

New Zealand Food Safety Authority Policy Statement on Supplemented Food

Purpose

It is widely acknowledged that the existing regulatory arrangements for dietary supplements in New Zealand under the Dietary Supplements Regulations 1985 (the Regulations) do not provide adequate coverage for the range of such products currently available. At their inception, the Dietary Supplements Regulations were intended to cover products that were neither foods in use, appearance or presentation nor medicines in the generally accepted sense. The range of dietary supplements, which originally comprised substances derived from food in tablet, capsule or powder form, has expanded to include highly fortified foods, such as muesli bars and drinks. Many dietary supplements are also now presented as having a therapeutic use as well as a nutritional effect.

Products currently sold under the Dietary Supplements Regulations can be broadly divided into two categories, therapeutic type dietary supplements (those products in controlled dosage form) and food type dietary supplements (those products generally used as food or represented for use as food). The majority (some 80 per cent) are therapeutic type dietary supplements, with food type dietary supplements accounting for the remaining 20 per cent.

The Dietary Supplements Regulations are empowered under the Food Act 1981. When the Regulations were promulgated, administration of the Food Act was the responsibility of the Ministry of Health. The New Zealand Food Safety Authority (NZFSA) is now responsible for the administration of the Food Act and its regulations. The core business of NZFSA is promoting and ensuring food safety. 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. The Ministry of Health is, therefore, considered to be the appropriate government department to oversee the regulation of therapeutic products.

NZFSA therefore intends to remove food type dietary supplements from coverage under the Dietary Supplements Regulations and transfer administrative responsibility for the Regulations to the Ministry of Health. Under this new regulatory arrangement, food type dietary supplements will be known as “supplemented foods” and will be regulated by a New Zealand (Supplemented Food) Food Standard (the Standard) issued by the Minister of Food Safety under the Food Act.

The objectives of the proposed Standard are to:

- provide adequate regulatory coverage for supplemented food in order to:
 - protect public health and safety while maintaining consumer choice;
 - support economic growth (the trade in supplemented food is estimated at \$30 million annually);
- and

- maintain an existing right for New Zealand consumers, manufacturers, importers and exporters.
- to align supplemented food with the requirements of the Australia New Zealand Food Standards Code (the Code) to the maximum extent possible pending the development of appropriate permissions in the Code. This is consistent with the objectives of the Single Economic Market and Trans Tasman Mutual Recognition Arrangement. The proposed Standard will also facilitate the transfer of products to regulation under the Code when appropriate permissions become available; and
- to prevent the addition of substances to food that have a function of and/or have a purpose of intoxication.

The proposed Standard was developed following two rounds of consultation: the first in 2004 and the second in 2007. The submissions received during the 2004 and 2007 consultation process informed the development of the draft Standard.

Transitional Arrangements

To enable manufacturers, importers and retailers to meet the terms of the proposed Standard there will be a transitional period of two years. During this time industry can choose to comply with either the existing requirements of the Regulations (which will be set out in Part B of the proposed Standard and amended to exclude therapeutic type dietary supplements), or with the new requirements of Part A of the proposed Standard. Part B will expire two years after the proposed Standard is issued, at which time all products that fall under the definition of supplemented food must comply with the new requirements set out in Part A.

Food-Medicine Interface Decisions

The appropriate regulatory category (ie. as supplemented food or therapeutic type dietary supplement) for most products should be relatively clear. There are some products, however, for which such determinations are more difficult. These are products that sit at the food-medicine interface. Consideration of the regulatory status of such products will be on a case-by-case basis. To facilitate consistent and transparent decision-making for products at the food-medicine interface, food and therapeutic product regulators will establish an expert panel to provide advice to regulators and industry. Regulators are also developing a guidance tool that sets out the factors to take into account in deciding whether a product should be regulated as a food or as a therapeutic product.

While this guidance tool has yet to be finalised, some of the factors that will be considered are:

- The presentation of the product: is it in a pharmaceutical dosage form (tablets, capsules etc) or is it in the form of a food? How would a reasonable person perceive the product?
- What are the dose/serving instructions?

- Is it making claims? (remembering that therapeutic claims are prohibited under the Dietary Supplements Regulations)
- What is the main ingredient? What is its effect (at the level present), history of use, and current regulatory status?

Arrangements for Therapeutic-Type Dietary Supplements

As noted above, responsibility for administration of the Dietary Supplements Regulations will be transferred to the Ministry of Health. It is also intended that the Regulations will be amended to:

- exclude food-type dietary supplements;
- require sponsors of therapeutic-type dietary supplements to register products on a database maintained by the Ministry of Health; and
- provide an additional permission allowing a maximum daily dose of 500 mcg of folic acid in dietary supplement capsules where the product has been made under Good Manufacturing Practice

Information regarding changes to therapeutic-type dietary supplements is available on the Medsafe website at www.medsafe.govt.nz.