Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the Australia New Zealand Food Standards Code (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P242 to develop a Standard for food for special medical purposes (FSMP), being food that is specifically formulated for the dietary management of individuals with particular medical conditions and which is intended to be used under medical supervision.

The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard and a draft variation. This Explanatory Statement deals with the draft variation.

Following consideration by COAG Legislative and Governance Forum on Food Regulation (the Forum), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sun setting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

This variation was prepared to complement new Standard 2.9.5 (Food for special medical purposes) by making necessary consequential changes to Standards 1.1.1, 1.1A.6, 1.2.1, 1.3.1 and 1.3.4 of the Code.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

The Authority's consideration of Proposal P242 has included four rounds of public consultation following assessments, the preparation of a draft Standard, a draft variation and associated reports. Public submissions were called for in 2001, 2002, 2004 and 2010. In addition, targeted consultation was undertaken in 2010 and 2011 after the project re-commenced with key stakeholder groups i.e. manufacturers, health professionals, jurisdictions and other interested parties.

The Office of Best Practice Regulation was also consulted and advised FSANZ that a Regulation Impact Statement was not required because the proposed Standard 2.9.5 was likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variations

Item 1 varies clause 2 of Standard 1.1.1 by applying the definitions of small package and transportation outer to the Code as a whole. Item 3 removes these definitions from Standard 1.2.1. Item 1 also varies clause 2 by referencing the definition of food for special medical purposes and by amending the definition of warning statement to include the prescribed warning statement in new Standard 2.9.5. Finally, Item 1 also varies Standard 1.1.1 by inserting the symbol MJ into the glossary of symbols and units at clause 8.

Item 2 varies Standard 1.1A.6 to ensure that Standard 1.1A.6 will not cease to have effect on the date of commencement of Standard 2.9.5 in relation to food formulated and represented as being for the dietary management of obesity. The purpose of this variation is to allow the continued regulation under Standard 1.1A.6 of very low energy diet products which are manufactured in, or imported into, New Zealand.

Item 4 varies Schedule 1 of Standard 1.3.1 to apply a number of food additive permissions to food for special medical purposes.

Item 5 varies the Schedule to Standard 1.3.4 by adding a specification for selenium-enriched yeast.