21 March 2022
194-22

Approval report – Application A1230

Very Low Energy Diets (VLED)

Food Standards Australia New Zealand (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.

On 19 November 2021, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received thirteen submissions.

FSANZ approved the draft variation on 7 March 2022. The Food Ministers' Meeting was notified of FSANZ's decision on 21 March 2022.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting documents

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

SD1 Nutrition Assessment (at Approval)
SD2 Labelling Assessment (at Approval)

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 foods that are formulated and sold to form part of a very low energy diet (VLED) that are currently in the Australian and New Zealand (ANZ) market, and to align that regulation with the *CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction* (Codex STAN 203-1995). The application proposed regulation of VLED by Standard 2.9.5 of the Code 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 were 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 (TDR) for a period up to 12 weeks and provide 3344 kilojoules (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 safe use, FSANZ considered the Codex STAN 203-1995 nutrient composition to be an appropriate and safe standard to adopt. FSANZ's nutrition assessment concluded there was 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. Regulation of VLED as FSMP under Standard 2.9.5 further ensures safe and adequate use due to the existing regulatory measures of the standard.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 19 November 2021 to 17 December 2021. Thirteen submissions were received, all of which FSANZ had regard to (see Section 2.1 of this report for details of submissions made).

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the proposed draft variation following assessment with amendments. The effect of the approved draft variation is that VLED will be permitted as FSMP in accordance with the Code. The approved draft variation will:

- add definitions for *very low energy diet* and for *very low energy food* to the Code
- amend the exclusion related to foods formulated and represented as being for the dietary management of obesity or overweight so that it does not apply to VLED
- set requirements to ensure VLED are consumed within the recommended daily quantity when used as the sole source of nutrition
- add specific labelling requirements to ensure VLED are used appropriately
- include a new division in Standard 2.9.5 to set compositional requirements for VLED, and
- include a provision stating that Standard 2.9.6 will cease to apply to VLED three years after commencement of the draft variation.

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.

1.2 The Application

The application sought to regulate foods that are formulated and sold to form part of a very low energy diet i.e. a diet comprised 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 Approval Report, these foods are referred to as 'VLED').

VLED are used as a total diet replacement (TDR) for a period up to 12 weeks. Very low energy diets typically provide 3344 kJ or less per day, whilst consisting of sufficient protein, fatty acids, carbohydrates, vitamins and minerals for safe and fast weight loss. In accordance with the intensive level total diet replacement plan, a daily intake typically consists of three VLED and the optional addition of 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 regulated by a specific standard within the Australia New Zealand Food Standards Code (the Code). They were originally 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 by an applicable standard.

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

The application also sought to amend Standard 2.9.5 of 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 relevant requirements in the Code. The requirements in the Code relevant to the application are summarised below.

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'.*

Application A1230 – Very Low Energy Diets (VLED) sought 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 to have effect in relation to VLED three years after the approved draft variation 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. Application A1230 – Very Low Energy Diets (VLED) sought to create a separate division within Standard 2.9.5 for the nutritional composition of VLED that reflects the use of these foods as sole source of nutrition within a narrow energy range.

1.3.1.2 Labelling requirements

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

A detailed analysis of the labelling requirements in the Code is provided at Supporting Document 2.

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 requested that the regulation adopted within the Code aligned with this international standard.

1.3.2.2 European Union (EU)

The EU regulation 2017/1798 regulates 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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with amendments. The amendments made to the draft variation are explained in section 2 of this report. The approved draft variation, as varied after consideration of submissions, takes effect on Gazettal. The approved draft variation is at Attachment A.

The related 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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 19 November 2021 to 17 December 2021. Thirteen submissions were received - five from government agencies, six from industry bodies and two from public health groups. The Australian Government Department of Agriculture, Water and the Environment (DAWE), New Zealand Food and Grocery Council (NZFGC) and Nestlé fully supported the draft variation. Other submitters supported the need for the variation but requested further consideration on some elements of the proposed regulation. Industry submitters raised concerns relating to the omission of VLED from previous Proposal P242 and the appropriateness of considering such regulation under an application. Several submitters sought clarity regarding the interpretation of the proposed amendments.

The issues raised in submissions and the FSANZ response are provided in Table 1.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Alignment with Codex STAN 203-1995		
Concerns regarding the appropriateness of aligning with Codex STAN 203-1995 in: - ensuring the protection of public health and safety of the ANZ population - developing regulation based on the best available scientific evidence. Consideration of alignment with international guidelines should be secondary to the above.	Victorian Department of Health and the Victorian Department of Jobs	As detailed in this Report, FSANZ undertook a rigorous and independent assessment of the application which included consideration of previous work completed under Proposal P242, an evidence-based assessment of the risk to public health and safety in aligning with the requested product composition in this application and the appropriateness of international alignment, noting the significant importation of these products into Australia and New Zealand. FSANZ previously assessed VLED within Proposal P242 – Foods for Special Medical Purposes (FSMP) where it was proposed by FSANZ that Codex STAN 203-1995 would form a basis for the nutrient composition. Further to this, submitters involved in the 2010 Targeted Stakeholder Consultation supported the approach of aligning with Codex STAN 203-1995. FSANZ omitted VLED at the Final Assessment Report (FAR) for Proposal P242 to prevent delays in the gazettal of Standard 2.9.5, and allow sufficient time to specifically investigate the most appropriate way to regulate VLED relative to all other formulated foods for weight reduction purposes. This was an emerging issue at the time. Omission

Issue	Raised by	FSANZ response
		was not related to public health and safety concerns with aligning with Codex STAN 203-1995. Nevertheless, under this application, FSANZ completed a new independent assessment which considered the public health and safety of aligning with Codex STAN 203-1995 within the context of the ANZ population. This assessment also gave consideration to the EU 2017/1798 where applicable, however FSANZ notes the EU 2017/1798 has extended the transition period on adopting the regulation due to issues raised regarding the technical feasibility of the nutrient composition and may be subject to change. Given the majority of FSMP (including VLED) are imported into ANZ, FSANZ considered it appropriate to align with an international standard, which was demonstrated to be safe and suitable for the intended use, to minimise any barriers to the supply of these products to Australia and New Zealand.
Defining characteristics of VLED		
Concerns regarding removal of the clause from Standard 2.9.5 *"a food is not food for special medical purposes if it is: (a) formulated and represented as being for the dietary management of obesity or overweight"* as its removal could potentially create issues at the food medicine interface by opening up the standard to other products that may reposition themselves as FSMP.	Victorian Department of Health and the Victorian Department of Jobs New Zealand Food Safety	Noted. FSANZ noted that therapeutic weight loss and fat burning supplements are regulated by the Therapeutic Goods Administration (TGA) because those supplements are therapeutic goods within the meaning of the *Therapeutic Goods Act 1989.* Moreover, other weight loss products such as Formulated Meal Replacements (FMR) would also be unable to be repositioned as VLED due to the comprehensive nutrient composition they must comply with, including the significant differences in energy content, under the approved draft variation. However, FSANZ has made amendments to the drafting to ensure clarity and further mitigate the potential risk of other weight loss products attempting to inappropriately reposition as VLED or FSMP. FSANZ has also provided further clarification on this issue under section 2.3.2.2 of this report.
Requests to clarify the definitions for VLED and include defining features for very low energy foods to enable enforcement officers to identify the product and differentiate from FMR.	Queensland Health Victorian Department of Health and the Victorian Department of Jobs	The definitions used reflect and are consistent with the nature of the product being regulated and the fact that the Code regulates food products and not 'diets'. The Code and Food Acts can only regulate individual food products at the point of sale. Given the intended purpose of VLED and very low energy foods their compositional requirements have to be set by reference to the diet.

Issue	Raised by	FSANZ response
	NSW Food Authority Dietitians Australia New Zealand Food Safety	The definitions include identifying characteristics. • In the case of very low energy foods, it is that be 'a food for special medical purposes' (as defined by section 1.1.2—5 of the Code) and that food be produced for consumption as part of a very low energy diet (as also defined) • In the case of a very low energy diet, the identifying characteristics included that it comprise 'food for special medical purposes specially formulated for the dietary management of overweight and obesity' and that those foods provide the sole source of nutrition when consumed in accordance with the manufacturers' directions for use on the label of the foods. The Code will also require foods sold for use in and as part of a very low energy diet to bear a mandatory statement on the label noting the name or description of the food sufficient to indicate the true nature of that food and the medical purpose of that food. The above must also be read in light of the fact VLED will also be the *only* FSMP formulated for the dietary management of overweight and obesity. FSANZ remains satisfied that these requirements will enable enforcement officers to be able to identify very low energy foods for compliance purposes. No evidence has been provided to the contrary. FSANZ acknowledges that the definitions used differ to the definition provided by Codex STAN 203-1995, however remains satisfied that is appropriate within the framework of the Code. Concerns raised in relation to the need for a prescribed name are addressed below.
Use as sole source of nutrition		
Concerns surrounding the suitability of referring to the product as 'sole source of nutrition' or 'nutritionally complete' as the Code does not define these terms and the products are not complete without the optional additions.	Victorian Department of Health and the Victorian Department of Jobs Dietitians Australia Opti-Pharm New Zealand Food Safety	Noted. FSANZ does not consider the use of 'sole source of nutrition' as unsuitable within the context of the Code, and in particular, Standard 2.9.5. 'Suitable for use as sole source of nutrition' is an existing term used within Standard 2.9.5, which has been carried through the approved draft variation for consistency. For example, sections 2.9.5—7 and S29—21 of the Code contain compositional requirements for FSMP represented as being suitable for use as sole source of nutrition. Requirements include minimum and maximum amounts of nutrients, noting

Issue	Raised by	FSANZ response
	Pharmacare Laboratories	that manufacturers can vary the micronutrient composition for a declared specific medical purpose only. The term 'suitable for use as sole source of nutrition' is applied in the same way to VLED in the approved draft variation for consistency with existing FSMP requirements. The required composition includes all essential nutrients that are required to provide nutritional adequacy for use specifically for the medically-supervised dietary management of overweight and obesity. However, unlike for other FSMP, the approved draft variation does not permit the essential composition of a VLED to be varied. More broadly, FSANZ's current and previous assessments relating to Standard 2.9.5 considered the potential risk of inadequate and excessive nutrient intakes to be minimal as FSMPs are used under medical supervision, and the nutritional status of the patient is closely monitored.
Concerns regarding the proposed compositional requirements applying to a group of products (amounting to total daily intake), rather than an individual product and the products within the range will be able to be labelled as 'nutritionally complete'.	Queensland Health	FSANZ noted that the draft variation states that 'very low energy food must, when consumed according to the manufacturer's directions for use, result in a diet that' and then specifies the essential composition. This stipulates that each individual 'very low energy food' must be able to meet the nutrient composition of 'very low energy diet' when consumed in the prescribed daily quantity. Submitters raised concern regarding foods which provide minimal nutritional value, such as herbal products, being included as part of the very low energy diet. FSANZ reiterates that the approved variation requires that each individual very low energy food must be able to meet the essential composition when consumed according to the manufactures directions of use. VLED require labelling on whether it is suitable for use as sole source of nutrition. VLED must also be labelled with directions for use which state the quantity of 'very low energy food' products to be consumed to meet the daily requirement for use as sole source of nutrition. Very low energy foods are also not sold individually. They are sold in packs to support appropriate consumption of a very low energy diet. FSANZ considers the wording 'nutritionally complete' could be used to meet the requirement when labelling whether the product is suitable for use as sole source of nutrition.

Issue	Raised by	FSANZ response
		Use of the term 'nutritionally complete' is further discussed within section 2.3.2.3.1 of this report.
Additional labelling requirements for directions about additional food, nutrients and fluid required, to ensure sole source of nutrition statement is accurate.	NSW Food Authority Dietitians Australia	FSANZ understands this comment relates to the advice provided by manufacturers to medical professionals and consumers who are using VLED as a sole source of nutrition (commercially known as the 'intensive level' or 'total diet replacement'). This phase is accompanied by advice that optional additions can be consumed while following a very low energy diet to aid compliance, increase fluid intake and provide additional nutrition such as fibre. Despite the above guidance, VLED are still required to meet the nutrient composition requirements in accordance with 2.9.5—18 to be used as sole source of nutrition. Some patients will use VLED without consuming the optional additions. There is also a requirement to state on the label the recommended daily quantity of very low energy foods to be consumed to meet the requirements for a very low energy diet. How the total diet replacement plan is individualised is dependent on the medical practitioner's discretion. It is FSANZ's opinion that VLED should be regulated based on its intended purpose and in the case of VLED, the purpose is for use as a sole source of nutrition for the medically supervised dietary management of overweight and obesity. Manufacturers currently provide information on the total diet replacement plan and optional additions in a leaflet that accompanies the products. FSANZ does not consider it necessary or feasible to provide this detailed information on the outer label given it is expected that these products are intended for use under medical supervision. Discussion about labelling requirements for fluid intake are addressed further in this table.
Addition of nutritive substances and novel foods to VLED, and associated claims		
If nutrients outside of the essential composition in S29—22 are added to VLED from S29—20 such as additional vitamins and minerals, it should be mandatory that these are declared.	Nestlé	The proposed drafting required the declaration of any substance listed in the table to section S29—22 that has been used as a nutritive substance in the food. As other nutritive substances in addition to those listed in S29—22 can be added to VLED, FSANZ has amended the draft variation to require the mandatory declaration of any other vitamin, mineral or electrolyte that has been used as a nutritive substance in

Issue	Raised by	FSANZ response
		the food. This aligns with the existing FSMP labelling requirements under Standard 2.9.5. Refer to Section 7 of SD2 for further information.
Concerns regarding addition of non-approved nutritive substances or novel foods to VLED.	New Zealand Food Safety NSW Food Authority	Standard 2.9.5—3(a) allows for FSMP, including VLED, to contain novel or nutritive substances (as defined under Standard 1.1.1) that are not permitted for addition to other food. Where appropriate, FSMP regulations should be flexible enough to accommodate new ingredients or future innovation for the specific disease, disorder or medical condition for which the food has been formulated. This approach is consistent internationally with Codex STAN 203-1995 and EU 2017/1798. Codex STAN 203-1995 states that 'other essential nutrients not specified (within the essential composition) may also be included and under 3.3 'very low energy diets shall be prepared… from other suitable ingredients necessary to achieve the essential composition of the product'. EU 2017/1798 states 'in order to ensure innovation and product development, the voluntary addition to total diet replacement for weight control products of ingredients not covered by specific requirements of this Regulation, with particular attention to dietary fibre, should be possible'. On this matter, FSANZ considered alignment with two safe and suitable standards as appropriate and further considered that the essential composition of VLED is self-limiting due to the discrete energy range and specific nutrient requirements. Further, evidence of known composition risks to public health and safety, occurring domestically or internationally, was not provided to FSANZ to support a change in approach. Finally, amendment of this requirement for VLED would result in inconsistencies within Standard 2.9.5 and anticipated trade barriers.
Do not support unregulated claims. Suggest prohibiting health and nutrition content claims.	Queensland Health Victorian Department of Health and the Victorian Department of Jobs NSW Food Authority New Zealand Food Safety	In response to submitter comments, FSANZ has reconsidered the approach for claims made about VLED. *Health claims* – FSANZ has decided to prohibit the use of health claims in the labelling and advertising of VLED. Under 2.9.5—10(1)(c) VLED will still require a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated. That mandatory statement is not a health claim. *Nutrition content claims* – FSANZ considers these claims can be useful to inform the target consumer and medical professionals as to what has been added to the VLED.

Issue	Raised by	FSANZ response
		Nutrition content claims in the labelling and advertising of foods will therefore be permitted as proposed in the Call for Submissions. See section 8 of SD2 and section 2.3.3.3 of this report for further discussion.
Labelling requirements		
A statement to the effect that VLED are appropriate for the dietary management of obesity should be included on the label.	NSW Food Authority	FSANZ considers the approach proposed in the Call for Submissions to be adequate. A mandatory statement is required indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated, along with the properties or characteristics that make the food appropriate for that purpose. Additionally, the definition of a FSMP means that a VLED must be either represented as being a food for special medical purposes and/or for the dietary management of a disease, disorder or medical condition. Not mandating set wording allows flexibility on labels to aid trade and imports as in some countries public health sectors only refer to obesity and not overweight.
Inclusion of a mandatory statement about adequate daily fluid intake as VLED promote mild ketosis.	NSW Food Authority New Zealand Food Safety	In response to submitter comments, FSANZ has reconsidered this issue and decided to require a mandatory statement about the importance of maintaining an adequate daily fluid intake on the label of VLED. As VLED promote mild ketosis there is an increased risk of dehydration if consumers do not have adequate fluid intake. This requirement is also consistent internationally with the Codex STAN 203-1995 and EU 2017/1798. For further information see Section 10.5 within SD2 and Section 2.3.3.3 of this report.
Inclusion of a mandatory statement to the effect that the product is not recommended for children, pregnant or lactating women, or older adults.	NSW Food Authority New Zealand Food Safety Dietitians Australia	In response to submitter comments, FSANZ has reconsidered this issue and decided to specifically require an advisory statement to the effect that the product is not recommended for pregnant, nursing, lactating women or use by infants, children, adolescents and elderly, other than under medical supervision. FSANZ previously proposed this statement would be adequately covered within the framework of Standard 2.9.5, under 2.9.5—10(1)(b) and (e), which requires the labels of FSMP's to state 'any precautions and contraindications associated with consumption of the food' and 'a statement to the effect that the food is intended for persons within the specified age group'. This amendment therefore aims to assist regulatory clarity. For further information refer to Section 10.4 of SD2.

Issue	Raised by	FSANZ response
Require a statement about the appropriate time period for use of VLED.	New Zealand Food Safety	FSMP are intended to be used under medical supervision. Due to the specialised nature and purpose of these foods, detailed information regarding use is individualised and should be advised by a medical professional. FSANZ notes that VLED do include detailed information leaflets which provide guidance on appropriate use including time periods.
Enforceability issues if products cannot be easily identified as VLED. Consider use of a prescribed name.	New Zealand Food Safety NSW Food Authority Queensland Health	VLED are the only FSMP specific to the dietary management of overweight and obesity. As noted above, VLED will be identifiable through the mandatory labelling required in section 2.9.5—9 (1)(a) and 2.9.5—10(1)(c), which require labelling of a name to indicate the true nature of the food and a statement indicating the medical purpose of the food. Similarly, submitters also commented that there should be a prescribed name for very low energy food. FSANZ does not consider a prescribed name to be needed or appropriate for the products. FSANZ will not require a prescribed name given the existing regulatory measures of Standard 2.9.5, and the potential barriers to trade which a prescribed name may create. As noted above, the Code and Food Act can only regulate individual food products. If a prescribed name was considered it would need to reflect the food, very low energy food, which is not consistent with international requirements under Codex STAN 203-1995 and EU 2017/1798. Further to this, a prescribed name would need to be reflective of products on the ANZ market and internationally, which further presents inconsistencies due to units of energy expression. As the majority of VLED are imported it is anticipated that the requirement of a prescribed name would create further trade barriers and regulatory burden. FSANZ concluded that there are extensive mandatory labelling requirements in place to be able to identify if a product is suitable for use as VLED or not, without the labelling of a prescribed name.
FSANZ received concerns regarding the proposed maximum energy level having more than three significant figures.	Opti-Pharm	The Nutrition Assessment converted the Codex STAN 203-1995 energy range from kilocalories (kcal) to kilojoules (kJ) using the conversation factor of 4.18 listed in Schedule 11. The Codex STAN 203-1995 kJ equivalent is 1881 - 3344 kJ/day. The energy minimum was rounded down to the nearest 5, whereas the energy maximum was rounded up to the nearest 5 to ensure that the Codex STAN 203-1995 energy range was accounted for in the proposed requirement.

Issue	Raised by	FSANZ response
		FSANZ notes that standard 1.2.8—7(3), which requires the use of not more than three significant figures when expressing the average energy content in a nutrition information panel, does not apply to VLED. FSANZ considers it appropriate to retain the maximum energy level of 3345kJ/day.
Unsupervised use		
Insufficient risk mitigation measures are proposed to adequately protect against the risk of unsupervised and inappropriate use of VLED.	New Zealand Food Safety Pharmacare Laboratories	It is FSANZ view that the risk management strategies embedded within Standard 2.9.5 are appropriate and effective. In addition, VLED will also have specific compositional provisions in S29—22 which are complemented by additional labelling requirements to advise on the safe and appropriate use of such food including, where necessary, labelling requirements for use under medical supervision and advice where relevant against inappropriate use. Restrictions relating to access and sale also remain in place. Further discussion on this issue is under section 2.3 of this report.
Concerns regarding difficulties in the enforcement and regulation of online sales of VLED.	Queensland Health Chemist Warehouse	Concerns regarding difficulties with enforcement relating to e-commerce (online sales) of foods is not within the scope of this application, or the remit of FSANZ. FSANZ is also aware that products that are to be used under a medical professional are typically accompanied by an online declaration and/or wavier that outlines this important information to consumers at the point of purchase.
Proposal P242 – Foods for Special Medical Purposes		
Opposition to the acceptance of the application due to omission of VLED from previous Proposal P242, and the justification for regulation, given the longstanding sale and consumption of VLED safely by ANZ consumers.	Chemist Warehouse Opti-Pharm	Details relating to the omission of very low energy diets from Proposal P242 have been addressed above in this table. Applications to develop or vary a food regulatory measure can be made by individuals, a company, or a body representing an industry, consumer or other group. There are no restrictions on who can make an application. All applications are subject to an administrative assessment on receipt to determine whether the application meets the mandatory format and information requirements under Part 3 of the FSANZ Act and the procedure by which it should be assessed. In following the requirements for a general procedure, FSANZ met its statutory requirements, which included a minimum of one public consultation period. FSANZ also

Issue	Raised by	FSANZ response
		undertook targeted consultation with industry, jurisdictional and public health stakeholders. FSANZ has independently assessed the application and determined there is ample justification for regulatory change as a result of Application A1230 – Very Low Energy Diets (VLED). This is supported by the fact that there is currently no applicable food standard for VLED within Australia and that FSANZ had previously agreed to assess and regulate VLED when resourcing allowed. Further, the amendments to the Code will provide regulatory clarity for industry and enforcement, and also reduce barriers to import and export opportunities.
Request for the proposed advertising restrictions developed during Proposal P242 – Foods for Special Medical Purposes (FSMP) to be reintroduced under this application.	Queensland Health Victorian Department of Health and the Victorian Department of Jobs New Zealand Food Safety	As discussed above, FSANZ reconsidered its decision on health claims and has prohibited health claims in the labelling and advertising of VLED, noting the restriction on sale for FSMP also applies to VLED. FSANZ considers that this amendment, in addition to other risk management strategies under 2.9.5, is appropriate.
Placement within the Code		
VLED should be regulated within a new separate standard or within Standard 2.9.3 as it is not appropriate to regulate them as FSMP.	Opti-Pharm Chemist Warehouse	FSANZ considers Standard 2.9.3 to be an inappropriate standard to regulate VLED as the standard specifically excludes foods used as a 'total diet replacement'. Regulating VLED within Standard 2.9.5 as a FSMP is consistent with the intended purpose of the food and the required level of risk management, as well as being consistent with international regulations. Further discussion on this issue is under section 2.3.2.2 of this report.
Nutrient Composition		
Adopt EU 2017/1798 for protein, fibre and linoleic acid minimum.	Bariatric Special Interest Group – Dietitians NZ	While alignment with EU 2017/1798 regulation was not requested in this application, FSANZ did consider this within the Nutritional Adequacy and Safety Assessment (see SD1 for details) when evaluating the most appropriate nutrient composition for the ANZ population. FSANZ is aware that the European Commission has received significant feedback on the ability for manufacturers to comply with the compositional requirements of EU

Issue	Raised by	FSANZ response
		2017/1798 due to the technical feasibility of manufacturing within recommended levels. As such, the European Commission has extended the transition period and also noted that the regulation could be subject to further changes. Concerns from industry on the technical feasibility of the nutrient composition in particular regarded the recommended levels for protein, linoleic acid, α-linoleic acid, choline and the upper level of magnesium. Further, there is significant concern that such a composition cannot be achieved within the restricted energy requirements. With regards to fibre, few of the Member States of the *Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control* requested the addition of dietary fibre on a mandatory basis, however supported allowing the addition on a voluntary basis. As requested in this application and demonstrated in the subsequent assessment, FSANZ considered it appropriate to retain the nutrient composition provided in the Call for Submissions which is consistent with Codex STAN 203-1995. FSANZ also reiterates that the nutrient composition in Codex STAN 203-1995 is more closely aligned with the ANZ NRV's and is the intentional standard that products on the ANZ market have been complying with during the absence of an applicable food standard over the last 20 years. Alignment with the EU Regulation, in part or in its entirety, would in most cases require reformulation of the products currently on the ANZ market and which would incur a considerable cost to industry. FSANZ would also note that there is a greater preference to align with international standards and not jurisdiction regulations.
Adopt EU 2017/1798 carbohydrate minimum.	NSW Food Authority	As noted above, FSANZ does not consider it appropriate to align with the EU 2017/1798 as the regulation could be subject to further change and it imposes significant barriers to industry with regards to technical feasibility. The Codex STAN 203-1995 carbohydrate minimum of 50 g carbohydrate per day was adopted by FSANZ as diets containing 50-70 g of carbohydrate are considered low enough in carbohydrate to produce ketones (i.e. rapid weight loss via ketosis) and this compositional requirement is also in line with what is currently available on the ANZ market, which has a demonstrated safe and effective history of use.
Remove protein quality score of PDCAAS 1.	Manildra Opti-Pharm	FSANZ does not consider removing the requirement for protein to have a PDCAAS score of 1 to be appropriate based on public health grounds and trade implications. FSANZ's primary objective in standards development is to protect public health and safety, which is particularly important for this vulnerable population when undergoing

Issue	Raised by	FSANZ response
		rapid weight loss. The prescribed compositional requirements for both protein quantity and quality ensures that there is not excessive muscle wastage during the rapid weight loss and prevents serious complications occurring from malnutrition. This decision reiterates the stance from the P242 Preliminary FAR and aligns with the approach FSANZ has undertaken within other applications and proposals. This also ensures international alignment, as a PDCAAS score of 1 is required by both Codex STAN 203-1995 and the EU 2017/1798. Further discussion on this issue is within section 3.2. of SD1 and section 2.3.2.3.2 of this report.

2.2 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 the 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. For completeness, the assessment also included evaluation of the EU 2017/1798 as these are another set of international standards regulating VLED. 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. The compositional average of four nutrients, including linoleic acid, α-linolenic acid, zinc and potassium, did not exceed 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 may pose potential risk for inadequacy within ANZ adult males if they are not consuming a variety of VLED. However, further context is provided for each nutrient assessment:

- Linoleic acid and α-linolenic acid were assessed against the ANZ Adequate Intake (AI) which is based on median population intakes, meaning usual intakes around or above this level have a low probability of inadequacy.
- Zinc and potassium were assessed against the ANZ Recommended Dietary Intake (RDI), which is based on the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all healthy individuals. This NRV incorporates generous factors to accommodate variations in diets and typically exceeds actual nutrient requirements.

The nutrients and their associated reference values were considered in the nutritional adequacy assessment relative to the level of certainty and degree of judgement required. In considering this and the acute period of use associated with VLED, it was 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 the majority 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 to public health and safety within the context of the ANZ population. Based on this, the nutrient composition is outlined in Table 2. 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 2: Nutrient composition for very low energy diets

Nutrient	Unit	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.

2.3 Risk management

Regulating VLED within Standard 2.9.5 as a FSMP is consistent with the intended purpose of the food and the required level of risk management, as well as consistent with international regulations. FSANZ considered adoption of the Codex STAN 203-1995 nutrient composition ensured both nutritional adequacy and safety within the ANZ population, while also supporting technical feasibility, and minimisation of any barriers to the supply of these products. The risk management response to matters raised within the nutrition assessment and other varying aspects of VLED are detailed below.

2.3.1 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 into Australia and New Zealand. 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 medical supervision 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 nutrient 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 proposal would be initiated to specifically investigate the most appropriate way to regulate VLED relative to all other formulated foods for weight reduction purposes.

2.3.2 Amendment of Standard 2.9.5 to include VLED

2.3.2.1 Definition

Subsection 1.1.2—5(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 1.1.2—5(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. VLED are:

a) 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 2
    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) intended to be used under medical supervision
c) represented as a FSMP and for the dietary management of overweight and obesity.

However, at present, paragraph 1.1.2—5(2)(a) expressly provides that a VLED is not a FSMP. This reflects the decision to exclude VLED from the P242 FAR which set Code requirements for FSMP.

Given the above rationale, FSANZ considered that very low energy diets are appropriately represented by the definition of FSMP but for paragraph 1.1.2—5(2)(a). FSANZ decided to amend the exclusion in that paragraph so that the exclusion does not apply to VLED but continues to apply to other weight loss type products. This amendment was preferred by submitters over removal of the statement in its entirety to ensure other weight loss type products do not inappropriately reposition as FSMP.

The amendment to the FSMP definition to include *very low energy food* and *very low energy diet* – 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. Separate definitions have been produced for very low energy food and very low energy diet, as the Code regulates food products and not ‘diets’. VLED differ to how other foods are regulated due to their complex nature as a prescribed ‘diet’ and the nutrient composition being based on daily intake instead of intake per serve or per 100 kJ.

Code definitions should not impose an obligation or state a requirement. Compositional standards should only establish compositional requirements and not attempt to define foods or food products. Definitions include only the identifying characteristics of the food and compositional requirements must be stated separately. In 2015, as part of P1025 – Code

Revision - Australian and New Zealand Food Ministers approved this approach and agreed to the removal of substantive requirements from food definitions and restating compositional requirements independently of those definition.

Given this, the definition that captures the diet notes the intended purpose and the definition for very low energy food is further complimented by the details noted in the very low energy diet definition. Creating separate definitions allows the approved draft variation to be fit for purpose and reflect the complex nature of the diet and product.

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

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

2.3.2.2 Required permissions for VLED as FSMP

Submitters commented that VLED should not be regulated under Standard 2.9.5 and that Standard 2.9.3 — Formulated meal replacements and formulated supplementary foods or a new Standard would be more appropriate. FSANZ considers Standard 2.9.3 to be an inappropriate standard to regulate VLED as:

- that standard regulates formulated meal replacements (FMR) and formulated supplementary foods
- the definition of 'formulated meal replacement' in section 1.1.2—3 of the Code specifically excludes from that definition foods, such as VLED, which are formulated to be used as a 'total diet replacement' (TDR), and
- 'formulated supplementary food' is defined as food specifically formulated as, and sold on the basis that it is, *a supplement to a normal diet* for the purposes of addressing specific dietary insufficiencies.

Regulating VLED within Standard 2.9.5 as a FSMP is consistent with the intended purpose of the food and the required level of risk management, as well as consistent with international regulations.

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 TDR in the dietary management of overweight and obesity. As discussed above, 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 TDR. They are also not generally used under medical supervision and do not have conditions of sale restricted by the Code.

Submitters commented that other weight loss products may attempt to reposition as VLED. Based on the comprehensive and mandatory essential VLED nutrient composition, and FSMP requirements that VLED must comply with under Standard 2.9.5, products that are not intended for use in a very low energy diet would be unable to be positioned as such. FSANZ considers the approved draft variation is adequate to ensure clarity and further mitigate the risk of other weight loss products attempting to inappropriately reposition as VLED.

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 considered that regulation of VLED by Standard 2.9.5 will not create any interpretation issues with international stakeholders that would affect trade and exports.

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

2.3.2.3 Nutrient composition

This application sought 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 2.2 of this report and SD1.

2.3.2.3.1 Sole source of nutrition

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.

Submitters commented on the accuracy of VLED being labelled as sole source of nutrition when they are typically consumed alongside optional additions described within the total diet replacement plan. The consumption of VLED with optional additions within a total diet replacement plan does not change FSANZ's conclusions regarding VLED being labelled as sole source of nutrition because:

- very low energy diets provide all essential nutrients at amounts that meet the average needs of the intended population and purpose, and
- optional additions are made available to customise the diet to address individual differences or needs that are not accounted for in the general compositions.

The overseeing medical professional will advise what optional additions are or are not needed. For some individuals - no optional additions will be required to sustain the very low energy diet.

Codex STAN 203-1995 requires VLED to provide a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450-800 kcal which represents the sole source of energy intake. Inclusion of all essential nutrients within the sole source of energy intake is interpreted as sole source of nutrition. The nutrient composition for VLED in the ANZ market reflects this and therefore provides the sole source of nutrition to consumers. Moreover, the sole source of nutrition provided through very low energy diets is medically determined through nutrient requirements to ensure safe rapid weight loss. FSANZ considered the wording 'nutritionally complete' could be used to meet the requirement when labelling whether the product is suitable for use as sole source of nutrition. Submitters

commented on the labelling of individual products ‘suitable for use as sole source of nutrition’ when sole source of nutrition is not achieved through consumption of one very low energy food. This issue is addressed through the requirement that the label must state ‘the recommended daily quantity of all very low energy foods to be consumed’.

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 to return to normal eating and supports weight maintenance following the intensive level total diet replacement plan. VLED’s primary purpose is 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 medical supervision.

2.3.2.3.2 Protein quality

Submitters commented on the requirement for protein in VLED to have a PDCAAS score of 1. Some industry submitters did not support this requirement as a PDCAAS score of 1 can typically only be achieved through animal protein sources. Submitters noted that this is problematic as there is an increasing consumer demand for plant protein. As discussed in Table 1, FSANZ’s primary objective in standards development is to protect public health and safety, which is particularly important for this vulnerable population when undergoing rapid weight loss. The prescribed compositional requirements for both protein quantity and quality ensures that there is not excessive muscle wastage during the rapid weight loss and prevents serious complications occurring from malnutrition (NTPTO 1993, Pi-Sunyer 1994).

FSANZ maintained its approach to include a compositional requirement for protein in VLED to have a PDCAAS score of 1. However, this does not limit innovation or diversity of protein sources. Plant based proteins can be used within the nutrient composition, however addition of amino acids may be needed to meet protein quality requirements. Further evidence, through a separate application seeking pre-market assessment, would be required for FSANZ to consider amending the PDCAAS score requirement as this would oppose two safe and suitable international regulations (Codex STAN 203-1995 and the EU 2017/1798). FSANZ also considered that inconsistency with international standards may create future concerns regarding exports and trade.

2.3.2.3.3 Addition of nutritive substances and novel foods

Standard 2.9.5 permits FSMPs to contain novel foods and nutritive substances (as defined in Standard 1.1.2) as an ingredient or component. Where appropriate, FSMP regulations, including those for VLED, should be flexible enough to accommodate new ingredients for the required composition for the specific disease, disorder or medical condition for which the food has been formulated. This approach is consistent internationally with Codex STAN 203-1995 and EU 2017/1798.

FSANZ has taken into consideration a request from a submitter to require the mandatory declaration of additional nutrients listed in S29-20 when used (outside of the essential composition). The draft variation proposed in the Call for Submissions has been amended to also require declaration of any vitamin, mineral or electrolyte used as a nutritive substance in the VLED, consistent with the approach for FSMP. FSANZ considers this is appropriate as it further ensures information regarding the products nutritional information is provided to medical professionals and consumers. This information also aids medical professional’s clinical guidance and judgement regarding product selection and use.

2.3.2.4 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 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 differing individual needs and requirements are not met, due to increased requirements attributed to size difference, predisposed nutrient deficiencies or other comorbidities this would be monitored and treated under medical supervision. 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 additions 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), a minimum daily intake of two litres of water and the optional addition of two cups of low starch vegetables, one teaspoon of vegetable oil and additional low energy fluids. The additional intakes support adequate intake of essential nutrients such as vitamin K and essential fatty acids, and also dietary fibre. They also aid compliance to the program, consumer's 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 the sale of VLED in line with their intended purpose.

2.3.3 Labelling requirements

FSANZ considered the labelling requirements for VLED in response to the applicant's request to apply specific labelling requirements and specific exemptions for VLED from existing requirements in the Code. Submitter comments in response to the Call for Submissions have also been taken into account. This aspect of the regulation is further assessed and discussed within SD2.

As discussed in Sections 2.3.2.1 and 2.3.2.2 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.

Labelling requirements proposed to apply to VLED during development of P242 – Foods for Special Medical purposes - were also taken into consideration.

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 labelling requirements for packages of VLED; exemptions from the generic labelling requirements within the Code and Standard 2.9.5; and existing requirements that will apply to VLED with variations.

All 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 or food for sale, not across the very low energy diet, however the label for a VLED must also state the recommended daily quantity of all VLED to be consumed in order to constitute a very low energy diet which provides the sole source of nutrition.

2.3.3.1 Labelling requirements for VLED consistent with current FSMP requirements

The following requirements that currently apply to FSMP will apply to VLED for retail sale:

- 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'

[1] Available at Food Regulation - Food policies

- directions for use and storage (with additional requirement – see Section 2.3.3.3 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. Modification of VLED from prescribed compositional limits is not permitted, therefore this requirement will not apply.

FSANZ maintains its position that nutrition content claims in the labelling and advertising of foods will be permitted. FSANZ considered these claims are useful to alert the target consumer and medical professionals as to what has been added to the VLED.

Nutrition content claims also enable VLED suppliers to highlight the presence and levels of energy and nutrients as appropriate to their product, enabling product differentiation, for example, ‘high protein’. The average amount or minimum quantity of any substance about which a nutrition content claim is made will also need to be declared.

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.

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.

The exemption from labelling requirements for FSMP served by institutions such as hospitals in a container such as a plate, cup or tray will also apply to VLED.

2.3.3.2 Variations from current FSMP requirements for VLED

Nutrition information requirements in Standard 2.9.5 will apply 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 the following will be specifically required:

- 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
- declaration of linoleic acid and α-linolenic acid (in addition to the requirement to declare any substances used as a nutritive substance).

Following consideration of a submitter request, FSANZ has amended the draft variation proposed in the Call for Submissions to also require declaration of any vitamin, mineral or electrolyte used as a nutritive substance in the VLED, consistent with the approach for FSMP. Overall, this approach will ensure relevant information is provided to consumers and medical professionals about the composition of VLED, which is important given the very low energy diet is intended to be the sole source of nutrition. The mandatory declaration will also assist with checking against the compositional requirements to assist with enforcement.

2.3.3.3 Additional requirements 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. There will be an additional requirement for the recommended daily quantity of all VLED to be consumed for use as sole source of nutrition, to be declared on the labels of VLED with the quantity to be established by the manufacturer.

Following consideration of submitter comments, FSANZ has decided to amend the approach proposed for health claims and certain mandatory advisory statements, as follows (refer to SD2 for further detail).

To address submitter concerns about unregulated health claims and the marketing and advertising of VLED, and suggestions to take a similar approach to the EU, FSANZ has decided to prohibit health claims. A statement of the medical purpose of the product, which may include reference to dietary management of overweight or obesity, will still need to be declared on the label and such a statement is not regulated as a claim, however health claims, including those that may attract the non-target consumer, will not be permitted. FSANZ considers this approach aligns with the intent of VLED, i.e. a special purpose food formulated for the dietary management of overweight and obesity, to be used under medical supervision.

One submitter suggested rather than permitting broad, unregulated health claims, a specific pre-approved claim is permitted for VLED related solely to its special medical purpose. FSANZ has not permitted a pre-approved claim as suggested, for the reasons outlined above, in particular that VLED must refer to the medical purpose of the food. This does not preclude manufacturers from seeking future permitted representations for such products.

FSANZ has also decided to mandate a statement on the label about the importance of maintaining an adequate daily fluid intake while consuming VLED. FSANZ considers this requirement mitigates risks associated with dehydration and notes that it is also consistent internationally with the Codex STAN 203-1995 and EU 2017/1798.

Additionally, an advisory statement to the effect that the product is not recommended for pregnant, nursing, lactating women or use by infants, children, adolescents and elderly, other than under medical supervision will be required on the labels of VLED. This amendment is a more prescriptive requirement than the general FSMP requirement for a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food, to assist regulatory clarity.

2.3.3.4 Existing labelling requirements in the Code not applying to VLED

The following labelling requirements in the Code do not apply to VLED (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 some labelling requirements (Divisions 1 – 5 of Standard 1.2.1)
- some mandatory warning and advisory statements (Standard 1.2.3)
- nutrition information requirements, other than as indicated in Section 2.3.3.2 above.

2.3.4 Risk management conclusion

Overall, FSANZ concluded that establishing regulation of VLED within Standard 2.9.5, and primarily in alignment with the *CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction* (Codex STAN 203-1995) is appropriate. This was further supported by the existing requirements in the Code, including the intended use under medical supervision, restrictions relating to access and sale, and prohibition of health claims in the labelling and advertising of VLED.

Having considered the submissions and weighed all aspects of the assessment against the statutory requirements including the Ministerial Policy Guidelines, FSANZ approved a draft variation to the Code to permit the use of VLED as FSMP in accordance with the Code.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. Subscribers, interested parties and members of the public were notified about the public consultation period via the FSANZ Notification Circular, a media release, FSANZ's social media tools and Food Standards News.

A public consultation paper called for submissions from 19 November 2021 to 17 December 2021. Thirteen submissions were received.

FSANZ had regard to all submissions received for this application.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.4.2 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.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 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 the Code to permit the use of VLED as FSMP in accordance with the Code. 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 sought to highlight the likely positives and negatives of moving away from the status quo by amending the Code to permit the use of VLED as FSMP in accordance with the Code.

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

consumers to use 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 and exporting VLED. Greater competition between manufacturers may reduce costs and increase availability of VLED for wholesalers and retailers of these products.

Some industry submitters raised concerns about production costs from meeting the PDCAAS score of 1 for protein quality, required under the draft regulatory measure.

FSANZ, however, does not find it appropriate to have a PDCAAS score under 1 for public health reasons. The prescribed protein levels and quality are needed to ensure that muscle mass of individuals consuming VLED is retained and that there is not excessive muscle wastage during the rapid weight loss program. The requirement for a PDCAAS score of 1 also aligns with international standards, so would promote trade and availability of raw materials for VLED manufacturers.

There may be some costs associated with certain products changing labels to meet the prescribed labelling requirements. However, the majority of the labelling requirements are consistent with international regulations, and already being included on the labels of VLED products in the ANZ market.

A three-year transition period will help mitigate any extra production costs from relevant product label changes and in meeting a PDCAAS score of 1. FSANZ would also consider pre-market assessment, via an application, supporting the use of total proteins scoring below 1 in VLED products.

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 of greater and more reliable availability of VLED that would arise from approving the amended draft variation, most likely outweigh the associated costs.

2.5.1.2 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.

2.5.1.3 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. Standard 2.9.6 will cease applying to VLED three years after the approved draft variation is gazetted.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 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 the Code to permit the use of VLED as FSMP in accordance with the Code, in alignment with Codex STAN 203-1995.

2.5.2.2 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 those undertaking medical supervision, to determine whether the FSMP is appropriate and safe for their patients' specific needs.

Existing labelling requirements for FSMP apply to VLED (see sections 2.3.3.1), which would provide information to assist those undertaking medical supervision, and enable informed consumer choice. Additional labelling requirements specifically for VLED will also apply to further ensure consumer understanding and safety (see section 2.3.3.3).

2.5.2.3 The prevention of misleading or deceptive conduct

The prohibition on making health claims will help to prevent consumers from being misled about the nature and appropriate use of VLED.

2.5.3 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 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 approved draft variation to the Code to permit the use of VLED as FSMP in accordance with the Code aligns with Codex STAN 203-1995 and will promote international consistency and harmonisation. Permitting the use of VLED as FSMP in accordance with the Code will also promote consistency on a domestic level.

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

The approved draft variation 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. Adequate information should also be provided, including through labelling and advertising of special purpose foods, to assist consumer understanding of the specific nature of the food, and where appropriate consider the application of controls to restrict access to protect public health and safety.

Additional policy guidance also outlines that relevant standards contained in Part 2.9 of the Code should be consistent with internationally recognised codes of practice, such as Codex, specifically relating to the manufacture and/or labelling of special purpose foods.

Based on our assessment, FSANZ considers that the Policy Guideline has been met.

3 Transitional arrangements

FSANZ has decided 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.

In the Call for Submissions, FSANZ proposed a two year transition period would apply to VLED. FSANZ has reconsidered this period and instead is proposing the approved draft variation will take effect on the date of gazettal, with a three year transition period.

FSANZ reconsidered this period to account for the additional changes made to the regulation post CFS, including mandatory advisory statements and the prohibition of health claims. Increasing the transition period was also suggested by submitters during consultation. FSANZ considers a three year transition period is more appropriate as there is currently no applicable food standard to which VLED can comply with.

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

These transitional arrangements take account of stock-in-trade and have been included within the approved draft variation because the 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 three years after the commencement of any 'alternative applicable provisions elsewhere in this Code'. The Note to that provision explains that (among other things) Standard 2.9.6 will continue to apply to VLEDs until a joint standard is published. Standard 2.9.6 deals with products other than VLED. For that reason, in the interests of clarity, the approved draft variation amends section 2.9.6—3 to provide that a provision of this Standard ceases to have

effect in relation to a VLED 3 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

Nutritional Taskforce on the Prevention and Treatment of Obesity (NTPTO); (1993); *Very Low-Calorie Diets*; JAMA, Vol 270(8): 967-974.

Pi-Sunyer FX (1994); *Obesity* in: Shils ME (ed) Olsen JA (ed) Shike M (ed) (1994), 8th Edition; *Modern Nutrition in Health and Disease;* Lea & Febiger, Philadelphia; p96.

Attachments

A. Approved draft variations to the Australia New Zealand Food Standards Code
B. Explanatory Statement
C. Draft variations to the Australia New Zealand Food Standards Code (Call for Submissions)

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 36 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:

(a) an infant formula product; or
(b) a food specially formulated for the dietary management of overweight and obesity and which is not a *very low energy food.

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*** if it is***"***, substitute:

(a) an infant formula product; or
(b) a food specially formulated for the dietary management of overweight and obesity and which is not a *very low energy food.

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

Insert:

Note 4 In this Code (see section 1.1.2—2):

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 subsection, 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 in order to provide the sole source of nutrition.

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

[2.5] **Subparagraph 2.9.5—10(1)(g)(ii)**

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

[2.6] **Sub-subparagraph 2.9.5—10(1)(g)(ii)(B)**

Omit "appropriate.", substitute "appropriate;"

[2.7] **After paragraph 2.9.5—10(1)(g)**

Add

(h) if the food is a *very low energy food:

(i) a statement to the effect that it is important to maintain adequate daily fluid intake while using the food; and

(ii) 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

(iii) 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.

[2.8] **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) 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), any other substance in respect of which a *nutrition content claim has been made.

[2.9] **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 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(2), 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.

2.9.5—19 Prohibition on health claims in relation to very low energy foods

A *health claim 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)

[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 3 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 Nutritional content requirements for 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
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 – 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) 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 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 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 sunsetting 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 sunsetting 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 sunsetting 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.

Attachment C – Draft variation/s to the Australia New Zealand Food Standards Code (call for submissions)

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

(2) 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]

Column 1	***Column 2***
Nutrient	*Minimum amount per daily intake*
Riboflavin	1.2 mg
Thiamin	0.8 mg
Folic Acid	200 µg
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.