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Draft Assessment Report (Abandonment) – Proposal P235

Review of Food-type Dietary Supplements

Food Standards Australia New Zealand (FSANZ) prepared a Proposal to review food-type dietary supplements.

On 26 June 2002, FSANZ sought submissions on an Initial Assessment Report and received 39 submissions.

FSANZ has decided to abandon the Proposal pursuant to paragraph 15B(b) of the *Food Standards Australia New Zealand Act 1991* as was in force on 1 July 2007. Information on the reasons for FSANZ's decision is contained in this Report.

This decision is not reviewable under section 63 of the FSANZ Act (as was in force prior to 1 July 2007).

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Executive summary

Proposal P235 commenced in 2001 to develop a food standard to regulate food-type dietary supplements (FTDS) within the context of the harmonisation of food regulations between Australia and New Zealand. In 2003, work on the Proposal was deferred after consultation on an Initial Assessment Report, pending Ministerial policy guidance and other work priorities.

Since then, the food regulatory environment has significantly changed with the introduction of regulation in 2006 for formulated beverages that provided for the majority of FTDS previously under consideration, and more recently, nutrition and health claims. Also, the *New Zealand Food (Supplemented Food) Standard (2013)* (abbreviated in this report as the New Zealand Standard) now regulates many FTDS, a small proportion of which are imported to Australia under the Trans-Tasman Mutual Recognition Arrangement.

Since this Proposal was last considered, the market, product range and composition of FTDS have also changed significantly and changes to regulation appear to have generally met the needs of the FTDS industry and consumers. Many products have been regulated by permissions for formulated beverages. Of the remaining products, some have been discontinued or reformulated whereas others continue to be manufactured under the New Zealand Standard. In relation to current products, the New Zealand Ministry for Primary Industries (MPI) is currently collecting product data to determine the uptake of the Standard and whether a review of the New Zealand Standard is warranted.

FSANZ's decision to abandon this Proposal is a result of several developments in food regulation applicable to FTDS, which have occurred over the past decade. In addition, current and future changes to the *Australia New Zealand Food Standards Code* in relation to novel foods and sports foods are expected to address many outstanding issues related to addition of substances, except for the levels of vitamins and minerals. FSANZ will await further developments in relation to MPI's consideration of supplemented food including a possible review of the New Zealand Standard. FSANZ retains the option of preparing a new Proposal on further trans-Tasman alignment in light of the findings of any New Zealand review.

1 Introduction

1.1 The Proposal

Proposal P235 – Review of Food-Type Dietary Supplements[1] commenced in 2001 during the transition to the joint *Australia New Zealand Food Standards Code* (the Code). The aim of the Proposal was to develop a harmonised trans-Tasman regulatory framework for food type dietary supplements (FTDS).

Work on the Proposal was deferred after consultation on the Initial Assessment Report in 2003, pending notification of the then Ministerial Council's[2] policy guidance on dietary supplements[3] however FSANZ then needed to address higher work priorities.

1.2 Current Standards

There are currently no specific permissions in the Code related to FTDS. However, some subsequent amendments to the Code relate to some types of FTDS.

Clause 9 of Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks was gazetted in 2006 to specifically regulate formulated beverages[4]. This amendment was the result of an industry application which sought permission to add vitamins and minerals to formulated beverages to address the then disadvantage of Australian manufacturers unable to compete with beverages imported from New Zealand under the Trans-Tasman Mutual Recognition Arrangement (TTMRA). Under the TTMRA, food products which generally comply with the *New Zealand Food (Supplemented Food) Standard (2013)* (abbreviated in this report as the New Zealand Standard) may be lawfully imported into Australia.

In Australia and New Zealand, novel foods and novel food ingredients are regulated under Standard 1.5.1 – Novel Foods in the Code. They are defined as non-traditional foods that require assessment by FSANZ in order to establish their safety before being added to the food supply. A novel food cannot be sold as food or used as a food ingredient unless it is listed in the Standard.

Standard 1.2.7 – Nutrition, Health and Related Claims is due to come into full effect in January 2016, replacing the existing transitional Health Claims Standard (Standard 1.1A.2). The new Standard sets out rules to regulate voluntary statements made on labels and in advertising about the content of certain nutrients or substances in a food, or the relationship between food and health. It was developed to help ensure that the requirements for food businesses are clear and that health claims are scientifically substantiated. It will also provide greater certainty for agencies, reduce the risk of misleading and deceptive claims about food, expand the range of permitted claims and encourage industry to innovate so that new healthy food choices may become available.

[1] Food-type dietary supplements (FTDS) are described as foods which are *similar in appearance to conventional foods and intended to be consumed as part of a usual diet, but have been modified to subserve physiological roles beyond the provision of simple nutrient requirements*. Examples include bars, powders or beverages with added vitamins, minerals or other substances such as caffeine, herbs and other botanicals.
[2] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council).
[3] Subsequently notified to FSANZ as the *Addition to food of substances other than vitamins and minerals.*
[4] Formulated beverages are described as non-alcoholic, water-based beverages containing claimable amounts of vitamins and minerals.

The New Zealand Standard is a New Zealand-only standard which applies outside the joint trans-Tasman food standards regulatory system. It was developed as an interim regulatory arrangement to provide short to medium term regulatory coverage for food products that were previously regulated by the New Zealand *Dietary Supplements Regulations* (1985) (NZDSR). A supplemented food is defined as a product that is represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement.

The New Zealand Standard provides more liberal permissions than the Code, particularly for the range and amounts of added substances including vitamins and minerals (maximum 50% Upper Level/ one day quantity). It has recently been amended to include Standard 1.2.7 as one of several standards in the Code that apply to supplemented food. The New Zealand Ministry for Primary Industries (MPI) has advised that the New Zealand Standard has become more relevant to New Zealand's export markets to the Asian region than to Australia, and is listed on the MPI's work program for a future full review.

1.2.1 International regulations

Codex has revised the Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) at Step 8 which are relevant to FTDS. The previous version of these principles was consulted during the development of the Ministerial Policy Guideline on the Fortification of Food with Vitamins and Minerals[5]. Codex has also established a Guideline for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) which applies only in jurisdictions that regulate concentrated vitamin and mineral supplements as food, which excludes Australia.

1.3 Reasons for preparing the Proposal

P235 was prepared to develop a harmonised trans-Tasman regulatory framework for FTDS, particularly in relation to Australia, which previously had not specifically regulated FTDS and, in relation to New Zealand, to accommodate foods that were regulated by the then NZDSR in response to the growing international market for that type of food.

1.4 Decision

The Authority has decided to abandon Proposal P235 because of several developments in food regulation over the past decade that are applicable to FTDS, as described in section 1.2. In addition, current and future changes to the Code are expected to address many outstanding issues, which generally relate to the regulation of substances added to food. For example, Proposal P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods is currently considering the regulation of substances added to food, including FTDS, which may provide a mechanism for better alignment of trans-Tasman food regulations. Also, FTDS-type products targeted to the sports market would be considered in a future proposal (PP1010) to review Standard 2.9.4 – Formulated Supplementary Sports Foods. One remaining issue is the disparity in vitamin and mineral permissions formulated under different policy environments between general and special purpose food in the Code, and the New Zealand Standard.

The market, product range and composition of FTDS have changed significantly since this Proposal was last considered. Many products have either been regulated under provisions for formulated beverages or novel foods. Of the remaining products, some have been discontinued or reformulated whereas others continue to be manufactured under the New Zealand Standard.

[5] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

The MPI is currently undertaking further work in relation to the New Zealand Standard. FSANZ retains the option of preparing a new Proposal on further trans-Tasman alignment in light of the New Zealand findings.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought public comment in an Initial Assessment Report in June 2002 on issues relating to regulating FTDS in Australia and New Zealand. Issues discussed included the appropriate regulatory framework and its impact, the underpinning regulatory policy, scope and definition of FTDS and compositional and labelling requirements. In addition, three regulatory options were put forward for comment: full revised regulatory provisions, co-regulation with an industry code of conduct including no overt recognition of FTDS in the Code; and maintaining the status quo.

Thirty-nine submissions were received in response to the Initial Assessment Report. The submissions indicated that, of the three regulatory options presented, full regulation was the preferred approach to managing FTDS. Most submitters who opted for full regulation supported a vertical standard. There was general consensus that this would create a level playing field and equitable marketing opportunities for industry in both countries. Full regulation was also seen to provide clarification regarding the status of products at the food/therapeutic interface.

Submitters favouring full regulation contended that it would afford consumers the greatest protection, also ensure consumers would be provided with consistent and comparable information to facilitate informed decision-making about products and would allow greater choice to consume supplementary substances in food form. Furthermore, industry would benefit from both greater credibility and consumer trust.

No submitters opted for co-regulation. There was some discussion of this option by a number of submitters who noted that previous experience had shown that this is not an effective means of regulation and that the reputation of industry was likely to be compromised.

There was some support for retaining the status quo from several New Zealand-based companies dealing largely with imported products. Their main objection to the other regulatory options centred on a discontinuation of the then NZDSR. The majority of these submitters, however, recognised that the current situation was not feasible nor could it be sustained long term and that a new regulatory approach was needed to ensure both harmonisation and an equitable playing field between Australia and New Zealand. It was also noted that the then situation resulted in additional costs to the Australian industry as products imported via New Zealand were ultimately passed onto the consumer.

Several submitters favoured none of the options presented but did suggest alternative options which included:

- a New Zealand only regulation of FTDS, not within the Code
- placing P235 on hold pending further policy advice from the Food Regulation Standing Committee
- regulating FTDS as therapeutic goods (i.e. should not be in the Code)
- adopting the then NZDSR as the regulatory model for FTDS.

2.1.1 Targeted consultation on sports foods, 2011

FSANZ released a discussion paper for targeted consultation in April 2011 signalling the intent to review Standard 2.9.4. At that time, FSANZ sought feedback on the inclusion of FTDS as part of that review. The approach was generally supported by industry and jurisdictional stakeholders.

2.2 Risk assessment

FSANZ is unaware of any risk to public health and safety caused by FTDS in Australia or New Zealand. Regulations, as described in section 1.2, now exist to regulate many FTDS. As explained, some of these regulations are also the subject of further work.

A number of sports foods and slimming bars were previously manufactured under the then NZDSR as a means of circumventing the more prescriptive requirements of the relevant sports food or formulated supplementary food standards[6] in the Code. Over time, some products have either been discontinued (as a result of poor uptake and low sales) or reformulated.

A product survey conducted in New Zealand between December 2011 and January 2012 identified the types of products categorised as supplemented foods on the New Zealand market and also the health claims made by these products. The majority of products were sports foods and beverages, slimming products or meal replacements, and water- or juice-based beverages or powders, a small number of herbal teas and honey products, and children's vitamin 'gummies' – a product at the food/therapeutic good interface.

Today, the majority of FTDS on the market are manufactured in or imported into New Zealand and a small proportion of these are subsequently imported into Australia under the TTMRA. The Australian industry has not raised any concerns since 2002 with FSANZ regarding possible competitive disadvantage under the current arrangements.

2.3 Risk communication

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to provide submissions on this Proposal. Every submission on an application or proposal is reviewed by FSANZ staff who examine the issues identified and prepare a response to those issues. All submissions are valued and contribute to the rigour of our assessment.

Copies of all submissions on the Initial Assessment Report are available on the FSANZ website[7].

Where relevant, issues remaining from P235 as outlined above will be addressed by the framework developed by P1024, the future sports foods proposal and any future work arising from further developments in relation to New Zealand supplemented foods.

No further public consultation on the Proposal has occurred since 2003. The FSANZ web page relating to P235 indicates that FTDS is under review.

[6] Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods.
[7] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp235reviewoffoodtypedietarysupplements/Default.aspx

The decision to abandon P235 will be notified in the FSANZ Circular. All previous submitters, appropriate government agencies and other identified stakeholders will also be notified of this decision. All previous submitters and other identified stakeholders will be added to the interested parties list for any future work to review the Standard 2.9.4 under a new proposal. They will also be notified should FSANZ decide to undertake any future work on FTDS.

2.4 FSANZ Act requirements

Wide-ranging amendments to *Food Standards Australia New Zealand Act 1991 (*the FSANZ Act) took effect on 1 July 2007. These included changes to the processes for assessing applications and proposals which affected all applications received and proposals prepared after 1 October 2007.

However, transitional arrangements have the effect that processes for assessing and progressing proposals set out in the FSANZ Act (as was in force prior to 1 July 2007) continue to apply to this Proposal.

2.4.1 Section 15AA of the FSANZ Act (as was in force prior to 1 July 2007)

In reaching its decision, FSANZ had regard to the following matters under section 15AA of the *Food Standards Australia New Zealand Act 1991* in force prior to 1 July 2007:

- Any submissions made to it within the specified period in response to a notice sent or published under section 14A of the FSANZ Act (as was in force prior to 1 July 2007).

  Many issues raised in submissions on the Initial Assessment Report are no longer a concern or relevant because of changes to regulation over the last decade, particularly in relation to the greater emphasis on standards in Chapter 1 of the Code such as the health claims standard. Furthermore, P1024 provides an opportunity to address ongoing issues in relation to addition of substances generally, and those specifically relevant to sports food will be considered in a future proposal. This work, as well as MPI consideration of the New Zealand Standard will enable FSANZ to more appropriately respond to the current market and consider the issues under the current FSANZ regulatory and administrative arrangements.

- The objectives and matters listed under section 10 of the FSANZ Act (as was in force prior to 1 July 2007) – these are addressed in section 2.4.2 of this report.

- Any relevant New Zealand standards – the *New Zealand Supplemented Food Standard (2013)* is relevant to this Proposal as discussed in sections 1.2 and 1.4.

- Any other relevant matters – there are no other relevant matters.

2.4.2 Subsection 10(1) (as was in force prior to 1 July 2007)

FSANZ has considered the three objectives in subsection 10(1) during the assessment of this Proposal as follows.

2.4.2.1 Protection of public health and safety

As explained above, FSANZ is unaware of any immediate risk to public health and safety caused by FTDS in Australia or New Zealand.

As this decision results in no regulatory amendment, there is no change to the current level of adequate protection of public health and safety. Regulations, as described in section 1.2, now exist to regulate the majority of FTDS. As explained above, some of these are also subject of review under other proposals.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

There is no change to the amount of information required to be provided to consumers to enable informed choice. The marketing of FTDS is largely dependent on express and implied claims including health and nutrition related claims. Compliance with the regulation of these claims will ensure that consumers are able to make informed choices about FTDS and readily compare them with other available products. When Standard 1.2.7 comes fully into effect, consumers will have credible information on which to base their decision making.

2.4.2.3 The prevention of misleading or deceptive conduct

Manufacturers will continue to be required to provide the same level of information to consumers as they do today. The introduction of the Standard 1.2.7 and requirements to ensure health claims are scientifically substantiated will provide consumers with protection against fraudulent behaviour.

2.4.3 Subsection 10(2) (as was in force prior to 1 July 2007) considerations

FSANZ has also had regard to the objectives set out in subsection 10(2):

- **the need for standards to be based on risk analysis using the best available scientific evidence**

The risk analysis underpinning the development of the standards described in section 2.2 utilised the best available scientific data.

- **the promotion of consistency between domestic and international food standards**

As the outcome of this decision results in no regulatory change being proposed, there is no impact on existing markets. As mentioned above, there are no specific international FTDS regulations.

The New Zealand Standard operates outside the joint Australia New Zealand regulatory system. In terms of the FTDS-type products manufactured under the New Zealand Standard, the previously mentioned work by MPI will provide a better understanding of the supplemented food market. FSANZ retains the option of preparing a new Proposal on further trans-Tasman alignment in light of the New Zealand findings. The Australian industry has not raised any concerns with FSANZ regarding possible competitive disadvantage under the current arrangements.

- **the desirability of an efficient and internationally competitive food industry**

As no amendment to the Code is proposed, there is no impact on the food industry. Although the TTMRA allows supplemented foods to be imported into Australia, only a small proportion of products are exported across the Tasman Sea. Instead, New Zealand manufacturers are focusing their attention on the Southeast Asian region which is experiencing rapid economic growth and increased purchasing power amongst consumers that is creating an ideal target for imported products.

Australian manufacturers are not precluded from competing in this international market.

- **the promotion of fair trading in food**

As no amendment to the Code is proposed, there is no impact on trading in food. The latter also remains subject to the fair trading and consumer protection laws in Australia and New Zealand.

- **any written policy guidelines formulated by the then Ministerial Council**

There are no specific policy guidelines for FTDS. Policy guidelines on the Fortification of Foods with Vitamins and Minerals; Nutrition, Health and Related Claims; the Addition of Substances other than Vitamins and Minerals, the Intent of Part 2.9 – Special Purpose Foods, and Novel Foods informed the development of the standards outlined in section 1.2.

3 Rights of review

Under section 63 of the FSANZ Act (as was in force prior to 1 July 2007), the decision is not reviewable by the Administrative Appeals Tribunal.