SUBMISSION TO
THE NEW ZEALAND FOOD SAFETY AUTHORITY
IN RESPONSE TO THE PROPOSED CHANGES TO
THE DIETARY SUPPLEMENTS REGULATIONS 1985
NZFSA PUBLIC DISCUSSION PAPER NO. 01/04

Submitted by
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1. The New Zealand Health Trust is a charitable trust which contains amongst its objectives the protection of health choices and access to high quality health information for all New Zealanders.

2. As part of its objectives the Trust has been closely monitoring the Medsafe proposal to establish the Trans-Tasman Therapeutic Goods Agency. The Trust is opposed to the establishment of such an agency and has been, and is continuing to rally support from the natural health product industry at large, consumers of the products and the media. The Trust continues to be confident that there is likelihood the implementing legislation required to establish the agency will not succeed.

3. In the Trust's submission it is quite inappropriate to be calling for submissions as to how "food type dietary supplements" should be handled as a consequence of the Trans-Tasman agency being established given that the establishment of this agency is far from a certainty.

4. As the Dietary Supplements regulations will not need to go through the normal legislative process to be altered, and accordingly there will be no other opportunity for public submission in respect of the proposed changes, this consultation should not be called for until there is certainty as to the outcome of the treaty signed between the Australian and New Zealand Governments in this regard.

5. Given that there have been two Health Select Committee reports which strongly condemn the establishment of the Trans-Tasman Therapeutic Goods Agency it is, in our submission, inappropriate for NZFSA to give industry stakeholders and the public their only opportunity to comment on the proposed changes on the assumption that the Therapeutic Goods Agency will proceed when this is anything but certain.

6. One of the principal areas of objection to the Trans-Tasman Therapeutic Agency and one which the Select Committee have endorsed in its report is that natural health products should be regulated as their own entity distinct from both medicines and food. What is instead proposed by the current Government is that natural health products be arbitrarily divided for incorporation into both medicines and food.

7. Natural health products by their nature are not only separate and distinct from medicines and food, but as an industry are often in effective competition with the same. To force industries in this business to be regulated and controlled by bodies reflecting their competitors is both unwarranted and unjust. In addition many businesses in the industry will find themselves having to straddle both compliance systems and have an enormous compliance burden as a result.

8. It is our submission that natural health products should be separated from both medicines and foods and regulated by a separate and distinct body. As noted above this submission has been endorsed by the Health Select Committee and in light of their endorsement should not be discounted. Until this issue is comprehensively addressed we submit that it is inappropriate to make any amendment to the Dietary Supplement Regulations.

9. Prior to there being any move in the future to amend the Dietary Supplements Regulations it is our submission that more information needs to be provided on the Codex regime, New Zealand's involvement and obligations to it and public consultation be sought based on full disclosure of this information.

10. By way of specific comment to some of the issues raised in the Discussion Document the Trust supports increasing the maximum daily allowable dose of folic acid however, submits that the limit of 500 mcg is still patently inadequate. In support of this we note that over the counter supplies of folic acid from any pharmacy record that the usual dosage is between 5 and 20 mg (the equivalent of 5000 to 20,000 mcg). Based on this there is no justification whatsoever for compelling natural health products to have no more than a patently inadequate level of folic acid when their pharmaceutical competitors are entitled to provide folic acid and indeed recommend to clients that they take folic acid, at a far higher level.

11. The Trust supports the removal of a maximum daily dose rate for vitamin B12.

12. The Trust supports natural health products being entitled to contain any ingredients or additives which foods are entitled to contain, however as an aside we would note that many of the artificial sweeteners listed would be considered by many in the natural health product industry as being undesirable additives, that notwithstanding whilst they are permitted in food they should properly be able to be included in health products.

13. Because of the assumption made in the discussion document that the Trans-Tasman Therapeutic Products Agency will proceed and that remaining natural health products outside the scope of those regulations should be included as food, the Discussion Document repeatedly fails to set out all options and instead asks comment on a predetermined and somewhat limited range of options. In this way the document guides readers towards the conclusion that the NZFSA clearly wish to reach. We do not support the scope or presentation of the document for this reason. In the submission of the Trust the Discussion Document is inadequate public consultation for these reasons.

3 September 2004