a food standard.

73) **ANZFA asks**, What other key features may need to be addressed?

- Evidence-based risk assessment, public health, honest labeling, free and informed choice.

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

- It can never be achieved so should even be considered. It is a value driven thought and unless backed by scientific evidence should be discarded as a consideration.

75) **ANZFA asks**, What is the most appropriate definition of a sports food?

- The present definition 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 is an interesting definition given the fact that it is a therapeutic purpose.
- This highlights the need to redefine the term "therapeutic purpose" for regulatory function.
- As noted earlier, a large proportion of consumers of sports foods are not in fact sports people.

76) **ANZFA says**, 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.

- What is the public health concern here?
- How high is "particularly high?"
- Is this in terms of risk analysis and proven upper safe levels, or is it a values statement by dietetics?
- Given the fact that there is no scientific evidence of adverse effects due to excess folic acid intake, and a large body of scientific evidence of the benefits of increased folic acid intake, why should this be of concern to regulators?

77) **ANZFA asks**, 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?

- The answer here is simple. If ANZFA has undertaken a risk analysis and has legitimate evidence of harm then it has grounds to exclude single ingredient foods – otherwise, sports foods should not be singled out for special attention.

78) **ANZFA asks**, 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?

- Again, if legitimate evidence-based risk analyses have established legitimate cause for concern then that substance should be regulated appropriately, regardless of how it is presented. These issues should be dealt with generically, not via a plethora of standards.

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

- This is not a public health issue – it is a choice issue.
- So long as caffeine is declared on the label, there is no public health reason why it should not be able to be added as an ingredient.

- It is the responsibility of athletes to ensure that they do not consume caffeine – all they need to do is learn how to read the label.
- Given that most consumers of sports foods are not elite athletes, the likelihood of this being a problem is small. It's worth noting that Coca Cola and Pepsi are major sports sponsors, and most sports people are likely to consume their caffeine containing products..

80) **ANZFA asks**, Is the labelling of products with general advisory statements that warn against consumption by vulnerable groups an appropriate risk management strategy for sports foods?

- Australian regulators penchant for advisory and warning statements is only immunizing consumers when it comes to legitimate concerns.
- Advisory and warning statements should be reserved for when there are genuine public health concerns, not when regulators and/or their advisors have value driven opinions.
- There is no place for the UAF in harmonized food standards.

81) Is ANZFA intending to re-regulate soft drinks in light of the fact that soda is causing nutritional deficiencies in children? [8]

- Children and adolescents who drink soda may be depriving themselves of several important vitamins and minerals, results of a new survey suggest.
- The researchers note that soda consumption among children and adolescents rose 41% between 1989-1991 and 1994-1995, mostly displacing milk and juice, the leading sources of many vitamins and minerals in the American diet.
- The results are based on data from more than 4,000 children aged 2 to 17 years.
- Among children aged 2 to 5:
  - 75% drank milk, 53% drank juice, 34% drank soda
- In those aged 12 to 17:
  - 63% of boy and 49% of girls drank milk, 34% drank juice, 68% of boys and 63% of girls drank soda
- Soda drinkers were less likely to get the recommended levels of:
  - vitamin A, calcium, magnesium

The NNFA strongly encourages ANZFA to continue to move away from regulation based on the UAF[9] and move toward international best practice using the least restrictive regulation required to protect public health, enable free trade, and informed freedom of choice. **Any other regulatory environment is anathema to good regulatory practice.**

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[8] Archives of Pediatric and Adolescent Medicine November, 2000; 154: 1148-1152

[9] Unique Australian Factor