

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 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1230 which seeks to amend Standard 2.9.5 to regulate the use of very low energy foods as food for special medical purposes (FSMP) in accordance with the Code. Very low energy foods are foods that are specially formulated for the dietary management of overweight and obesity and that are sold to form part of a very low energy diet; that is, a diet comprised of very low energy foods which, together, provide the sole source of nutrition when consumed according to the manufacturer's directions for use. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Variation will be a legislative instrument

The approved draft variation will be a legislative instrument for the purposes of the *Legislation Act 2003*. See section 94 of the FSANZ Act. Once made, the draft approved variation will be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

The variation will not be subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

2. Purpose

The Authority has approved a draft variation to the Code to amend Standards 1.1.2, 2.9.5, 2.9.6 and Schedule 29 to permit the use of very low energy foods as FSMP in accordance with the Code.

3. Documents incorporated by reference

The approved draft variation does incorporate a document by reference.

New subsection 2.9.5—18(3) incorporates a method of calculating a protein digestibility corrected amino acid score by reference to a specific document that will be in force or existing at the commencement of the variation. The document is the Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4-8 December 1989, FAO Food and Nutrition Paper No. 51, Food and Agriculture Organisation of the United Nations, Rome, 1991. Subsection 2.9.5—18(3) provides that the protein digestibility corrected amino acid score required by paragraph 2.9.5 –18(1)(c) must be calculated and expressed in accordance with the method referred to on page 23 of that publication. This reference by incorporation is consistent with the current practice in the Code.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1230 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment report. Submissions were called for on 19 November 2021 for a four-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (OBPR correspondence dated 14 May 2021, OBPR ID:44071). This exemption was provided as the OBPR assessed the impacts of this application to be below the threshold for a RIS.

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 (see above).

6. Variation

Items [1] to [4] in the Schedule of the approved draft variation make the following amendments to the Code.

Standard 1.1.2 – Definitions used throughout the Code

Item [1.1] varies subsection 1.1.2—2(3) by inserting, in alphabetical order, the following definitions for *very low energy diet* and *very low energy food*:

- ***very low energy diet*** means a range of food for special medical purposes specially formulated for the dietary management of overweight and obesity and which provide the sole source of nutrition when consumed according to the directions for use on the label.

- **very low energy food** means a food for special medical purposes produced for consumption as part of a very low energy diet.

Item [1.2] varies subsection 1.1.2—5(2) to specify that the definition of ‘a food for special medical purposes’ does not exclude very low energy food.

The effect of this variation is clarification that very low energy food is FSMP; but food formulated and represented as being for the dietary management of obesity or overweight, *other than very low energy food*, are not FSMP for the purposes of the Code.

Standard 2.9.5 – Food for Special Medical Purposes

Item [2.1] varies Note 1 to subsection 2.9.5—2 to insert ‘and which is not a *very low energy food’ after ‘a food is not food for special medical purposes if it is: ... (b) formulated and represented as being for the dietary management of obesity and overweight’.

This variation reflects the amendment made to subsection 1.1.2 – 5(2) (see item [1.2] above).

Item [2.2] inserts new Note 4 in subsection 2.9.5—2.

The new Note 4 refers readers to the definitions of *very low energy diet* and *very low energy food* added to subsection 1.1.2—2(3) by item [1.1] above.

Item [2.3] inserts a new subsection after subsection 2.9.5—7(2).

New subsection 2.9.5—7(3) states that ‘Subsection (1) does not apply to a *very low energy food’.

Section 2.9.5—7 sets the compositional requirements for FSMP represented as being suitable as the sole source of nutrition. This amendment provides that these compositional requirements do not apply to very low energy foods – which are also represented as being suitable as the sole source of nutrition. The amendment is required as new subsection 2.9.5—18 will be included in Standard 2.9.5 to set stand-alone compositional requirements for very low energy foods (see item [2.9] below).

Item [2.4] replaces subsection 2.9.5—9(2) with two new subsections.

New subsection 2.9.5—9(2) requires the label for a food for special medical purposes that is a very low energy food to state the recommended daily quantity of all very low energy foods to be consumed in order to provide the sole source of nutrition. This requirement applies in addition to the requirements imposed by subsection 2.9.5—9(1) on all food for special medical purposes including very low energy foods.

New subsection 2.9.5—9(3) provides that the label must comply with Division 6 of Standard 1.2.1. It restates the current requirement in subsection 2.9.5—9(2).

Item [2.5] varies subparagraph 2.9.5—10(1)(g)(ii) to replace the words ‘(if applicable):’ with ‘(if applicable), and the food is not a *very low energy food:’.

This amendment is consequential to and reflects the amendment made to section 2.9.5—7 (see item [2.3] above).

Item [2.6] varies sub-subparagraph 2.9.5—10(1)(g)(ii)(B) to replace the text “appropriate.”, with “appropriate;”.

This amendment is consequential to and reflects the amendment made to section 2.9.5—10 (see item [2.7] below).

Item [2.7] varies subsection 2.9.5—10(1) by adding new paragraph 2.9.5—10(1)(h) after paragraph 2.9.5—10(1)(g).

Subsection 2.9.5—10(1) sets out what advisory statements are required for the purposes of the mandatory labelling requirements contained in section 2.9.5—9.

New paragraph 2.9.5—10(1)(h) lists the statements specifically required for very low energy food. The statements are:

- a statement to the effect that it is important to maintain adequate daily fluid intake while using the product; and
- a statement to the effect that the food is not recommended for pregnant, nursing, or lactating women or use by infants, children, adolescents and elderly, other than under medical supervision; and
- a statement indicating that the food is suitable for use as a sole source of nutrition when consumed according to the directions for use on the label.

An aim of the last statement is to clarify that an individual very low energy food does not provide the sole source of nutrition. Instead, very low energy foods are consumed as part of a very low energy diet; and these foods provide the sole source of nutrition when taken together according to the manufacturer’s directions for use.

Item [2.8] varies section 2.9.5—13 by repealing the section and replacing it with two new subsections.

New subsection 2.9.5—13(1) sets out the nutrition information that paragraph 2.9.5—9(1)(h) requires to be stated on a label of FSMP that is not very low energy food. The nutrition information required will be the same as that currently required for FSMP.

New subsection 2.9.5—13(2) sets out the nutrition information that paragraph 2.9.5—9(1)(h) requires to be stated on a label of very low energy food. The following nutrition information must be stated:

- the *average quantity* (as defined in subsection 1.1.2—2(3)) of that food per serving; and
- the *average energy content* (as defined in subsection 1.1.2—2(3)) per serving; and
- the minimum amount or average quantity per serving of:
 - (i) protein, fat and carbohydrate; and
 - (ii) linoleic acid and α -linolenic acid; and
 - (iii) any substance listed in the table to section S29—22 that has been *used as a nutritive substance* (as defined in section 1.1.2—12) in the food; and
 - (iv) any other vitamin, mineral or electrolyte that has been used as a nutritive substance in the food; and
 - (v) subject to paragraph 2.9.5—9(1)(i) of the Code, any other substance in respect of which a *nutrition content claim* (as defined in section 1.1.2—9) has been made.

The above reflect the mandatory compositional requirements for the very low energy foods

that together constitute a very low energy diet (see item [2.9] below).

Item [2.9] inserts a new division after subsection 2.9.5—17.

The new division is 'Division 5 – Very Low Energy Diets' and contains new sections 2.9.5—18 and 2.9.5—19.

New section 2.9.5—18 contains the mandatory compositional requirements for the very low energy foods that comprise a very low energy diet.

New subsection 2.9.5—18(1) requires that a very low energy food must, when consumed with other very low energy foods according to the manufacturer's directions for use, result in a diet that meets each of the following compositional requirements:

- the diet has an average energy content of no less than 1880 kJ/day and no more than 3345 kJ/day ('the required average energy content');
- the diet contains not less than 50 g of *available carbohydrates* (as defined in subsection 1.1.2—2(3)) present within the required average energy content;
- the diet contains not less than 50 g protein per day with a nutritional quality equivalent to a protein digestibility corrected amino acid score (as defined in new subsection 2.9.5—18(3) – see below) of 1, present within the required average energy content;
- the diet contains, within the required average energy content, not less than 3 g of linoleic acid and not less than 0.5 g of α -linolenic acid;
- the diet has a linoleic acid to α -linolenic acid ratio of between 5 and 15;
- the diet contains not less than the minimum amount per daily intake, as specified in column 2 of the table to new section S29—22, of each vitamin and mineral listed in Column 1 of that table (see item [4.1] below).

New subsection 2.9.5—18(2) provides that, despite subsection 2.9.5—6(2), the amount of L-amino acids listed in Column 2 of the table to section S29—20 may only be added to a very low energy food to an amount that is necessary to improve protein quality.

Under subsection 2.9.5—6(1), L-amino acids listed in Column 1 of the table to section S29—20, which are in a corresponding form listed in Column 2 of that table, may be added to FSMP. Subsection 2.9.5—6(2) provides that, if a provision of the Code limits the amount of those L-amino acids that may be added to a food, that limit does not apply in relation to FSMP. New subsection 2.9.5—18(2) provides that subsection 2.9.5—6(2) does not apply to the limit imposed by new subsection 2.9.5—18(2).

New subsection 2.9.5—18(3) provides that, for the purposes of section 2.9.5—18, the 'protein digestibility corrected amino acid score' means the score calculated and expressed in accordance with the method referred to on page 23 of the Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4-8 December 1989, FAO Food and Nutrition Paper No. 51, Food and Agriculture Organisation of the United Nations, Rome, 1991.

New section 2.9.5—19 provides that a *health claim* (as defined by subsection 1.1.2—2(3)) must not be made about a very low energy food.

Standard 2.9.6 – Transitional standard for special purpose foods (including amino acid modified foods)

Item [3.1] varies *Standard 2.9.6 – Transitional standard for special purpose foods (including amino acid modified foods)*.

Standard 2.9.6 applies only in New Zealand and only to special purpose foods sold or

imported into New Zealand that are not FSMPs for the purposes of Standard 2.9.5. At present, very low energy foods are not FSMPs for the purposes of Standard 2.9.5 and, as such, are currently regulated in New Zealand by Standard 2.9.6.

Item [3.1] replaces the Note after subsection 2.9.6—3(3) with new subsection 2.9.6—3(4). The new subsection provides that provisions in Standard 2.9.6 cease to have effect in relation to very low energy food on the date that is three years after the date of commencement (i.e. the date of gazettal) of the approved draft variation.

Schedule 29 – Special Purpose Foods

Item [4.1] varies Schedule 29 of the Code by adding new section S29—22 to that Schedule.

New section S29—22 contains a table setting out the nutritional content requirements for a very low energy diet.

Column 1 of the table lists the nutrients and their corresponding minimum amounts per daily intake for the purposes of new paragraph 2.9.5—18(1)(f).

New paragraph 2.9.5—18(1)(f) requires that a very low energy food must, when consumed with other very low energy foods in accordance with the manufacturer's directions for use must result in a diet that contains not less than the minimum amount per daily intake (as specified in column 2 of the table to new section S29—22), of each nutrient listed in Column 1 of that table (see item 2.9 above).

Transitional arrangements

The above variations will commence or take effect on the date of gazettal. See clause 3 of the approved draft variation.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of those amendments. See clause 4 of the approved draft variation.

Instead, clause 4 of the approved draft variation provides a 36 month transition period, which commences on the variation's date of commencement and ends 36 months after that date.

During the transition period, a very low energy food can comply with either:

- the Code as in force without the variations made by the approved draft variation (meaning VLED in New Zealand can continue to comply with Standard 2.9.6 and VLED already available in Australia can remain on the market); or
- the Code as amended by the approved draft variation.

After the transition period, all very low energy food available in Australia and New Zealand must comply with the Code as amended by the approved draft variation.

