

7-04

11 August 2004

Public Notification and Statement of Reasons

Proposal P250 – Development of a Co-regulatory System for Health, Nutrition Content & Related Claims

The Initial Assessment Report for Proposal P250 finalised by the former Australia New Zealand Food Authority (ANZFA) in February 2002, was focussed on the development of an effective and efficient co-regulatory system featuring a Code of Practice, to be overseen by a Code of Practice Management Committee, to support the implementation and enforcement of a standard for health claims and for nutrient content claims. It was determined at that time that there would be efficiencies in developing a management system that could apply to both health claims and to nutrient content claims rather than separate systems for each category of claim.

Further to this, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council), which replaced the Australia New Zealand Food Standards Council (ANZFSC) under the new regulatory arrangements, undertook to provide advice on a policy framework to underpin the regulation of nutrition, health and related claims. Despite the Initial Assessment Report for Proposal P250 being finalised and agreed to by the ANZFA Board, stakeholder consultation on the Report was delayed in anticipation of the finalisation of the policy advice.

The policy advice, with the exception of the process for the pre-market assessment and verification of biomarker maintenance claims, was agreed by the Ministerial Council in December 2003¹. The Policy Guideline on Nutrition, Health and Related Claims (the Policy Guideline) describes a number of elements of a management framework for implementing and enforcing requirements for nutrition, health and related claims that were not addressed in Proposal P250. To date no public consultation on Proposal P250 has been undertaken although the proposal has remained active on the Food Standards Australia New Zealand (FSANZ) Food Standards Work Plan.

FSANZ considers that the regulatory framework described in the Policy Guideline would best be developed in a single FSANZ proposal that encompasses all the necessary elements of the management system proposed for nutrition, health and related claims. It is not desirable to consider the various elements of the regulatory framework in a number of separate proposals as this could increase the potential for inconsistency in the establishment of the framework and might result in individual proposals being subject to different consultation and assessment timeframes.

¹ In May 2004, the Ministerial Council agreed that biomarker maintenance claims are subject to pre-market assessment and approval by FSANZ.

In order to minimise stakeholder confusion and to maximise stakeholder input into the development of the regulatory framework for the management of nutrition, health and related claims, FSANZ considers that Proposal P250 should be abandoned and replaced by Proposal P293, the new proposal on Nutrition, Health and Related Claims. Proposal P293 considers options, including the development of a system for the management of nutrition, health and related claims that has regard to all the aspects of the Policy Guideline.

FSANZ has convened a Standard Development Advisory Committee (SDAC) with broad stakeholder representation to assist in the provision of information and advice regarding Proposal P293 and the development of the Standard for Nutrition, Health and Related Claims and the associated management framework described in the Policy Guideline. The Initial Assessment Report for Proposal P293 will be available for public comment in August 2004.