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 Standard.

Following consideration by the 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

There is currently no separate standard for FSMP within the Code with the result that FSMP is subject to generic (Chapter 1) food standards. However, the specially formulated nature and specialised use of FSMPs often makes it difficult for these products to comply with the generic food standards.

FSMPs are formulated for the dietary management of individuals with certain diseases, disorders or medical conditions. An FSMP is necessary when the dietary management of an individual cannot be completely or easily achieved with other dietary modification, including the use of other special purpose foods.

The purpose of Standard 2.9.5 is to protect the health and safety of FSMP consumers. This is achieved through three types of requirements as follows. Firstly, the Standard requires that FSMP which is represented as being suitable for use as an individual's as a sole source of nutrition contains certain vitamins, minerals and electrolytes in amounts necessary for human health.

The Standard allows for these amounts to be varied for particular medical conditions.

Secondly, the Standard contains a number of labelling requirements which are intended to ensure that health professionals are provided with enough information about an FSMP product to make appropriate decisions regarding its use by a consumer.

Finally, the Standard restricts the premises at which, and the persons by whom, FSMP may be sold directly to consumers. This restriction on the sale of FSMPs is intended to promote consumers' access to medical or health professional advice about the appropriate use of the FSMP they are purchasing. It is also intended to prevent the sale of FSMP to unintended users, and to maintain the supply chain of FSMP to consumers.

Since almost all FSMPs are imported from overseas, Standard 2.9.5 is, where possible, consistent with relevant international regulations to minimise any barriers to the supply of these products to Australia and New Zealand.

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

Clause 1 defines an FSMP by reference to what it is formulated for, its intended use, and how the food is represented. This definition enables FSMPs to be identified in the market place and distinguished from other foods. Subclause 1(2) clarifies that a food is not an FSMP if it is formulated and represented as being for the dietary management of obesity or overweight. The intention of this subclause is to ensure that Standard 2.9.5 does not apply to very low energy diet products. A food is also not an FSMP if the food is an infant formula product.

Clause 2 defines and clarifies other terms used in this Standard, including the definitions of inner package and responsible institution. It also clarifies the meaning of package where it appears in Standard 2.9.5.

Clause 3 provides for the application and exclusion of certain other Standards and provisions in the Code to FSMP, for example only some Standards in Part 1.2 of the Code apply to FSMP.

Clause 4 provides that a therapeutic claim must not be made about an FSMP.

Clause 5 prohibits the sale of FSMPs to a consumer, unless the sale is from or by one of the persons or premises listed in the subclause (1). FSMPs may be sold by medical practitioners and dietitians, and from medical practices, pharmacies and responsible institutions.

An FSMP may also be sold to a consumer by a person who supplies that particular FSMP to any of the above listed persons or premises, provided that person sells more than half of that particular FSMP to those persons or premises during a 24-month period. The purpose of this provision is to ensure that bone fide distributors of FSMPs, who are aware of the medical nature of these foods, are permitted to sell directly to consumers as is the current practice. The provision is intended to balance the need for consumers to be provided with adequate access to medical or health professional advice about the appropriate use of FSMPs, with the need to ensure the supply chain remains open and that consumers are able to access FSMPs through a distributor when appropriate.

Clause 6 contains a permission to add any substance listed in either Schedule 1 of Standard 2.9.5 or Schedule 1 of the infant formula Standard (Standard 2.9.1) to an FSMP, provided the substance is in the particular form specified in the relevant Schedule. Any provision in another Standard, that imposes a limit on the amount of one of the substances listed in either Schedule that can be added to a food, does not apply to FSMPs.

However, if a substance is not listed in either of the Schedules, the substance may be added to an FSMP in any form, provided the addition of the substance complies with any other applicable Standard. For example, if a food additive is added to an FSMP, the additive must comply with Standard 1.3.1.

Clause 7 contains compositional requirements for FSMP that is represented as being suitable for use as an individual's sole source of nutrition. An FSMP that is represented in this way is required to contain at least the minimum specified level of the vitamins, minerals and electrolytes listed in Schedule 2 to the Standard. In the case of some of these listed nutrients, a maximum level is also imposed. However, subclause 7(2) allows the amount of a nutrient in an FSMP to exceed the prescribed maximum, or fall below the prescribed minimum, if a variation from the maximum or minimum is necessary for a particular medical purpose. If the amount of a particular nutrient falls outside its prescribed maximum or minimum level, the FSMP must be labelled in accordance with paragraph 10(2)(b). That is, the label must contain a statement indicating the nutrient or nutrients effected, and whether each nutrient has been increased, decreased, or eliminated from the food. However, subclause 10(5) provides that information on how the level of each nutrient has been varied (e.g. increased, decreased, or eliminated) is not required to be on the label, if the information is provided in other documentation about the FSMP.

Clause 8 requires a package of FSMP to have a label. Clause 8 also makes it clear that the requirements of Subdivision 2 of Division 4 of the Standard do not apply to a package which is an inner package (in which case Subdivision 3 applies to the package) or a transportation outer (in which case Subdivision 4 applies to the package).

Subdivision 2 of Division 4 (which contains clause 9 to 16 of the Standard) contains the general labelling requirements for packages of FSMPs:

Clause 9 contains a list of information that must be included on the label on a package of FSMP.

Clause 10 contains a list of statements that must be declared on the label on a package of FSMP.

Some of the statements will not be applicable to all FSMPs and are only required where relevant. For example, if there are any precautions or contraindications associated with consumption of the FSMP, these must be declared on the label on the package of FSMP.

Clause 11 requires the presence of certain substances in an FSMP to be declared on the label on any package of the FSMP.

Clause 12 requires the label on a package of FSMP to contain a statement of ingredients that complies with either Standard 1.2.4, the relevant Directive of the European Parliament and Council, or the relevant provision in the United States Code of Federal Regulations.

Clause 13 requires FSMP to comply with date marking requirements in Standard 1.2.5. However, the words 'Expiry Date' or similar words may be used in place of the words 'Use By'.

Clauses 14 and 15 set out the conditions that must be met if a claim about lactose or gluten is made about an FSMP. These conditions mirror the conditions that apply to claims made about the lactose or glucose content of regular food.

Clause 16 requires the label on a package of FSMP to meet the legibility requirements contained in Standard 1.2.9.

Subdivision 3 of Division 4 (or clause 17 of the Standard) requires inner package of FSMP to have a label, and specifies what the label must include.

Subdivision 4 of Division 4 (or clause 18 of the Standard) requires a transportation outer (defined in Standard 1.1.1 of the Code) that contains packages of FSMPs to have a label which includes certain specified information. However, clause 18 makes it clear that the transportation outer is not required to have a label if the information specified is clearly discernible through the transportation outer on the labels on the packages inside.