19 November 2021
180-21

Call for submissions – Application A1230

Very Low Energy Diets (VLED)

FSANZ has assessed an Application made by Nestlé Australia Ltd. and Nestlé New Zealand Ltd.to vary Standard 2.9.5 to include Very Low Energy Diets (VLED) and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 17 December 2021

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the assessment of Application A1230 are available on the FSANZ website:

SD1 Nutrition Assessment
SD2 Labelling Assessment

Executive summary

Nestlé Australia Ltd. and Nestlé New Zealand Ltd. lodged a joint application to amend the Australia New Zealand Food Standards Code (the Code) to regulate Very Low Energy Diets (VLED) currently in the Australian and New Zealand (ANZ) market in alignment with the *CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction* (Codex STAN 203-1995). The application proposes regulation of VLED by Standard 2.9.5 as food for special medical purposes (FSMP). FSMP partially or totally replace the daily diet and are recommended for use under medical supervision.

VLED were previously included in FSANZ Proposal P242, however were omitted at the Final Assessment Report (FAR) in 2012. Since 2012, imported and locally produced VLED have remained on the ANZ market. VLED in New Zealand are covered by Standard 2.9.6 - Transitional standard for special purpose foods, however there is no applicable standard for the Australian market. This amendment aims to provide regulatory clarity and certainty for these products within the ANZ market.

VLED are formulated for the dietary management of overweight and obesity and are developed to be used under medical supervision. VLED are used as a total diet replacement for a period up to 12 weeks and provide 3344 kJ or less per day, whilst consisting of sufficient protein, fatty acids, carbohydrates, vitamins and minerals for safe and fast weight loss.

Based on history of use, FSANZ considers the Codex STAN 203-1995 nutrient composition to be an appropriate and safe standard to adopt. FSANZ's nutrition assessment concludes there is minimal evidence to suggest that adoption of the Codex STAN 203-1995 nutrient composition would pose risk of nutritional adequacy or safety within the ANZ population. Inclusion of VLED within Standard 2.9.5 further ensures safe and adequate use due to the existing regulatory measures of the standard.

FSANZ has prepared a draft variation of the Code proposing the following amendments:

- adding definitions for *very low energy diet* and for *very low energy food* to the Code
- removing the exclusion of foods formulated and represented as being for the dietary management of obesity or overweight from being FSMP
- setting requirement to ensure VLED are consumed within the recommended daily quantity when used as the sole source of nutrition
- including a new division to set compositional requirements for very low energy diets, and
- including a provision stating that Standard 2.9.6 will cease to apply to VLED two years after commencement of the draft variation.

The draft variation, if approved, would regulate the use of VLED as FSMP in accordance with the Code.

1 Introduction

1.1 The Applicant

Nestlé Australia Ltd. and Nestlé New Zealand Ltd (collectively referred to as Nestlé from here in) are subsidiaries of the Swiss-based global food and beverages company Nestlé S.A. Nestlé manufactures and markets over 2000 brands of consumer food and beverage products which are sold in 187 countries worldwide. Nestlé has a diverse product range.

1.2 The Application

The purpose of this application relates to foods that are formulated and sold to form part of a very low energy diet; that is, a diet compromised of foods specially formulated for the dietary management of overweight and obesity and which, together, provide the sole source of nutrition when consumed according to the manufacturer's directions for use (for the purposes of this call for submissions, these foods are referred to as 'VLED').

VLED are used as a total diet replacement for a period up to 12 weeks. VLED typically provide a diet of 3344 kJ or less per day, whilst consisting of sufficient protein, fatty acids, carbohydrates, vitamins and minerals for safe and fast weight loss. A daily intake typically consists of three VLED, two cups of low starch vegetables, one teaspoon of vegetable oil and additional low energy fluids. Following the initial use period an ongoing program gradually introduces low calorie meals allowing program participants to transition from the above-mentioned VLED based diet to a more regular dietary pattern.

VLED are not currently covered by a specific standard within the Code. They were previously included in FSANZ Proposal P242, however were omitted at the Final Assessment Report (FAR) in 2012. In the P242 FAR, FSANZ committed to commence a project to address VLED on completion of that Proposal, but this has not eventuated. Meanwhile imported and locally produced VLED have remained on the Australian and New Zealand (ANZ) market, but without coverage of an applicable standard.

This amendment aims to provide regulatory clarity and certainty for these products within the ANZ market

The application also seeks to amend Standard 2.9.5 of the Australia New Zealand Food Standards Code (the Code) to regulate VLED as FSMP and to align the Code's requirements for VLED as FSMP with those set by Codex STAN 203-1995.

1.3 The current standard

1.3.1 Australia and New Zealand

Australian and New Zealand food laws require food for sale to comply with the following requirements in the Code.

1.3.1.1 Permitted use

VLED are currently not covered by an applicable food standard within Australia. In New Zealand, Standard 2.9.6 – Transitional Standard for Special Purpose Foods regulates VLED.

In both countries, Standard 2.9.5 – Food for Special Medical Purposes regulates FSMP and is applicable to products for use by adults and children under medical supervision, however 2.9.5-2(2) states that a FSMP is not a food that is *'formulated and represented as being for*

the dietary management of obesity or overweight'.

This application seeks to amend Standard 2.9.5 to include a new division for VLED that is consistent with their specific use in the dietary management of overweight and obesity. It is expected that Standard 2.9.6 would cease once a joint standard applicable to VLED is gazetted.

Section 2.9.5—7 includes compositional requirements for FSMP that are represented as being suitable for use as a sole source of nutrition. This application seeks to create a separate division within Standard 2.9.5 for the nutritional composition of VLED that reflects these foods supplying complete nutrition within a narrow energy range.

1.3.1.2 Labelling requirements

VLED are currently not covered by an applicable food standard within Australia. Transitional Standard 2.9.6 in New Zealand does not specify labelling requirements for VLED.

Supporting Document 2 provides a detailed analysis of the labelling requirements in the Code.

1.3.2 International Standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards.

1.3.2.1 Codex Alimentarius (Codex)

Codex has an established standard for VLED, which is the *Standard for formula foods used in very low energy diets for weight reduction*, Codex STAN 203-1995. This standard was adopted in 1995. The majority of VLED in the ANZ market are manufactured according to the international standard Codex STAN 203-1995. This application requests that the regulation adopted within the Code aligns with this international standard.

1.3.2.2 European Union (EU)

The EU regulation 2017/1798 regards the specific compositional and information requirements for total diet replacement for weight control. This regulation is substantially different to Codex STAN 203-1995 and adoption of the EU measures would require significant reformulation of products currently on the ANZ market.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Nutrition assessment

FSANZ conducted a comprehensive assessment that evaluated the nutrient composition requirement for setting an applicable food standard for VLED. The assessment determined the nutritional adequacy and safety of VLED currently on the ANZ market that are formulated in alignment with Codex STAN 203-1995. The nutrition assessment is included at Supporting Document 1 (SD1). This section provides a summary of these assessments.

The nutritional adequacy and safety assessments evaluated the nutrient composition prescribed in Codex STAN 203-1995 against relevant ANZ Nutrient Reference Values (NRVs) and the current composition of VLED on the ANZ market. VLED were assessed according to directions of use and in the context of the intensive level of the total diet replacement plan. The nutrient content of VLED was assessed for 24 nutrients prescribed in Codex STAN 203-1995 with the majority exceeding the relevant ANZ NRV. Four nutrients, including linoleic acid, α-linolenic acid, zinc and potassium, did not satisfy the adult male ANZ NRV. Only the upper end of the average nutrient range present within VLED on the ANZ market met the NRV, which poses potential risk for inadequacy within ANZ adult males. However, the nutritional adequacy assessment further considered the acute period of use associated with VLED and determined that the plausibility of risk of deficiency or inadequacy was relatively low. The assessment concluded that the use of the Codex STAN 203-1995 nutrient composition poses low risk to ANZ individuals achieving nutritional adequacy.

The nutrition assessment considered a further 11 nutrients that were not regulated within Codex STAN 203-1995, however were included within the EU 2017/1798 regulation and/or the ANZ NRVs. The assessment of VLED on the ANZ market found that biotin, pantothenic acid, vitamin K, chromium, molybdenum, selenium and chloride met the relevant ANZ NRV and/or EU 2017/1798 minimum. The assessment further concluded that aligning with Codex STAN 203-1995 and not setting any nutrient composition requirements for these nutrients would not pose risk to the nutritional adequacy of the ANZ population. Three nutrients - manganese, choline and fluoride - as well as dietary fibre, required further assessment which concluded that the nutritional concerns associated with these nutrients were minimal given the acute period of use and influence of other dietary factors that were not captured within the adequacy assessment.

The nutritional safety assessment followed the same process, however comparisons were made against the ANZ Upper Level of Intake (UL) where available. The nutritional safety assessment concluded that use of the Codex STAN 203-1995 nutrient composition did not pose risk to safety.

The ANZ market assessment evaluated data present on the labels of VLED. This assessment found that in the majority of cases VLED aligned with the Codex STAN 203-1995 regulation. However, for multiple nutrients, products on the ANZ market did not meet the EU 2017/1798 regulations. The assessment concluded that adoption of the Codex STAN 203-1995 would not require reformulation of VLED on the ANZ market.

The nutritional assessment, as a whole, concluded that adoption of the nutrient composition prescribed within Codex STAN 203-1995 posed low risk within the context of the ANZ population. Based on this, the proposed nutrient composition is outlined in Table 1. The nutrient composition is reflective of the total diet, as this allows variability in product type such as bars, soups and shakes. Due to the varied natured of products that comprise a very low energy diet, applying the nutrient composition to the total diet allows for variability when formulating products to mimic normal dietary practices.

Table 1: Application A1230 proposed nutrient composition for very low energy diets

Nutrient	Unit	A1230 Nutrient Composition^
Energy	kJ/day	1880 – 3345^
Protein	g/day	50
Protein Quality	PDCAAS	1*
LA	g/day	3
ALA	g/day	0.5
LA:ALA	ratio	5:15
Carbohydrate	g/day	50
Vitamin A	µg retinol equivalents/day	600
Vitamin D	µg/day	2.5
Vitamin E	mgTE/day	10
Vitamin C	mg/day	30
Vitamin B_6	mg/day	2
Vitamin B_{12}	µg/day	1
Niacin	mgNE/day	11
Riboflavin	mg/day	1.2
Thiamin	mg/day	0.8
Folic Acid	µg/day	200
Calcium	mg/day	500
Phosphorus	mg/day	500
Iron	mg/day	16
Iodine	µg/day	140
Magnesium	mg/day	350
Copper	mg/day	1.5
Zinc	mg/day	6
Potassium	g/day	1.6
Sodium	g/day	1

** Protein digestibility-corrected amino acid score (PDCAAS) - Essential amino acids may be added to improve protein quality only in amounts necessary for this purposes.*

^ The nutrient composition regulates minimum amounts per daily intake, expect for energy which is regulated as average energy content.

2.2 Risk management

On the basis of the findings of the nutrition assessment, FSANZ considers adoption of the Codex STAN 203-1995 nutrient composition ensures both nutritional adequacy and safety within the ANZ population. The risk management response to matters raised within the nutrition assessment and other varying aspects of VLED are detailed below.

2.2.1 Background to the overarching risk management strategies in Standard 2.9.5

Standard 2.9.5 regulates the sale, composition and labelling of foods specially formulated for the dietary management of individuals with certain diseases, disorders or medical conditions. FSMP are required when the dietary management of individuals cannot be easily or completely achieved with other dietary modification including the use of other special purpose foods. FSMP includes formulated dietary products that are intended for use as the sole source of nutrition, either consumed orally or through an enteral route (e.g. naso-gastric tube), as well as specialised supplementary formulated products. Food regulated by this standard is intended to be used under medical supervision. Due to the specialised nature and purpose of these foods, this standard also includes a restriction on the premises at which, and the persons by whom, FSMP may be sold to consumers.

Nearly all FSMP are imported from the EU or US, with the majority from EU. In order to limit the impost on manufacturers and therefore ensure continued supply of these products to

Australia and New Zealand, the existing compositional and labelling requirements in Standard 2.9.5 harmonise where possible with overseas regulations.

Standard 2.9.5 currently allows manufacturers to vary the micronutrient composition of FSMP from the specified limits for a specific medical purpose (including a particular medical condition, disease or disorder) but with an additional labelling requirement that indicates which nutrient levels have been varied. FSANZ's previous assessments in the development of Standard 2.9.5 considered the potential risk of inadequate and excessive nutrient intakes in both children and adults to be minimal as FSMP are used under the supervision of medical practitioners and dietitians, and the nutritional status of the patient is closely monitored.

The development of Standard 2.9.5 originally included VLED, however due to the specific nature of products outlined throughout targeted and public consultation they were omitted at the FAR. The consultation process found that VLED differed from other FSMP in that they required specific nutrition composition and other labelling elements that were not outlined within the proposed drafting for Standard 2.9.5. Proposal P242 also raised issues surrounding the overlap between VLED and other types of formulated foods used for weight reduction, both in the presentation of these two food categories and in the way in which the products are used. Other categories regulated by the Code include meal replacements under Standard 2.9.3 – Formulated Meal Replacements (FMR) and Formulated Supplementary Foods. To progress with the timely gazettal of Standard 2.9.5, VLED were removed and in response FSANZ proposed a new project would be initiated to specifically investigate the most appropriate way to regulate VLED relative to all other formulated foods for weight reduction purposes.

2.2.2 Amendment of Standard 2.9.5 to include VLED

2.2.2.1 Definition

Subsection 2.9.5—2(1) of the Code currently defines a food for special medical purposes as a food that is:

a) specially formulated for the dietary management of individuals:
    i. by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
    ii. whose dietary management cannot be completely achieved without the use of the food; and
b) intended to be used under medical supervision; and
c) represented as being:
    i. a food for special medical purposes; or
    ii. for the dietary management of a disease, disorder or medical condition.

Paragraph 2.9.5—2(2)(a) currently states that a food is not food for special medical purposes if it is formulated and represented as being for the dietary management of obesity or overweight.

VLED intended use aligns with all aspects of the FSMP definition, except for 2.9.5—2(2)(a), which specifically excludes VLED following their exclusion from the P242 FAR.

Very low energy diets:

a) are specially formulated for overweight and obese individuals
    i. provide a sole source of nutrition, which includes specific medically determined nutrient requirements detailed above in Table 1
    ii. are required as a sole source of nutrition to provide diets very low in energy while still supplying essential nutrients during intensive weight loss

b) are intended to be used under the supervision of a medical professional or dietitian
c) are represented as a FSMP and for the dietary management of overweight and obesity.

Given the above rationale, FSANZ considers that very low energy diets are appropriately represented by the definition of FSMP but for paragraph 2.9.5—2(2)(a). FSANZ proposes to remove from that paragraph the statement that 'a food is not FSMP if it is formulated and represented as being for the dietary management of obesity or overweight'.

The proposed amendment to the FSMP definition to include *very low energy diet* and *very low energy food* – and the regulation of VLED as FSMP which that amendment will result in – provides regulatory clarity for VLED. We note that following the 2010 P242 Call for Submissions, FSANZ considered the definition for very low energy diet needed to be further refined and acknowledge the products low energy range and its role as a sole source of nutrition for dietary management of overweight and obesity. The amended definition addresses this issue.

A definition of VLED will be required to delineate VLED from other FSMP for the purposes of the Code. Based on the above and current terminology used within the Code, the following definition is proposed to be added to section 1.1.2—2(3):

> ***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.

2.2.2.2 Required permissions for VLED as FSMP

This application seeks the regulation of VLED as FSMP by Standard 2.9.5. FSANZ supports this approach and agrees that Standard 2.9.5 is the most appropriate standard within the Code to regulate these products based on the above discussion and due to the significant risk management strategies embedded in the standard.

VLED do share some similarities with FMR regulated by Standard 2.9.3, however this standard does not reflect the intended purpose of VLED which are formulated to be used as a total diet replacement in the dietary management of overweight and obesity. Standard 2.9.3 specifically defines FMR as foods that have 'been specifically formulated as a replacement for one or more meals of the day, but not as a total diet replacement'. The compositional requirements of FMR are significantly different to VLED, and are inadequate as a total diet replacement. They are also not generally used under the supervision of a medical professional and do not have conditions of sale restricted by the Code.

FSANZ is of the opinion that as Standard 2.9.5 is reflective of the intended purpose of VLED as a sole source of nutrition, states the products are intended for use under the supervision of a medical professional and has specific sale and advertising restrictions, it is the most appropriate and safe standard for VLED to be integrated into.

In regard to alignment internationally, Standard 2.9.5 is also the most appropriate standard as it reflects and aligns with the overarching principles within Codex STAN 203-1995 and EU 2017/1798. Both international regulations define VLED as FSMP in the treatment of overweight or obesity. FSANZ considers that regulation of VLED by Standard 2.9.5 will not create any interpretation issues with international stakeholders that would affect trade and exports.

2.2.2.3 Nutrient composition

This application seeks to align Code requirements for very low energy diets nutrient composition with the nutrient composition outlined in Codex STAN 203-1995. This aspect of the regulation is assessed and discussed within Section 2.1 of this report and SD1 – Nutrition assessment.

Section S29—21 of the Code currently regulates the amounts of nutrients for FSMP as a sole source of nutrition. Despite very low energy diets also being intended for use as a sole source of nutrition, section S29—21 is not appropriate to regulate the nutrient composition due to difference in energy ranges between VLED and other FSMP. As very low energy diets are specifically formulated to provide a very narrow energy range to consumers, stricter nutrient composition is required to ensure that all essential nutrients are supplied. Other FSMP are not restricted in supplying nutrient amounts through energy range and therefore the nutrient composition differs. Based on this, FSANZ did not see it as an appropriate section to adopt for VLED and did not consider section S29—21 within the nutrition assessment.

VLED used as sole source of nutrition in the dietary management of overweight and obesity can also be used as partial diet replacement. This aspect of the product aids individuals return to normal eating and supports weight maintenance after following the intensive level total diet replacement plan. VLED primary purpose are to be used as a sole source of nutrition which will be reflected in the regulation. There is minimal risk associated with VLED being used as a partial diet replacement as they are nutritionally complete and intended for use under the supervision of medical practitioners and dietitians.

2.2.2.4 Additional Risk Management Strategies

Standard 2.9.5 currently requires manufacturers to provide information regarding the daily quantity of their product that is required to be consumed for nutritional adequacy when used as a sole source of nutrition (e.g. nutritionally complete in 1.5 litres or across three products per day) as well as the nutrient composition of a product. These are used to assess the nutritional adequacy of a product against disease specific requirements where known. If it is known that any nutrients are not complete in a given volume over a long period of time, this would be monitored by the medical practitioner or dietitian. Micronutrient supplements or multivitamin preparations can also be used where required to account for any nutrient deficit and ensure nutritional adequacy.

FSANZ's assessment of the ANZ VLED market confirmed that an accompanying information leaflet is standard practice with VLED. This includes information on the use as a sole source of nutrition, clear directions of use and information on the total diet replacement plan including how many VLED to consume, optional extras and appropriate usage length. Further, as the majority of VLED (imported and domestically manufactured) are compliant with Codex STAN 203-1995, most information leaflets are reflective of the requirement under Codex STAN 203-1995 section 9.7 – Additional Provisions that "…other statements, as required under Section 9.6 and Section 4.5 of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes, may appear on an accompanying leaflet in which case reference shall be made to this fact on the label of the package and/or sachet". As such, FSANZ considers existing risk management strategies are suitable in informing and protecting consumers of VLED.

The nutrient composition of VLED is also supported by optional additional intakes included in the total diet replacement plans prescribed by the manufacturers. The intensive level total diet replacement plan reflects when the products are used as a sole source of nutrition. This plan typically includes the consumption of three VLED per day (variability of product type is encouraged), two cups of low starch vegetables, one teaspoon of vegetable oil and two litres

of water every day. The additional intakes ensure adequate intake of essential nutrients such as vitamin K and essential fatty acids, and also dietary fibre. They also aid compliance to the program, consumers satiety levels and other health factors such as hydration and bowel movements. The additional intakes are detailed within the leaflets.

As mentioned above, the leaflet also covers usage time and states that the recommended timeframe to follow the intensive level total diet replacement plan is up to 12 weeks. Use of VLED as sole source of nutrition is only recommended over an acute period and is not for continuous use over an unlimited time frame. Compliance with the intensive level of the total diet replacement plan is typically not seen for longer than two to three weeks, which further evidences that individuals are not exceeding the recommended usage times as prescribed by the manufacturers and medical professionals. The acute period of use, oversight by the treating medical professional and strict nutrient composition are considered suitable risk management strategies to protect consumers from nutritional deficiencies.

In accordance with section 2.9.5—5 of the Code, VLED will be restricted for sale by the person whom and the premises at which they are sold. Sale of VLED will be limited to medical practitioners, dietitians, medical practices, pharmacies or other responsible institutions. This risk management strategy is seen as an appropriate way to regulate and sale of VLED in line with their intended purpose.

2.2.3 Labelling requirements

FSANZ has considered the labelling requirements for VLED in response to the applicant's request to apply specific labelling requirements and for specific exemptions for VLED from existing requirements in the Code.

As discussed in Section 2.2.2.1 and 2.2.2.2 above, VLED are considered by FSANZ to be specialised foods used for weight loss for specific medical purposes, within the broader group of FSMP. FSANZ has therefore sought to align labelling requirements for VLED where appropriate with the existing labelling requirements for FSMP but has also considered labelling requirements in Part 1.2 of the Code that apply to foods more generally.

FSANZ has also sought to align with the Codex STAN 203-1995 where appropriate. The requirements in the EU for the labelling of total diet replacement for weight control (EU 2017/1798) have also been taken into consideration.

Within the consideration of labelling requirements, FSANZ had regard to the Policy Guideline on the intent of Part 2.9 – Special Purpose Foods[1], in particular, the following principle:

Adequate information should be provided, including through labelling and advertising of special purpose foods, to:

- *assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and*
- *provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.*

The following lists summarise: the proposed labelling requirements for VLED; proposed exemptions from the generic labelling requirements within the Code and Standard 2.9.5; and existing requirements which are proposed to apply to VLED with variations.

[1] Available at Food Regulation - Food policies

All proposed labelling requirements apply individually to each VLED. They do not apply across all products comprising the very low energy diet unless stated, e.g. the statement of ingredients is to be for the individual product, not across the VLED.

2.2.3.1 Proposed labelling requirements for VLED consistent with current FSMP requirements

The requirements that currently apply to FSMP are proposed to apply to VLED for retail sale, as follows:

- legibility requirements
- irradiated food labelling requirements
- name or a description of the food sufficient to indicate the true nature of the food
- lot identification
- date marking, including allowing flexibility to use 'Expiry Date' or similar wording instead of 'Use By'
- directions for use and storage (with additional requirement – see 3 below)
- ingredient labelling, including allowances to use EU or USA ingredient labelling
- lactose and gluten claim conditions
- prohibition of claims of a therapeutic nature
- allergen declarations required by Standard 1.2.3
- certain advisory and warning statements required by Standard 1.2.3, if relevant to the product, e.g. if the food contains aspartame or aspartame-acesulphame salt, a statement to the effect that the food contains phenylalanine
- a statement to the effect that the VLED must be used under medical supervision
- a statement indicating the medical purpose of the food, which may include any disease, disorder or medical condition for which the food has been formulated
- a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated
- a statement indicating whether or not the food is suitable for use as a sole source of nutrition
- if a VLED is represented as being suitable for use as a sole source of nutrition, a statement to the effect that the food is not for parenteral use
- a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food
- a statement indicating where the food is intended for a specific age group.

Subsection 2.9.5—10(1) specifies that if a food is modified to vary from compositional requirements, then a statement indicating the nutrient or nutrients which have been modified is required. FSANZ is proposing to not permit modification of VLED from prescribed compositional limits, therefore this requirement will not apply.

Proposed labelling requirements for inner packages of VLED are:

- name or a description of the food sufficient to indicate the true nature of the food
- lot identification
- allergen declarations
- date marking.

Proposed labelling requirements for transportation outers for VLED are (unless clearly discernible through the transportation outer, or in the case of the supplier name and address, is provided in documentation accompanying the VLED):

- name or a description of the food sufficient to indicate the true nature of the food
- lot identification

- name and address of supplier in Australia or New Zealand.

FSANZ also proposes to apply the exemption (currently in place for FSMP) from labelling requirements to VLED served by institutions such as hospitals in a container such as a plate, cup or tray.

2.2.3.2 Proposed variations from current FSMP requirements for VLED

It is proposed to apply nutrition information requirements in Standard 2.9.5 to VLED. Section 2.9.5—13 of that Standard does not prescribe how nutrition information is expressed, which allows flexibility in presentation of this information. However FSANZ is proposing to specifically require:

- the nutrition information to be provided on a per serving basis (rather than per 'given amount'), with the average quantity of the serving size also stated
- declaration of the average energy content rather than minimum amount.

2.2.3.3 Additional requirements proposed for VLED

Section 2.9.5—9 requires the label to state the directions for the use or storage of the food if the food is of a nature to require these directions. FSANZ is proposing the additional requirement that the recommended daily quantity of the product to be consumed, with the quantity to be established by the manufacturer, is declared on the labels of VLED.

2.2.3.4 Existing labelling requirements in the Code not proposed to apply to VLED

FSANZ proposes that the following labelling requirements in the Code do not apply to VLED products (consistent with the existing approach for FSMP):

- percentage of characterising ingredients and components labelling (Standard 1.2.10)
- Standard 1.2.7 – Nutrition, Health and Related Claims
- application of labelling requirements (Standard 1.2.1)
- some mandatory warning and advisory statements (Standard 1.2.3)
- nutrition information requirements, other than as indicated in Section 2.2.3.2 above.

2.2.4 Risk management conclusion

Based on the nutrition assessment and consideration of the objectives of the FSANZ Act (see section 2.4) and relevant Ministerial Policy Guidelines (see section 2.4.3), the preferred approach is to prepare a draft variation for a new division to Standard 2.9.5 to regulate VLED as FSMP.

The draft variation would permit VLED in Australia and New Zealand as FSMP in accordance with the Code.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views

of interested parties on issues raised by this application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account all submissions received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the Code to align with Codex STAN 203-1995 is unlikely to have a significant effect on international trade as this will create international harmonisation and products within the Australia and New Zealand market are already aligned with this standard.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act.

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29 (2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considers amending Standard 2.9.5 to include the use of VLED as FSMP. FSANZ is of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by codifying VLED within Standard 2.9.5 - FSMP.

Consumers
Consumers who are overweight (Body Mass Index (BMI) 27+) with health conditions, or consumers who are obese (BMI 30+) may benefit from greater availability of VLED as FSMP, and therefore greater ability to lose weight safely. This may have positive overall health effects.

Greater availability of VLED may also increase competition between manufacturers and wholesalers and reduce costs to consumers.

Given the nature and relative costs of FSMP, there appears little incentive for non-target groups to consume these products, although there are potential risks in the unsupervised and inappropriate use of formulas for VLED. Those risks are likely to be mitigated by subsection 2.9.5—5(1) of the Code which will provide that VLED may only be sold through medical practitioners, dietitians, pharmacies, responsible institutions or a majority seller for special medical purposes.

Industry
Industry, including manufacturers and sellers of VLED, will likely benefit overall from greater regulatory certainty, including from fewer barriers to importing VLED. Greater competition between manufacturers may reduce costs and increase availability of VLED for wholesalers and retailers of these products. It is also unlikely that compliance to the new regulation will generate additional costs as evidence suggests products on the ANZ market are currently compliant with FSMP requirements and Codex STAN 203-1995, which the proposed regulations align with.

Government
Approving this application would provide greater regulatory certainty and may reduce overall enforcement costs, although more VLED may need to be monitored for compliance.

Conclusions from cost benefit considerations
FSANZ's assessment is that the direct and indirect benefits that would arise from approving this application, most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.3 Any relevant New Zealand standards

Standard 2.9.6 – Transitional standard for special purpose foods (including amino acid modified foods) is applicable in New Zealand. This standard was introduced following the exclusion of VLED during the development of Standard 2.9.5, under Proposal P242. It is expected that Standard 2.9.6 will cease to apply to VLED once a joint standard applicable to VLED is gazetted.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a nutritional adequacy and safety assessment (see SD1) and concluded there is no evidence of a public health and safety concern associated with amending Standard 2.9.5 to include VLED as FSMP, in alignment with Codex STAN 203-1995.

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

Under Standard 2.9.5, FSMP are intended to be used under medical supervision, ultimately allowing medical practitioners and dietitians to determine whether the FSMP is appropriate and safe for their patients' specific needs.

Existing labelling requirements for FSMP apply to VLED (see sections 2.2.3.1), which would provide information to assist medical practitioners and dietitians, and enable informed consumer choice. Additional labelling requirements specifically for VLED are also proposed to further ensure consumer understanding and safety (see section 2.2.3.3).

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to assess this application. The applicant submitted comprehensive nutrition composition details for Optifast VLED. FSANZ also had regard to other relevant information including VLED on the ANZ market, international standards such as Codex STAN 203-1995 and EU regulation 2017/1798, and scientific literature in assessing this application.

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

The proposed amendment to the Code to include VLED within Standard 2.9.5 aligns with Codex STAN 203-1995 and will promote international consistency and harmonisation. Regulating VLED as FSMP under Standard 2.9.5 will also promote consistency on a domestic level.

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

The proposed division in the Code would allow for a competitive food industry in relation to VLED.

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

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The *Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose*

Foods states the composition of special purpose food should be consistent with the intended purpose. Based on our assessment, FSANZ considers that the Policy Guideline has been met.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

3.1 Transitional arrangements

FSANZ is proposing not to apply the Code's default standard transition arrangements provided by section 1.1.1—9 of the Code. This section provides for a 12 month stock-in-trade period for variations to the Code.

Instead, FSANZ is proposing for the draft variation to take effect on the date of gazettal, with a two year transition period.

During the two years, a VLED can comply with either the Code as in force as if the variation had not taken effect, or with the Code as amended by the variation. After the transition period, all VLED available in the ANZ market would need to comply with the variation.

These transitional arrangements take account of stock-in-trade and have been included within the draft variation because the proposed changes will be affecting products with a longer shelf life.

Subsection 2.9.6—3(3) of Standard 2.9.6 provides that the Standard ceases to have effect two years after the commencement of any 'alternative applicable provisions elsewhere in this Code'. That Standard deals with products other than VLED. For that reason, in the interests of clarity, the drafting proposes to amend section 2.9.6—3 to provide that *"a provision of this Standard ceases to have effect in relation to a VLED 2 years after the commencement of the Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation.*

4 References

Baker Heart and Diabetes Institute (2020) Very Low Energy Diet Program, Baker Institute Resources, Melbourne, Vic 3004 Australia. Available at: https://baker.edu.au/-/media/documents/fact-sheets/Baker-Institute-factsheet-VLED-program.pdf

Codex (1995) Standard for Formula Foods used in Very Low Energy Diets for Weight. Codex Alimentarius CODEX STAN 203-1995. Codex Alimentarius Commission, Rome. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B203-1995%252FCXS_203e.pdf

Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control http://data.europa.eu/eli/reg_del/2017/1798/oj

FSANZ (2012) Final Assessment Report. Proposal P242 – Foods for Special Medical Purposes. Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/code/proposals/documents/P242%20FSMP%20FAR%20FINAL.pdf

NHMRC and NZ MOH (2006) Nutrient Reference Values for Australia and New Zealand. Commonwealth of Australia, Canberra. http://www.nrv.gov.au/

NHMRC and NZ MOH (2017) Australia and New Zealand Nutrient Reference Values for Fluoride. Commonwealth of Australia, Canberra. https://www.nrv.gov.au/sites/default/files/content/resources/2017%20NRV%20Fluoride%20Report.pdf

Attachments

A. Draft variation to the *Australia New Zealand Food Standards Code*
B. Draft Explanatory Statement

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name and position of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation.*

2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the food product complies with one of the following:

(a) the Code as in force without the variations made by this instrument; or
(b) the Code as amended by the variations made by this instrument.

(3) For the purposes of this clause:

transition period means the period commencing on the variation's date of commencement and ending 24 months after the date of commencement.

Schedule

Standard 1.1.2 Definitions used throughout the Code

[1.1] **Subsection 1.1.2—2(3)**

Insert:

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.

[1.2] **Subsection 1.1.2—5(2)**

Repeal the subsection, substitute:

(2) Despite subsection (1), a food is not ***food for special medical purposes*** if it is an infant formula product.

Standard 2.9.5 Food for Special Medical Purposes

[2.1] **Section 2.9.5—2 (Note 1)**

Omit all the words after "a food is not ***food for special medical purposes"***, substitute:

"if it is an infant formula product"

[2.2] **Section 2.9.5—2 (after Note 3)**

Insert:

Note 4 In this Code (see section 1.1.2—3):

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.

[2.3] **After subsection 2.9.5—7(2)**

Insert:

(3) Subsection (1) does not apply to a *very low energy food.

[2.4] **Subsection 2.9.5—9(2)**

Repeal the paragraph, substitute:

(2) The label for a food for special medical purposes that is a *very low energy food must also state the recommended daily quantity of all very low energy foods to be consumed.

(3) The label must comply with Division 6 of Standard 1.2.1.

[2.5] **Paragraph 2.9.5—10(1)(g)**

Omit ”(if applicable):”, substitute “(if applicable), and the food is not a *very low energy food:”

[2.6] **Section 2.9.5—13**

Repeal the section, substitute:

2.9.5—13 Nutrition information—food for special medical purposes

(1) For paragraph 2.9.5—9(1)(h), the nutrition information required for a food that is not a *very low energy food is the following, expressed per given amount of the food:

(a) the minimum or *average energy content; and

(b) the minimum amount or *average quantity of:

(i) protein, fat and carbohydrate; and

(ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and

(iii) any substance listed in the table to section S29—20 that has been *used as a nutritive substance in the food; and

(iv) subject to paragraph 2.9.5—9(1)(i), any other substance in respect of which a *nutrition content claim has been made.

(2) For paragraph 2.9.5—9(1)(h), the nutrition information required for a food that is a *very low energy food is the following:

(a) the *average quantity of that food per serving; and

(b) the *average energy content per serving; and

(c) 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 in the food; and

(iv) subject to paragraph 2.9.5—9(1)(i), any other substance in respect of which a *nutrition content claim has been made.

[2.7] **After section 2.9.5—17**

Insert:

Division 5 Very Low Energy Diets

2.9.5—18 Compositional requirements for very low energy diets

(1) 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:

(a) has an *average energy content of no less than 1880 kJ/day and no more than 3345 kJ/day; and

(b) contains not less than 50 g of *available carbohydrates present within the average energy content required by paragraph (a); and

(c) contains not less than 50 g protein per day with a nutritional quality

equivalent to a protein digestibility corrected amino acid score of 1, present within the average energy content required by paragraph (a); and

(d) contains within the average energy content required by paragraph (a) not less than:

(i) 3 g of linoleic acid; and

(ii) 0.5 g of α-linolenic acid; and

(e) has a ratio of linoleic acid to α-linolenic acid of between 5 and 15; and

(f) contains not less than the minimum amount per daily intake, as specified in column 2 of the table to section S29—22, of each nutrient listed in Column 1 of that table.

(2) Despite subsection 2.9.5—6(1), L-amino acids listed in Column 2 of the table to section S29—20 may be added to a *very low energy food only in an amount necessary to improve protein quality.

(3) For this section, **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.

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

[3.1] **After subsection 2.9.6—3(3)**

Repeal the Note, substitute:

(4) A provision of this Standard ceases to have effect in relation to a *very low energy food 2 years after the commencement of the *Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation*.

Schedule 29 Special Purpose Foods

[4.1] **After section S29—21**

Insert:

S29—22 Substances that may be used as nutritive substances in a very low energy diet

For paragraph 2.9.5—18(1)(f), the table is:

Amounts of nutrients in a very low energy diet

Column 1	***Column 2***
Nutrient	*Minimum amount per daily intake*
Vitamins	
Vitamin A	600 µg retinol equivalents[1]
Vitamin D	2.5 µg
Vitamin E	10 mg α-tocopherol equivalents[2]
Vitamin C	30 mg
Vitamin B_6	2 mg
Vitamin B_{12}	1 µg
Niacin	11 mg niacin equivalents[3]
Riboflavin	1.2 mg
Thiamin	0.8 mg
Folic Acid	200 µg

Column 1	***Column 2***
Nutrient	*Minimum amount per daily intake*
Minerals	
Calcium	500 mg
Phosphorus	500 mg
Iron	16 mg
Iodine	140 µg
Magnesium	350 mg
Copper	1.5 mg
Zinc	6 mg
Potassium	1.6 g
Sodium	1 g

Note 1 See paragraph 1.1.2—14(3)(a).

Note 2 See paragraph 1.1.2—14(3)(c).

Note 3 For niacin, add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60.

Attachment B – Draft 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 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) for the purposes of 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 compromised 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 prepared a draft variation.

2. Purpose

The Authority has prepared 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 draft variation incorporates a document by reference.

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) will provide 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a RIS for this application (OBPR correspondence dated 14 May 2021, OBPR ID:44071). This standing exemption was provided as, based on the information provided, 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 under section 94 of the FSANZ Act.

6. Variation

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] repeals subsection 1.1.2 – 5(2) and substitutes it with '(2) Despite subsection (1), a food is not ***food for special medical purposes*** if it is an infant formula product.'

The effect of this variation will be to remove the exclusion of foods formulated and represented as being for the dietary management of obesity or overweight from being 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 remove all the words after 'a food is not food for special medical purposes' and replace the latter with 'if it is an infant formula product'.

This variation is to reflect 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—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 will provide that these compositional requirements do not apply to very low energy foods – which are 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 [2.7] below).

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

New subsection 2.9.5—9(2) will require 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. This requirement will apply 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) will provide that the label must comply with Division 6 of Standard 1.2.1. It restates the current subsection 2.9.5—9(2).

Item [2.5] varies subsection 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 required to reflect the amendment made to section 2.9.5—7 (see Item [2.3] above).

Item [2.6] varies section 2.9.5—13 to prescribe the nutrition information that must be stated on the label of a very low energy food.

Section 2.9.5—13 lists the nutrition information that paragraph 2.9.5—9(1)(h) requires to be on a label of FSMP. The section reflects the fact that the requirements in Standard 1.2.8 for Nutrition Information Panels do not apply to FSMP.

Item [2.6] replaces section 2.9.5—13 with two new subsections.

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

Subsection 2.9.5—13(2) will list the nutrition information that paragraph 2.9.5—9(1)(h) requires to be stated on the label of a FSMP that is a very low energy food. The following nutrition information will be required to be stated:

- the average quantity of that food per serving; and
- the average energy content 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 in the food; and
  - (iv) subject to paragraph 2.9.5—9(1)(i) of the Code, any other substance in respect of which a nutrition content claim 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 [2.7] below).

Item [2.7] inserts a new division after subsection 2.9.5—17.

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

The new section will set the compositional requirements for very low energy foods that together constitute a very low energy diet. The new section will require 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 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' of 1, present within the required average energy content.

  New subsection 2.9.5—18(3) will provide that, for the purposes of this requirement, 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.

- 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, 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) will restrict the amount of L-amino acids that may be added to a very low energy food. Subsection 2.9.5—6(1) provides that the L-amino acids listed in Column 1 of the table to section S29—20 may be added to FSMP. New subsection 2.9.5—18(2) will provide that these L-amino acids may be added to a FSMP that is a very low energy food only in such an amount that is necessary to improve protein quality.

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 will provide that Standard 2.9.6 will cease to have effect in relation to very low energy food on the date that is two years after the date of commencement of the *Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation*.

Schedule 29 – Special Purpose Foods

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

The table to new section S29—22 lists the vitamins and minerals – and the minimum amount of each of those vitamins and minerals – that paragraph 2.9.5—18(1)(f) will require a very low energy diet to contain. Column 1 of that table lists the required vitamins and minerals. Column 2 of that table lists the required minimum amount per daily intake for each of these vitamins and minerals.

Transitional arrangements

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

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the above variations. See clause 4 of the instrument of variation.

Clause 4 provides a 24 month transition period. During this period, a very low energy food can comply with either the Code as in force as if the variation had not taken effect or with the Code as amended by the 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 variation.