

Regulation of products at the food-medicine interface

Summary

There are a growing number of dietary supplements at the food-medicine interface that are currently regulated under the Food Act 1981 and the Dietary Supplements Regulations (DSR) 1985. Proposed changes to the regulation of these products have been controversial and disputed in New Zealand for the last 3-4 years, especially the establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA).

Despite the establishment of the ANZTPA being on hold, many of the recommendations made by NZFSA in the related 2007 discussion paper have been agreed to by Cabinet and planned changes to the DSR are expected to come into effect during 2008.

These include:

- regulating food-type dietary supplements as **supplemented foods** under the Food Act (1981), initially under an interim Standard to be called the Supplemented Food Standard, and later under a joint standard through Food Standards Australia New Zealand (FSANZ); and
- transferring the administration of therapeutic-type dietary supplements, or **complementary medicines**, from NZFSA to Medsafe with a requirement for sponsors of therapeutic-type dietary supplements to enter details about their products into a database to be administered by Medsafe (Ministry of Health).

In light of the planned amendments, the challenge now for manufacturers and sponsors of dietary supplements is to determine where in the food-medicine interface their products fall. For some the alignment will be simple, for others not. Both NZFSA and Medsafe have put together a Guidance Tool to assist with these determinations.

For food-type dietary supplements FSANZ is proposing a new standard that will change the way food can be labelled and/or advertised regarding *Health, Nutrition and Related Claims*. These changes will enable **general level health claims** (but not therapeutic claims) to be made. Such claims can refer to the presence of a nutrient or substance in a food and to its effect on a health function. A general level health claim cannot refer to a serious disease or condition or to an indicator of a serious disease (e.g. blood cholesterol). Manufacturers must hold scientific evidence to substantiate such claims and produce this evidence, on request, for enforcement agencies.

For food-type dietary supplements, a two year period will be given to meet the Supplemented Food Standard requirements during which time these products must either continue to meet requirements equivalent to the Dietary Supplements Regulations or the new requirements.

Labelling and/or advertising for therapeutic-type dietary supplements (also referred to as complementary medicines) will continue to be governed by the Dietary Supplements Regulations 1985 unless sponsors apply for an exemption as a Related Product under the Medicines Act Regulations.

Background

Taken from the NZFSA website and adapted.

In New Zealand, food-type and therapeutic-type dietary supplements are regulated by the Dietary Supplements Regulations 1985, (the Regulations) set under the Food Act 1981 (the Act). The Regulations provide a definition of dietary supplements; prescribe some maximum daily doses; permit the addition of specified food additives; specify some labelling requirements; and prohibit therapeutic claims unless permitted under the Medicines Act (1981).

When the Regulations were drafted the products intended to be covered were not foods in use, appearance or presentation but nor were they medicines in the generally accepted sense. The range of products has expanded significantly in the last 20 years, and there are now many dietary supplements in tablet, capsule or powder form that are being used to achieve a therapeutic benefit. These products are commonly referred to as **therapeutic-type dietary supplements** or **complementary medicines**.

The range of products being sold as dietary supplements has also extended to include foods such as drinks and health bars with vitamins, minerals and other substances providing “health” benefits being added. These products are referred to as **food-type dietary supplements** or **supplemented foods**.

In 2004 the New Zealand Food Safety Authority (NZFSA) released a discussion document proposing changes to the Regulations. There was general support for the proposed changes but these were delayed pending the establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA).

In February 2007 NZFSA issued a consultation paper further recommending the amendments outlined in the 2004 discussion paper

Later in 2007, public and industry outcry over the proposed establishment of ANZTPA saw work on the project halted. Other recommendations made in the discussion and consultation papers however were agreed on by Cabinet with changes to the DSR expected to take place during 2008.

Supplemented food or complementary medicine?

In light of the planned amendments, the challenge now for manufacturers and sponsors of dietary supplements is to determine where in the food-medicine interface their product falls. For some the alignment will be simple, for others not. Medsafe have put together a Guidance Tool to assist with these determinations.

The guidance tool was initially developed to assist in identifying whether a product that sat at the food-medicine interface would be most appropriately regulated under food legislation or under therapeutic product legislation. It was based on the assumption that there would be only two

possible categories for such products – food (regulated under Food legislation) and medicine (regulated under Therapeutic Product legislation).

The guidance tool can be useful in identifying whether a dietary supplement would fall into the food-type dietary supplement category or the therapeutic-type dietary supplement category.

The basis for Medsafes' Guidance Tool is the following set of questions:

1. Is it in an oral medicinal dosage form?
2. Does it have medicine dosage instructions (rather than a food serving suggestion)?
3. Does it carry therapeutic claims (that is, claims relating to therapeutic use)? 'Therapeutic use' means use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or influencing, inhibiting or modifying a physiological process.
4. Does the product have a traditional or otherwise well-established therapeutic use (that is, it is primarily for therapeutic use)?

If the answer is 'Yes' to none or only one of questions 1, 2 and 3, the appropriate regulatory coverage for the product is under food legislation. These products fall into the **food-type dietary supplements** or **supplemented foods** category and will be governed under the proposed new Supplemented Foods Standard.

In general, if the answer to questions 1, 2 and 4 is “yes” the product is likely to be a **therapeutic-type dietary supplement** or **complementary medicine**.

(Note Question 3 is not relevant in dividing dietary supplements into the food-type and therapeutic-type categories, since therapeutic claims are not permitted for dietary supplements.) Once the proposed changes described above come into effect the governing organization for these products will be Medsafe.

Implementation of regulations

There are many products on sale at the Food-Medicine interface and starting January 2008 NZFSA along with Medsafe will commence a comprehensive compliance review to identify companies and products that are in breach of the current Dietary Supplements Regulations and/or the Medicines Act. The most significant area for non-compliance is in relation to therapeutic claims being made on therapeutic-type dietary supplements.

Therapeutic claims are permitted for medicines but are not permitted in respect of dietary supplements. Companies wishing to make therapeutic claims in respect of their products are considered to be positioning their product as a medicine and must therefore apply for and obtain Ministerial consent for the product's distribution as a medicine before the product can be lawfully sold.

With regards to food-type dietary supplements, a two year period will be given to meet the Supplemented Food Standard requirements during which time these products must either continue to meet requirements equivalent to the Dietary Supplements Regulations or the new requirements.

This will be effected through the Supplemented Food Standard being divided into two Parts: the first being the new requirements; the second containing the existing DSR requirements (as it relates to food). During that two years a sponsor may choose to comply with the first new part OR continue to be covered by the old requirements of the Dietary Supplements Regulations in the second part.

Guidance on compliance is available on the [Medsafe](#) and [NZFSA](#) websites.

For all foods (but not products that choose to remain under the Dietary Supplements Regulations requirements), Food Standards Australia New Zealand (FSANZ) is proposing a new standard that will change the way products can be labelled and/or advertised regarding *Health, Nutrition and Related Claims*. The new standard is currently under assessment. Detail can be found by visiting the following [link](#).

For the new standard, three classifications are under consideration:

- 1) nutrient content
- 2) general health claims
- 3) high level health claims.

Examples of possible nutrition and health claims for supplemented foods

1) **Nutrition content claims** are statements regarding the amount of a nutrient, energy or a biologically active substance in the food. Manufacturers must have proof that the nutrient, substance or property that is the subject of the claim is present at levels referred to in the claim.

Example

- *'this food is high in calcium'*

2) **General level health claims** can refer to the presence of a nutrient or substance in a food and to its effect on a health function. A general level health claim cannot refer to a serious disease or condition or to an indicator of a serious disease (e.g. blood cholesterol). Manufacturers must hold scientific evidence to substantiate such claims and produce this evidence, on request, for enforcement agencies.

Examples

- *'calcium is good for strong bones and teeth, when consumed as party of a healthy diet containing a variety of foods'*
- *'gives you energy, when consumed as part of a healthy diet with a variety of foods'*
- *'yoghurt high in X and Y may reduce your risk of stomach upset, when consumed as part of a healthy diet with a variety of foods'*

3) **High level health claims** refer to the presence of a nutrient or substance in a food and its relationship to a serious disease or condition or to an indicator of a serious disease. Manufacturers must obtain pre-market approval from FSANZ on a case-by-case basis to make high level health claims and provide scientific evidence to substantiate the claims.

Examples

- *'This food is high in calcium. Diets high in calcium from a variety of foods may increase bone mineral density, which has particular importance for women.'*
- *'This food is low in sodium. A healthy varied diet including foods low in sodium may assist in reducing blood pressure.'*

Two new pre-approved high level health claims are substantiated: “a diet high in vegetables and fruit and coronary heart disease” and “increased intake of vegetables and fruit and coronary heart disease”.

Timelines

January 2008	Compliance reviews commence
Mid 2008	Removal of food-type dietary supplements from the DSR and the promulgation of the Supplemented Food Standard
Mid 2008	Administration of therapeutic-type dietary supplements to transfer to Medsafe
Early 2009	Sponsors of therapeutic-type dietary supplements to have product details entered into the Medsafe database
Mid 2010	Part 2, the old DSR requirements, is revoked.