Submission relating to the

Draft
New Zealand Food (Supplemented Food) Standard 2008

A submission made jointly by the Submitters:

New Zealand Health Trust ("NZHT") and

New Health New Zealand Incorporated ("New Health")

- NZHT is a charitable trust focused on health education and New Health is an incorporated society representing the interests of the New Zealand Health Consumer.
- New Health currently has over 34,500 members.
- Both groups are non-profit organisations with no commercial interest in the matters under discussion.

September 2008

Contents

Introduction

The Submitters are concerned that the proposed food standard needs to be implemented in a wider context and not as an ad hoc standard that in essence continues to introduce policy that has failed to get the support of parliament, namely the shifting of the regulation of dietary supplements from food to pharmaceutical legislation.

The Submitters believe that **if** the food standard is to be introduced it should be amended, as we propose below to stop the industry from being fragmented.

1. The NZHT is currently working with consumers and industry, and has taken on the role of industry coordinator in this respect, to finalise a proposed regulatory framework for Natural and Traditional Health Products, which is intended to embrace the full range of products currently referred to as dietary/food supplements, ranging from supplementing diets to therapeutic purposes. To this end, we offer to hold a meeting to coordinate your proposed changes with those of our model on a helpful constructive basis.

2. Whilst the New Zealand Food Safety Authority (NZFSA) seeks submissions from all interested parties on any technical aspect of the proposed Supplemented Food Standard, the submitters request that the entire context and proposed fragmentation of the proposal be reviewed in light of the Regulations (Disallowance) Act 1989.

Political Context has Changed

3. At the same time that ANZFA was considering trans-Tasman harmonisation of foods, the Joint Therapeutic Products Agency (JTA) team (a preliminary working group formed between respective therapeutic products agencies in Australia and New Zealand) was also developing a proposal for harmonised regulation of medicines.

4. This proposal effectively gives teeth to the failed proposed joint Australia New Zealand Therapeutic Products Agency, which has not eventuated. This therefore removes the main rationale for this food standard.

5. The Submitters would caution that the context of the proposed changes is no longer valid.

Proposal is Ad Hoc and Inconsistent with International Best-Practice

6. The proposal is ad hoc and will have negative effects by adding cost to industry. The proposal will also fragment an emerging industry that involves the manufacture of food supplements and also functional foods, (ie, those proposed to be regulated by this standard) alongside encapsulated and tabletted food supplements that were to be reclassified as medicines.

7. The proposed standard is based on arbitrary upper levels which are scientifically weak, open to the establishment of artificial technical barriers to trade and inconsistant with good regulatory practice.

8. Nevertheless, the upper limits derived are, with some notable exceptions, reasonable.

    a. The upper level set for nicotiamide should be mg and not ug;

    b. There is recent evidence supporting a UL of 200mg for vitamin D;

    c. Boron is prohibited under the proposed standard even thoiugh the WHO now views Boron as an essential mineral.

Proposal Definitions Inconsistent with International Law

The Submitters ask why is the NZFSA adopting an ad hoc 'pick and choose' approach to food regulation when applying Codex standards and wrongly applies Codex guidelines?

9. The Submitters are puzzled as to why the New Zealand government and the NZFSA adopts the Codex guidelines for vitamin and mineral food supplements for the regulation of products in a conventional food form (for which the Codex guidelines are NOT intended), but then argues that vitamin and mineral food supplements in a dose form (for which the Codex guidelines ARE intended) should not be regulated as foods, but regulated as drugs.

    a. The Codex Procedural manual defines food as being, "*any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used **only** as drugs".*

    b. Clause 2.1 of the Codex Guidelines For Vitamin And Mineral Food Supplements CAC/GL 55 – 2005 defines vitamin and mineral food supplements as being; "*for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., that are designed to be taken in measured small-[physical]-unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet*."

New Zealand Law Not Administered: Form Does Not Define a Medicine

The NZFSA seems confused regarding the law it is mandated to administer.

10. In the problem definition section of the accompanying Discussion Paper; no. 05/08 {July 2008}, the NZFSA states: *"The legislation administered by NZFSA does not provide coverage for products intended for therapeutic purposes and NZFSA does not have the capacity or mandate to provide effective regulatory coverage for dietary supplements presented as therapeutic products."*

    a. The discussion paper sates; *"The definition also describes those products that are outside the scope of the Standard. Such products include therapeutic-type dietary supplements (to be regulated under the amended Dietary Supplements Regulations), medicines, and food for which there is a food standard in the Code. Such products include therapeutic-type dietary supplements (to be regulated under the amended Dietary Supplements Regulations), medicines, and food for which there is a food standard in the Code."*

    b. And yet the definition in the proposed standard does not make mention of the term 'therapeutic-type products' but it does exclude products currently defined as dietary supplements under the The New Zealand Dietary Supplement Regulations (DSR (1985)).

    c. The DSR (1985) aligns with the Codex definition but also includes non-vitamin and non-mineral food supplements in defining dietary supplements as; "*Dietary supplement means any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and*

vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food."

d. Dietary supplements, whether in capsule form or muesli bar form (by way of examples) are not used "only as drugs" so therefore meet the Codex definition of foods.

11. The NZFSA claims related to what it refers to as (undefined) 'therapeutic-type' dietary supplements has no legal basis in either New Zealand law or international law.

a. The accompanying Discussion Paper; no. 05/08 {July 2008} contradicts the Codex definition of vitamin and mineral food supplements, the definition of food supplements in the EU Directive 2002/46/EEC, the definition of dietary supplements in the USA dietary supplement act (DSHEA) and even existing New Zealand law when it claims that dietary supplements in a capsule or tablet form are not foods and that "*the NZFSA does not have the capacity or mandate to provide effective regulatory coverage for dietary supplements presented as therapeutic products.*

12. Recent case law does not support classifying products based on their presented form; being encapsulated or tabletised does not change the purpose of an ingredient nor does it inherently alter an ingredient's risk profile.

a. The European Commission's definition of food supplements does not differentiate foods & medicines based on dose form (Directive 2002/46/EEC). Food supplements are defined as:

"Foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop-dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities."

b. This is very similar to the definition of a dietary supplement in the DSR (1985):

c. The European Court of Justice (ECJ) endorsed this recognition that dose form does not define a food or medicine.[1] The capsule form is not exclusive to medicinal products, given that a large number of foodstuffs are in fact offered for sale in that form in order to facilitate their ingestion by consumers.

d. The ECJ ruled that Germany failed to fulfil its obligations concerning the free movement of goods by refusing to import garlic extract powder capsules. German authorities considered garlic capsules as a medicinal product not a foodstuff, and were concerned about the risks connected with taking garlic in general, and therefore refused to market them as a food supplement.

[1] Judgement in Case C-319/05 Commission of the European Communities v Federal Republic of Germany http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=docj&numaff=C-319/05 or http://tinyurl.com/6ajxjr

e. But the court ruled against this move. In the judgement, the court decided the capsules could not be called a medicinal product. It said that while presentation in capsule form is an indicator towards classification amongst medicinal products by presentation, this can not be the sole indicator, nor is the capsule form exclusive to medicinal products.

f. Regarding the concept of a medicinal product by function, the Court stated that garlic capsules do not contain any substance other than natural garlic and have no additional effects, either positive or negative, compared to those derived from the consumption of garlic in its natural state.

g. In contrast, a medicinal product must have the function of preventing or treating disease. Beneficial effects for health in general are not sufficient.

13. The Definition of a 'Supplemented Food' defines a supplemented food as a product that is represented as a food:

a. for consumption by the general population; and
b. that has a substance or substances added to it or that has been modified in some way;
c. to perform a physiological role **beyond the provision of a simple nutritive requirement**; and…

14. The term, **simple nutritive requirement** is not defined.

15. The Submitters suggest the same rules should apply to all dietary supplements including those in dose form otherwise a distortion of the market will be created whereby products with similar purposes of supplementing the normal diet will be treated differently for political and non scientific reasons.

a. In other words, we believe that the proposed food standard should be reconsidered for technical and political reasons especially given that the context for the proposed standards has disappeared.

Unscientific Prohibition of Emerging Essential Nutrients

16. The Submitters fully support appropriate regulation and reasonable and appropriate codes of practice that enable consumers to make informed choices, but **not** when such actions prevent consumers from making any choice, as is the case with the proposed ban on the addition of boron to foods as an essential element.

17. The development of a new food standard that effectively prohibits the addition of emerging essential nutrients such as boron is arbitrary, not risk based and is inconsistant with the government's code of good regulatory practice.

18. The NZFSA reference regarding UL acknowledges that the World Health Organisation recognises that boron and other nutrients and dietary factors may be important for long-term bone health[2], and yet they did not consider it to be essential and consequently, under the proposed standard boron would be a prohibited mineral as it is not included in any FSANZ standard that would permit its use.

[2] http://www.nhmrc.gov.au/publications/synopses/_files/n35.pdf

Use of Arbitrary Upper Limits (UL)

19. The application of an arbitrary 50 percent of the Australian derived upper safe level is contrary to good regulatory practice for several reasons.

20. There is **no** evidence to support the claim that this is normal practice and routinely used in the context of Codex.

21. There have been several international scientific bodies that have derived ULs with various outcomes based on the same data.

22. These ULs have been different due to differing safety factors built into the mathematics of each expert group.

23. Sometimes adverse effects used to set upper safe levels have been based on physiological effects and not affects that are hazardous or life threatening.

24. Upper Levels are based on the most toxic form of a given nutrient group. For example, the UL for iron is based on iron sulphate (used medically to treat anaemia) which causes gastrointestinal upset and has been implicated in child poisonings. This UL is then applied to all iron forms including forms such as ferrous bisglycinate which has no side effects at considerably higher dose ranges.

25. All documented cases of accidental iron poisoning as a result of young children accessing their mums iron tablets have recorded iron sulphate. No other iron form has been documented in such poisoning, and yet iron sulphate has not been regulated… rather, all forms of iron have been restricted unscientifically.

26. Choosing one set of ULs is arbitrary and opens the door to creating a technical barrier to trade and thus being challenged. By way of examples:

    a. Nicotinic acid: There are no adverse health effects from the consumption of naturally occurring niacin in foods. The UL for nicotinic acid is based on vasodilation (flushing) which is not hazardous to health, and is self limiting. To impose a regulatory limit on nicotinic acid when there is no significant hazard to health is arbitrary and contrary to good regulatory practice.

    b. Vitamin C: The 'adverse effects' relating to vitamin C intake used to establish ULs has been gastrointestinal disturbance at high doses of the acid form. This is an osmotic effect not unlike that following the eating of too much of certain fruits and is easily prevented by either consuming less ascorbic acid, or maintaining similar vitamin C levels by substituting the acid form with acsorbate salt or the form commonly known as ester C, neither of which exhibit the osmotic effect. Setting a very conservative upper limit of 500mg per serving defies good risk management practice and therefore is not evidence based and is contrary to good regulatory practice. Using 50 percent of the USA Institute of Medicine UL for vitamin C would result is an upper limit of 1,000mg, not 500mg.

    c. Vitamin D: Hathcock has recently undertaken an extensive risk analysis of vitamin D using the latest available data from extensive human trials[3]. This analysis demonstrated a USL based on a well defined NOAEL of 250ug per day, some 300 percent higher than the USL used by the NZFSA in setting a [50 percent] limit of 40ug per day.

[3] Hathcock JN, Shao A, Vieth R, Heaney R. Risk assessment for vitamin D. Am J Clin Nutr. 2007; 85(1): 6-18. http://www.ajcn.org/cgi/reprint/85/1/6

d. Boron: The failure to provide for the addition of boron to food supplements at all is anathema to good regulatory practice. There are numerous risk analyses showing that boron supplemetation is very safe including levels up to 10-20 mg per day.

Proposal Fragments Industry

27. Foods and therapeutic products are not defined by their form, attempting to do so not only fragments a diverse industry and adds extra regulatory burden, but such an arbitrary delineation is contrary to international case law.

28. The separation of dietary supplements into food-type and therapeutic type products is arbitrary, very Australian, and inconsistant with recent international case law.

29. The introduction to the initial ANZFA assessment of proposal P235 defined the term *food-type* dietary supplements (FTDS), where it emphasised that *"these products are regarded as foods and that FTDS… have predominantly more food characteristics whereas therapeutic-type dietary supplements (TTDS) (known as complementary medicines in Australia) are more therapeutic in nature. The factors that are taken into account to determine whether a product is a food or not include representations such as claims, other labeling information, dosage form and certain compositional characteristics."*

30. The proposal now simply uses dose form to fragment a legitimate industry. As noted earlier, this fragmentation has no basis in either domestic or international law.

31. Food companies that market, for example, sports supplements would have creatine capsules arbitrarily categorized as therapeutic products for no other reason than because the powder is presented in a capsule. In fact, a 500gm tin of creatine would be regulated as a food even though the chances of overdosing are much greater than consuming 2-3 capsules.

32. NZFSA needs to carefully reconsider the boundary that exists between food-type and therapeutic-type dietary supplements.

33. Under Article 11 of European Commission Directive 2001/83, 'medicinal product' provides:

    a. '*(1) Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive'*.

34. The separate classification of food-type and therapeutic-type dietary supplements is an administrative decision according to which products composed of dried garlic powder which are clearly not labelled or presented as medicinal products are treated as such. Other examples include the classification of creatine as a therapeutic product simply because they are marketed in a small container called a capsule. Creatine is not marketed for a therapeutic purpose, rather it is marketed as a food or nutritional supplement to support normal physiological processes.

Conclusion

We respectively request that:

1 the NZFSA works with the submitters to put in place risk proportionate legislation of natural and traditional health products at the therapeutic and Supplemented food interface;

2 the rationale for applying the use of the 50 percent of upper levels, derived for food supplements, to the regulation of another class of product be explained before any decision to implement the proposed standard;

3 mistakes be corrected, eg, nicotinamide (mg not ug);

4 ULs be updated in light of new evidence. The easiest way to achieve this would be to have a schedule of acceptable authorities regarding the establishment of Uls including the IOM, EU FSA, Hathcock and Shrimpton series of risk analyses;

5 a regulatory impact statement (RIS) be prepared as needed to assess any costs and benefits as required by the Cabinet operating manual and good regulatory practice;

6 an RIS is also required in order to be able to make an informed submission on regulatory burden due to the implementation of these proposed standards;

7 that the NZFSA works with the submitters and industry to establish a robust series of definitions to delineate the various classes of foods and related products;

8 the foods proposed to be regulated by this standard could be defined in terms of being foods that primarily provide a substantive portion of daily macronutrient requirements. Dietary supplements, on the other hand, could be defined as being foods that contain an insignificant macronutirent component, and are essentially micronutrients and phytonutrients in concentrated form intended to supplement their daily intake;

9 the NZFSA reconsiders its use of a Codex guideline for a purpose not intended in the guideline;

10 the NZFSA applies Codex's definition of food and food supplements when considering the setting of food standards;

11 the NZFSA accepts that it <u>does</u> have a legal mandate to regulate dietary supplements as defined in the DSR (1985);

12 in light of recent case law that confirms that the dose form does not define the purpose for which a product is sold, (nor does it define the intended use of a product,) the NZFSA refrains from arbitrarily redefining terms defined in statute and regulation;

13 the NZFSA includes boron in the table of ingredients with an upper level of intake;

13.1 In light of internationally derived UL, a level of 9mg per day poses no discernable risk to the general population and should be included in the schedule;

14 that reference to black cohosh be removed given the fact that no consultation was undertaken and no risk assessment was included in the proposal;

14.1 To do otherwise would be to accept a non-risk-based regulatory process which is contrary to the NZFSA's stated modus operandi, is

inconsistant with good regulatory practice, and is open to a complaint being laid under the Regulations (Disallowance) Act;

15 the NZFSA establishes a schedule of acceptable risk analysis derived upper levels of intake. It is accepted that there will be variations in the outcomes as most have used the same data but simply applied different uncertainty factors. Others are more recent reports that include more up to date science such as Hathcock's recent review of Vitamin D;

16 the NZFSA revisits its acceptance of the Australian driven and arbitrary definition of foods and pharmaceutical-type products based almost entirely on dose form;

17 arbitrary division of market products is inconsistant with good regulatory practice and will serve to fragment a significant and legitimate industry;

18 the NZFSA should not allow itself to become a trojan horse for the implementation of the failed proposed Australia New Zealand Therapeutic Products Agency;

19 the NZFSA works with the submitters and the wider industry to develop a modern risk proportionate legislative framework to regulate these products utilising the optimal regulatory model based on risk, rather than based on ideology or rejected policy;

- We would be very interested in arranging a meeting to constructively help coordinate and streamline all the proposed changes with our proposed Natural and Traditional Health Products model, to ensure a favourable outcome for New Zealand.
- This submission is made as constructive help and thank you for the opportunity to be involved.

Contact Details

David Sloan
PO Box 34-057
Christchurch

Tel: 03 351 9807
Fax: 03 351 7993