



Te Pou Oranga Kai O Aotearoa

FACSIMILE MESSAGE**To** Project Manager P235**Fax** 0061 2 6271 2278**Date** 30 August 2002

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From [REDACTED]**Subject** Submission: P235

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Our submission attached.

30 August 2002

Project Manager – Proposal P235 – Review of Food Type Dietary Supplements
Food Standards Australia New Zealand
PO Box 10559
Wellington

Dear Sir/Madam

P235 Review of Food-Type Dietary Supplements

Thank you for the extension of time for the New Zealand Food Safety Authority (NZFSA) to make a submission on the above proposal.

Introduction and scope of the review

The NZFSA supports an approach to the development of a food-type dietary supplements (FTDS)/functional/fortified foods regulatory regime that is based on responding to emerging trends in the areas of food fortification, functional foods and claims about food.

In our view key trends that need to be considered include:

- an on-going interest from industry to fortify general purpose food, in ways similar to what happens today with FTDS in New Zealand under the Dietary Supplement Regulations 1985. FSANZ will continue to attract applications from industry to amend the Code, such that the nutrition principles that underlie the Code are 'pushed past their usual interpretation';
- the development of foods that are loosely categorised as 'functional foods'. If this review is to have a successful long-term outcome it must be able to regulate this emerging group of foods;
- foods with added substances that are promoted as having a therapeutic effect, for instance margarines with added phytosterol esters. This is likely to be a growing area, with many of these foods requiring pre-market safety assessment as novel foods. Such foods may well contain refined herbal and other extracts; and

- the strong association between FTDS/functional/fortified foods and nutrition and health claims.

We note that proposal P235 is based, to an extent, on adapting the provisions in the New Zealand Dietary Supplement Regulations 1985 to provide a set of permissions for FTDS in the Food Standards Code. We are uncomfortable with this. The New Zealand Dietary Supplement Regulations 1985 were designed to regulate controlled dosage supplements, such as tablets and capsules.

The New Zealand Dietary Supplement Regulations were intended to cover products not regulated by the Food Regulations 1984, rather than provide a choice of regulatory regimes for the food industry. At the time the Dietary Supplement Regulations came into existence most dietary supplement products were vitamin and mineral capsules. Other products were not assessed for safety. Since 1985 there have been significant changes in dietary practice with respect to both dietary supplements and foods. As such, the New Zealand Dietary Supplement Regulations are not an adequate base to on which to model permissions within the Food Standards Code for FTDS/functional foods, not foods.

The NZFSA confirms that it is preparing a discussion document proposing that foods would not be allowed to be sold under the New Zealand Dietary Supplements Regulations. We advise that Government has not seen the discussion document and that any final policy position will be subject to the results of consultation. While it would be clearly preferable for any amendment to the scope of the Dietary Supplements Regulations to be completed prior to the finalisation of P235, no guarantees that this will be able to be delivered can be given.

Significant policy drivers

The NZFSA sees the following as being significant policy drivers for determining the framework for the regulation of FTDS/functional/ fortified food.

- National nutrition policy. The New Zealand national nutrition policy, which underpins the New Zealand Food and Nutrition Guidelines, recommends that people choose from a wide variety of foods, and that for most people dietary supplements are not necessary. It is recognised that some situations, such as pregnancy, may require additional nutritional supplementation. We note that Australia has a similar national nutrition policy to New Zealand's.
- The NZFSA is strongly of the view that general purpose foods, along with foods that will not be fortified (such as fruit and vegetables) should be the major source of nutrition for consumers. This is consistent with national dietary recommendations in both countries.
- Food that differs from general purpose foods should be clearly identified, including FTDS/functional/fortified food (or whatever they may eventually be called), special purpose foods etc.
- The increase in FTDS/functional/fortified foods in the market potentially raises both short-term and long-term safety issues. Science in many of these areas is still uncertain but knowledge is increasing rapidly.
- For effective marketing manufacturers/sellers of FTDS/functional/fortified foods will want to make claims about these foods.

- There is a significant number of consumers who are vulnerable to 'silver bullet' claims.

Policy response

The NZFSA supports the following policy responses to the development of standards for FTDS/functional foods.

- The NZFSA is concerned that FSANZ is following a process for the development of a regulatory regime for FTDS/functional/fortified foods, in which all the policy parameters do not yet exist. The NZFSA recommends that Proposal P235 be put on hold until the key policy issues have been resolved. The NZFSA recognises that a number of the policy issues relevant to this proposal may be resolved when Ministers consider policy principles for health and nutritional claims and for fortified foods.
- Given that the science is uncertain, the Australia New Zealand Food Regulation Ministerial Council (through the Food Regulation Standing Committee) or FSANZ may need to convene a number of technical expert working groups or draw on information from existing policy groups to examine relevant issues. The working groups need to identify what is known, what is not known, policy responses and possible directions for science research that may be appropriate to be carried out in Australia and New Zealand. Issues that expert groups could usefully examine include:
 - the addition of substances/fortification to food;
 - which foods could have substances added to them;
 - restricted substances; and
 - the relationship with the rest of the Food Standards Code.

The NZFSA has tentatively come to the following conclusions. They will need to be re-examined following the agreement of relevant policy principles by the Food Regulation Ministerial Council.

- FTDS/functional/fortified foods require a separate nutrition policy to general purpose foods. Determining what is an appropriate nutrition policy for FTSA/functional foods is an essential first step, prior to the development of a standard or standards.
- FTDS/functional/fortified foods should be regulated separately from general purpose foods. The NZFSA does not have a view at this point in time as to how this should be achieved.
- FTDS/functional/fortified foods should be clearly differentiated from general purpose foods by labelling. This clear differentiation should also apply to any associated promotion material, including advertising.
- FTDS/functional/fortified foods must be clearly distinguished from therapeutic products.
- Until a regulatory regime for FTDS/functional/fortified foods is finalised FSANZ should not accept proposals to amend the Food Standards Code that are inconsistent with current nutrition policy used to develop the Food Standards Code.

Policy on safety, efficacy, substantiation of claims, cost

A regulatory regime for FTDS/functional/fortified foods faces many of the same issues being addressed in the development of the health claims policy and standard and which may be addressed by the Food Regulation Standing Committee Working Group on fortification of foods. Prominent amongst the issues will be safety, efficacy, substantiation of claims, cost of assessment, any effect on vulnerable populations (eg children, the obese, the 'worried well') and cost of compliance. The NZFSA believes that the outcome of the development of the health and nutrition claims policy and standards will provide policy guidance for some of these aspects of a regulatory regime for FTDS/functional/fortified foods.

The NZFSA notes that some foods that will come under a FTDS/functional/fortified foods umbrella may well be assessed as novel foods under Standard 1.5.1 of the Food Standards Code. While these foods will be entered into the table to clause 2 of that standard, it is important that they are also identified in any other specific standard.

The NZFSA is aware that food regulation in New Zealand and Australia needs to change in the area of FTDS/functional/fortified foods. Internationally, this is a rapidly developing area of innovation for industry and one that poses many challenges for regulators. The NZFSA supports the development of a regulatory regime for FTDS/functional/fortified foods as part of the Food Standards Code. The NZFSA, while wanting to see the regulatory framework developed expeditiously, is also keen to see that the framework is robust and capable of meeting the challenges that are likely to exist in this area into at least the medium-term future.

Yours sincerely


Director

Policy and Regulatory Standards (labelling and composition)