An Application from Nestlé Australia and Nestlé New Zealand to vary Standard 2.9.5 to include Very Low Energy Diet (VLED) products

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Executive summary

An Application from Nestlé Australia Ltd and Nestlé New Zealand Ltd (Applicant) to vary Standard 2.9.5 to include Very Low Energy Diet (VLED) products.

The Application seeks to vary Standard 2.9.5 to include provision for Very Low Energy Diet (also known as Very Low Calorie Diet) products. Very Low Energy Diet) (VLED) products are formulated for the dietary management of overweight and obesity and are developed to be used under medical supervision. They are recommended for individuals who are overweight (Body Mass Index (BMI) 27+) with health conditions, or those who are obese (BMI 30+).

Used under medical supervision, VLED products are a total diet replacement and are used for a prescribed duration, typically 12 weeks. The VLED (total diet replacement) provides 800 kcal (3.35MJ) or less per day, whilst consisting of sufficient protein, fatty acids, carbohydrates, vitamins and minerals for safe and fast weight loss. A daily intake typically consists of 3 serves of VLED products, and a portion of low starch vegetables. Following the initial 12-week period, an ongoing program gradually introduces low calorie meals allowing program participants to transition from a very low energy diet to a more regular dietary pattern.

The Applicant, has been importing VLED products into the Australia New Zealand (ANZ) marketplace for more than 20 years. These products have been manufactured according to the international standard CODEX STAN 203/1995 and are supplied by the Applicant, using a harmonised approach to production, to Australia and New Zealand and a number of other important markets.

VLED products have been in the Australia New Zealand (ANZ) market, without issue, for more than 20 years, however there is no specific standard covering these products in the Australia New Zealand Food Standards Code (Code). VLED products were included in Food Standards Australia New Zealand (FSANZ) Proposal P242, Food for Special Medical Purposes (P242) which commenced in 2000, but were omitted from that Proposal at Final Assessment Report (FAR) in 2012. In the P242FAR, FSANZ committed to commence a project to address VLED products on completion of that Proposal, but this has not eventuated. Meanwhile imported and locally produced VLED products have remained on the ANZ market, but without coverage of an applicable standard.

The Applicant seeks regulatory clarity and certainty through development of an applicable standard to meet the requirements of Very Low Energy Diet products. The regulatory recognition of such products will provide the certainty of a regulated product to consumers, and assurance of the continued trade and availability of VLED products in the ANZ market.

The Applicant notes that products currently in the ANZ marketplace are aligned with the internationally recognised CODEX Standard for Formula Foods for use in Very Low Energy Diets for Weight Reduction (STAN 203-1995) and that as a proven safe and suitable standard, this standard be considered as a model for the proposed variation to Standard 2.9.5.

PART I: Application handbook - CHAPTER 3.1

B. Applicant details

(a) Company: Nestlé Australia Ltd. and Nestlé New Zealand Ltd.

(b) Contact person: [redacted]

(c) Address: [redacted]

(d) Telephone: [redacted]

(e) email: [redacted]

(f) Business type: Manufacturer and marketer of a wide range of consumer food products

(g) Details of other individuals, companies or organisations associated with the application: Not applicable

C. Purpose of the application

The Applicant is seeking a variation of an existing food regulatory measure - Standard 2.9.5 - Foods for Special Medical Purposes (FSMP) to include foods suited for Very Low Energy Diets (VLEDs) also termed Very Low Calorie Diets (VLCDs). This variation is seeking to 'codify' VLED products currently in the marketplace, and in doing so provide regulatory clarity and certainty for these products in the Australia New Zealand market.

This Application will use the term Very Low Energy Diet (VLED), except where part of third-party material, where the term Very Low Calorie Diet (VLCD) may be used.

The Applicant notes that that current VLED products on the market are formulated to meet the CODEX standard. The key objective is to provide market certainty and clarity through codifying the existing products that have served the market well for more than 20 years. Using the CODEX standard as a basis for the variation will facilitate the regulatory process and enable early progress on this matter.

Additional comment on other related standards is included in Section F, Assessment Procedure.

C.1 Amendment to definition Standard 2.9.5.-2(2)

The Applicant notes that Standard 2.9.5 –2 (2)a should be amended to remove the phrase that defines that a product 'which is formulated for the dietary management of obesity or overweight is not a food for special medical purposes'.

C.2 Other related standards

Additional comment on other related standards is included in Section F – Assessment Procedure

C.3 Transitional Standard 2.9.6

The Applicant understands that Standard 2.9.6(3) – Transitional Standard for Special Purpose Foods will cease to apply to VLEDs, once a joint standard applicable to VLEDs is published.

D. Justification for the application

Justification

VLED Products play an important role in management of overweight and obesity

VLED (Very Low Energy Diet) products are formulated for the dietary management of overweight and obesity and are developed to be used under medical supervision. They are recommended for individuals who are obese (BMI 30+) or those who are overweight (BMI 27+) with health conditions.

Under medical supervision, VLED products are a complete diet (total diet replacement) and are used for prescribed duration, typically 12 weeks. When used as a total diet replacement, VLED products provides 800 calories (3.35 MJ) or less per day, and contain sufficient protein, fatty acids, carbohydrates, vitamins and minerals for safe and fast weight loss. A daily intake, to replace 3 meals, typically consists of 3 serves of VLED product, together with a portion of low starch vegetables

Nearly two-thirds of Australian adults are overweight or obese with rates continuing to increase. (Australian Institute of Health and Welfare, July 2020). Obesity is strongly associated with several chronic diseases including type 2 diabetes, cardiovascular disease and some cancers. (Pi-Sunyer, 2009).

Weight loss achieved through calorie restriction using total diet replacements (such as VLEDs) have been shown to safely and effectively help to improve health outcomes in individuals with health conditions such as type 2 diabetes, heart disease and osteoarthritis. Many patients are medically-prescribed VLED products prior to bariatric surgery to improve the safety and success of surgery by reducing liver volume and visceral adipose tissue.

VLEDs are typically accompanied by an online support program, which may include such features as personalised meal and exercise plans, dietitian approved recipes, and connection with healthcare professionals to monitor and supervise suitability of the program and progress for individuals.

In summary, VLEDs play an essential role in the health and safety of Australian and New Zealand publics through clinical management of overweight and obesity. Weight loss though use of VLEDs can have beneficial flow on effects to other serious co-morbidities such as diabetes, and assist in the safety and success of bariatric surgery. Further, VLEDs play a role in managing health and emotional vulnerability of people who have overweight and obesity-related conditions.

VLED products are not yet covered by a joint Australia New Zealand Standard

Very Low Energy Diet (VLED) products have been in the Australia New Zealand market for more than 20 years, however they are not currently regulated as a joint standard in the Australia New Zealand Food Standards Code (Code). The Code does include an applicable transitional standard for New Zealand, Standard 2.9.6, but this is not applicable in Australia.

FSANZ has previously included VLED products in standards development proposals. FSANZ Proposal P49 (curtailed in 1995) and its successor Proposal P242 which was commenced in 2000 included VLED products in scope. The purpose of P242 was to regulate a range of previously unregulated special medical foods, including VLED products. The Final Assessment Report (FAR) of P242 asserted that the lack of regulatory clarity was causing difficulties for FSMP manufacturers, the State and Territory enforcement agencies, DAFF Biosecurity and MAF Biosecurity, New Zealand.

However, VLED products were removed from Proposal P242 scope following a targeted consultation process (2011) immediately prior to Final Assessment, and Standard 2.9.5 (Foods for Special Medical Purposes) finalised in 2012 **specifically excludes** VLED products from its scope. In the P242 FAR, FSANZ undertook to commence a new project to address VLED products on completion of P242. (Refer: Final Assessment Report Proposal P242 – Foods for Special Medical Purposes (May 2012), Section 2.1.1 Exclusion of very low energy diet products from the Standard.)

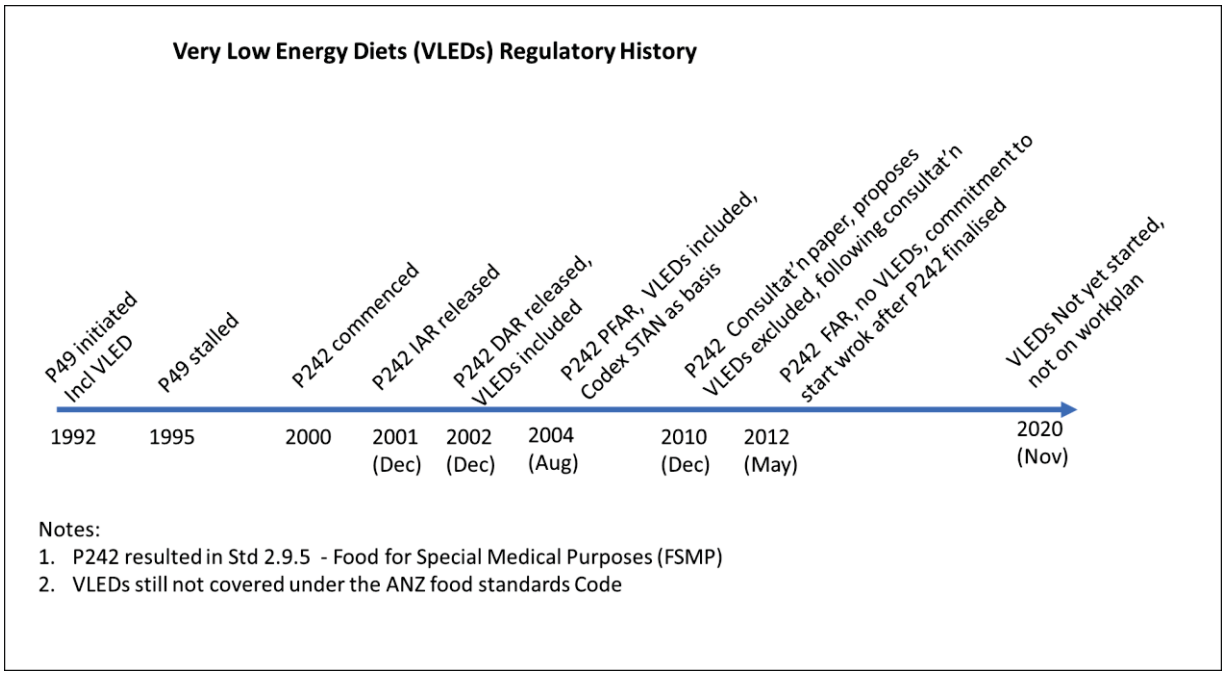

Figure 1: VLED regulatory history - timeline

Work has not progressed on a standard for VLED products and these products remain unregulated. Notwithstanding the absence of a standard, locally produced and imported VLED products remained on the market, and are still on the Australia New Zealand (ANZ) market today. VLED products have always been considered a significant food in the FSMP category, and that is still true today. (Refer Figure 1 VLED regulatory history – timeline).

Formulated meal replacements and formulated supplementary foods are covered by Standard 2.9.3

It is sometimes suggested that VLED products could be regulated under Standard 2.9.3 Formulated Meal Replacements (FMRs). However, FMRs are a significantly different product category and are **not comparable to** VLED products. Specifically:

- Product definition in Std 2.9.3-2 excludes use of FMRs as a total diet replacement.
- FMRs do not fulfil the intended purpose of the dietary management of obesity and overweight conditions
- Compositional requirements (energy, protein, micronutrients) are different, and inadequate as a total diet replacement.
- FMRs are unsuitable as a a total diet replacement and must be labelled accordingly. (Std 2.9.3-4(5).
- FMRs are not generally used under medical supervision.
- FMRs do not have conditions of sale restricted by the Code, as do FSMP (Standard 2.9.5).

Current market place

Currently, the ANZ market is supplied with locally manufactured and imported VLED products, although there is no applicable standard.

The Applicant's imported products are manufactured to a recognised international CODEX Standard STAN 203-1995 for VLED products, and are subject to phytosanitary supervision by European Union (EU) Authorities.

Confusingly, some products in the Australian market carry both FMR and VLED/VLCD descriptors. The definitions and product descriptors in Standards 2.9.3 and 2.9.5 are clear, and it is not possible for product to carry both descriptions, as the definition in the one standard excludes the other. (Under Standard 2.9.3-4 (5) FMRs must carry a statement to the effect that the product must not be used as a total diet replacement). Product carrying both descriptors may be confusing to consumers, and a VLED standard is likely to address that anomaly.

Potential health impact arising from regulatory uncertainty

The Applicant asserts that if its VLED products do not have regulatory certainty, there is some potential for market supply risk. If this risk should crystallise and product availability be compromised, there are likely to be health impacts on VLED consumers as maintaining consistency with the VLED program is important in meeting program objectives and maintaining adequate overall nutrition. This could not only affect weight loss and its subsequent improvements in health outcomes, but also affect the objectives of using a VLED pre-bariatric surgery, which aims to improve the safety and success of the surgery. Secondly, it could lead to weight re-gain and consequent loss of motivation to continue on the program.

Simon et al. suggest obesity is associated with an increase in mood and anxiety disorders (Simon et al., 2006). Rajan and Menon conclude that 'Obesity and depression have a significant and bidirectional association. Evidence is modest for anxiety disorders and inadequate for other psychiatric conditions.' (Rajan T. M., and Menon, V., 2017)

It may follow that where consumers are subject to external changes such as uncertainty or lack of supply of their recommended VLED product, such changes may increase anxiety and stress levels.

In summary, VLED consumers are in a state of significant health and emotional vulnerability which may be exacerbated by the inability to source their preferred product. That is, interruption of product supplies at retail may have consequential effects on the physiological and mental health and safety of VLED consumers.

Competition and consumer choice are facilitated

An orderly marketplace, including regulatory certainty, is essential for maintaining competition and consumer choice.
Development of an applicable standard provides that regulatory certainty, supporting manufacturer commitment to the market, continuity of supply, competition and consumer product choice so important in today's market economy.

Evidence that the food industry generally or other specific companies have an interest in, or support, the proposed change.

There are few manufacturers in the true VLED market and the Applicant is unaware of others' views of the proposed change. However, we believe that an applicable standard that provides clear regulatory status to VLED products should benefit the overall industry.

***Summing up**: The need for the proposed change and the advantages of the proposed change over the status quo*

The proposed changes resulting in VLED products having an 'applicable standard' will have several clear advantages

Regulatory

- The variation of FSC 2.9.5 to assign regulatory status to VLED products is an improvement to the current regulatory status in providing regulatory clarity and status for these products in the Australia New Zealand market.
- Vulnerable consumers, and clinicians will be able to have confidence in the suitability and availability of VLED products.
- Jurisdictions will have clear guidelines for any necessary regulatory intervention.

Health and safety

- Consumers who are overweight or obese will have access to codified nutrition products that will support their clinical journey - contributing positively to their physiological and emotional health and safety outcomes.

Competition and consumer choice

- Overall, consumer choice will be maintained, with the added benefit of VLED products now having regulatory underpinning.
- Clarity of product description may reduce potential confusion for consumers.

International trade

- VLED products are recognised in key international regulations like Codex and European standards. Having regulatory status in the Australian and New Zealand market will help facilitate trade.

D.1 Regulatory impact information

Costs and benefits to consumer, industry, government

Impact on consumers will be favourable. Consumers will benefit from security of product supply and product choice. If the lack of regulatory Standard were to continue, this could potentially lead to market disruption. Additionally, pricing competition in the marketplace will be maintained.

Industry will benefit from the knowledge that there is regulatory clarity from a VLED Standard and certainty in the marketplace. If the variation as proposed is accepted, it is suggested that **few costs will be incurred**, as the variation is well aligned with the formulation and labelling of current VLED products, and CODEX Standard.

It is possible that some product label changes may be required where products are using both Formulated Meal Replacement (FMR) and Very Low Calorie Diet (VLCD) descriptors on packaging. It is suggested that it is currently incorrect to use both descriptors on a package, and the remedy is not a direct result of the proposed standard.

Government will benefit from having a regulatory standard in place that will enable enforcement if necessary.

International trade: Impact on international trade will be **favourable** – as imported product will be able to enter the market provided it meets the relevant standard.

Overall, the regulatory impact is likely to be **favourable**.

E. Information to support the application

E.1 Data requirements

Refer to Part II of this document that addresses matters contained in Chapter 3.6.3 of the FSANZ Application Handbook.

F. Assessment procedure

Assessment procedure – General level 1

The Applicant indicates that the relevant procedure is **general level 1**.

This Application is not complex. Firstly, the international CODEX Standard STAN 203-1995 (CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction) provides a sound basis for regulation, having been through extensive, international pre-market assessment. Further detail is included in Parts II and III of this Application.

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Secondly, there is significant material arising from previous work in FSANZ proposal P242, where VLED products were included up until PFAR. Further comment regarding certain appropriable elements of Proposal P242 is included in Parts II and III of this Application.

Thirdly, the Applicant is not seeking any alignment with the pending EU regulation EU 2017/1798 Total Diet Replacement for Weight Control.

The Applicant notes that the CODEX derived product formulation used in Australia and New Zealand, is harmonised with a significant number of international markets. As the EU regulation is substantially different from the CODEX standard, adoption of EU measures would require reformulation resulting in disruption of the current market in Australia and New Zealand and in other markets using the harmonised formulation.

G. Confidential Commercial Information (CCI)

Confidential commercial information (CCI) is provided to support Section D, as follows:

Appendix 2: Dietary exposure data spreadsheet. The reasons are given in Attachment 4.

H. Other confidential information

Other information for which the Applicant is asserting **Confidential commercial information (CCI)** include:

Nil

I. Exclusive capturable commercial benefit (ECCB)

The outcome of this Application will be regulatory certainty for a class of Food for Special Medical Purposes i.e. Very Low Energy Diet products (VLED products) that has been up until now omitted from the Code. As the standard will apply generally and be available to the national and international food industry, there is no exclusive capturable economic benefit expected or sought. There is no relevant intellectual property.

J. International and other national standards

International and other standards or regulations

- There is a relevant CODEX standard STAN 203 – 1995 (CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction). This has been considered in the recommended compositional and labelling provisions.
- FSANZ Proposal P242 (PFAR and FAR) have been referenced in this Application.
- The Application to vary Standard 2.9.5 to include VLED products is favourable to and consistent with World Trade Organisation (WTO) and Technical Barrier to Trade (TBT) objectives.
- The Applicant is not seeking any alignment with the pending EU regulation EU 2017/1798 Total Diet Replacement for Weight Control. This regulation is substantially different from the CODEX Standard, and adoption of EU measures would require reformulation, itself leading to disruption in the current Australia and New Zealand market and also in a significant number of other important markets using the Applicant's harmonised formulation.

K. Statutory declaration

Statutory declaration made by a senior office of the Company

The Statutory declarations for both Australia and New Zealand are included in a separate file folder associated with this Application.

L. Checklist(s)

Checklist to be filled out and included (Appendix 1 of Application Handbook) – refer to Attachments 1 and 2, page 37-39.

PART II: Application handbook - CHAPTER 3.2.1 and CHAPTER 3.3.3

3.2.1 – Labelling

Labelling requirements relevant to this Application for VLED products are detailed in Part III Chapter 3.3.6, section C.

3.3.3 – Nutritive Substances

There are no additional requirements relevant to Nutritive Substances, that is, the required permissions are already covered in Standard 2.9.5, and Schedule 29. This matter is discussed further in Part III, Chapter 3.6.3, section A3.

PART III Application handbook - Chapter 3.6.3 incorporating Special purpose foods - Standard 2.9.5 - Foods for Special Medical Purposes

A. Information related to general compositional requirements

A.1 Information on the identity and physical and physiological need of the target population

*And **shall include** a description of the physical and physiological need of specific life stages e.g., infancy, physical disease, disorder and disability of the target population; or physical and physiological need of the target population that require altered energy or nutrient intake.*

General description

VLED products are very low energy, low carbohydrate total food replacement products for the dietary management of overweight and obesity. They provide 800 kcal (3.35MJ) or less energy per day, whilst consisting of sufficient protein, fatty acids, carbohydrates, vitamins and minerals for safe and fast weight loss. VLED products are intended for use under medical supervision as part of the dietary management of overweight where BMI is 27+ (where other risk factors are present) and obesity where BMI is 30+.

Overweight and obesity are recognised as being associated with other clinically significant diseases such as insulin sensitivity, diabetes, hypertension, and severe obstructive sleep apnoea. (Delbridge, E. and J. Proietto, 2006; Mustajoki, P. and T. Pekkarinen, 2001.)

Target population

The target population for the Applicant's VLED products is principally males and females who are overweight and obese, aged 18-65, who wish to reduce their weight to improve health conditions. Pregnant, nursing and lactating females, elderly and the otherwise unwell are specifically excluded from the target population.

The Applicant's in-house research shows that:

- VLED users are equally represented by males and females, represented across age groups 18-65 but predominantly aged 30-50, obese to severely obese and motivated to lose weight by a range of concerns such as 'look good-feel good', family focus, and health conditions.
- 'Intensive' (total diet replacement program) users are more likely to be female, in their 40s, severely obese and motivated to lose weight by health concerns.

To facilitate consumer choice and compliance to the VLED weight management program, the market has evolved a range of VLED foods including shakes, soups and bars.

Physical and physiological needs of the target population

Very Low Energy Diets (VLED) have been used for many years to assist with weight management and therefore improve health conditions for people with obesity. They have been proven to be safe and effective for fast weight loss. (Delbridge, E. and J. Proietto, 2006; Mustajoki, P. and T. Pekkarinen, 2001).

The link between obesity and diseases such as type 2 diabetes and coronary heart disease is well researched (Anderson 2003). The need for weight loss and maintenance in people who are

overweight or obese to aid in the prevention or management of obesity-related health conditions is evident.

Weight loss programs for people who are overweight or obese must consider the physical and physiological needs of this target population. These include:

- Support for lifestyle change (eg. Healthcare professional support to provide nutritional education, motivational support and medical monitoring) (NHMRC)
- Increased physical activity (NHMRC 2013)
- Reduced energy (calorie) intake (NHMRC 2013)
- Sufficient protein intake to maintain lean muscle mass (Gibson, A. A. et al., 2016)

VLED formulations contain all essential nutrients to ensure that products can be used as a total diet replacement, and research shows that VLED programs consisting of nutritionally complete products are safe and effective for rapid weight loss for people who are overweight or obese. VLED products are formulated to provide sufficient protein, carbohydrates, fatty acids, vitamins and minerals to ensure safe and rapid weight loss when used as a total diet replacement.

VLEDs are an effective tool to assist in weight loss whilst meeting the physiological requirements for this target population.

International standards

The CODEX standard (STAN 203-1995, CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction) has been developed by international consensus to meet the physiological needs of the target population. For the purposes of harmonisation and trade and reflecting existing products on the market, Codex is the preferred reference standard that will deliver the nutritional, physical and physiological needs of the target population.

A.2 Purpose of the compositional change.

*The application **must** include a brief description of all of the nutritive or health-related function(s) of the substance at the proposed level in the relevant food product(s).*

General

The purpose of the variation is to allow for an applicable standard for VLED products in the Code. Very Low Energy Diets (VLEDs) have been used for many years to assist with weight management and therefore improve health conditions for people with obesity. VLED products provide sufficient protein, carbohydrates, fatty acids, vitamins and minerals to ensure safe and rapid weight loss whilst being used as a total diet replacement, and they have been proven to be safe and effective for rapid weight loss. It is recognised that reducing energy intake to less than 800 kcal (3.35MJ) as well as reducing carbohydrate induces a mild ketosis resulting in body fat / lipid stores being utilised as the major source of energy. Advantages of using VLEDs include the motivating effect of rapid weight loss and a mild ketosis that may suppress hunger.

The Applicant is of the view that Standard 2.9.5 Foods for Special Medical Purposes (FSMP) is the appropriate standard for VLED products. The reasons for the placement in Standard 2.9.5 include:

- Consistency with the FSMP description in Standard 2.9.5. VLED products are specially formulated for the dietary management of the individual with a medical condition.
- VLEDS are formulated as a total diet replacement.

- It is intended that VLED products are to be used under medical supervision (noted on the Applicant's VLED product labels).
- Consistent with Standard 2.9.5, VLED products are retailed through medical practices, pharmacies or similar responsible institutions.

The Applicant notes that: VLED products are distinctly different to Formulated Meal Replacements (FMRs) codified in Standard 2.9.3 of the CODE.

- FMRs are different in their purpose – being, as stated, a meal replacement and not suitable as total diet replacement.
- They are not nutritionally complete and consumption of other foods is recommended.
- They have different compositional criteria along with fewer mandated nutrients than VLED products.
- FMRs are sold as suitable for general use and retail sale is not restricted.

VLED description (source CODEX STAN 203-1995)

CODEX describes VLED products as follows:

> 'A formula food for use in very low energy diets is a food specially prepared to supply 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'.

Compositional requirements

The Applicant notes that products currently in the ANZ marketplace are aligned with the internationally recognised CODEX Standard for Formula Foods for use in Very Low Energy Diets for Weight Reduction (STAN 203-1995) and that this standard be considered as a model for the proposed variation to Standard 2.9.5. As a proven safe and suitable standard, adopting the CODEX standard would facilitate early progress and resolve the current regulatory uncertainty and potential for trade, and consumer health and safety detriments.

Macronutrients

Table 1: Proposed VLED macronutrient compositional criteria – from CODEX STAN 203-1995

Macronutrient	Recommended daily intake	Source	Comment
Energy	1.88-3.35MJ (450-800 kcal)	CODEX (STAN 203-1995)	Also consistent with P242 PFAR (page 39)
Protein	Not less than 50 g protein	CODEX (STAN 203-1995).	Also consistent with P242 PFAR (page 39).
Carbohydrate	Very low energy diets shall provide not less than 50 g of available carbohydrates in the recommended daily intake of energy.	CODEX (STAN 203-1995)	Also consistent with P242 PFAR (page 39)
Linoleic acid	Not less than 3 g of linoleic acid.	CODEX (STAN 203-1995).	Also consistent with P242 PFAR (page 39).

Macronutrient	Recommended daily intake	Source	Comment
Alpha-linolenic acid	Not less than 0.5 g α-linolenic acid in the recommended daily intake with the linoleic acid/α-linolenic acid ratio between 5 and 15.	CODEX (STAN 203-1995)	Also consistent with P242 PFAR (page 39)

Nutritive or health-related function(s) of the substance at the proposed level in the relevant food product(s) – MACRONUTRIENTS

Energy

In order for weight loss to occur, an energy deficit is required. This means that energy intake must be less than energy expenditure over a period of time. VLEDs are based on energy restriction, by providing no more than 800 kcal per day. VLED products providing between 200 and 250 kcal will provide between the specified 450 and 800 kcal over the day, leading to an energy deficit which will result in fast weight loss. Fast weight loss with a VLED has been shown to be an effective intervention for weight management, as outlined in the NHMRC Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults, Adolescents and Children in Australia (2013).

Protein

Adequate protein intake during weight loss is important to help preserve fat free mass and control appetite. (Gibson, A. A., et al., 2016). Evidence suggests that loss of fat free mass during weight loss can be attenuated by diets providing protein intakes of >0.8 g/kg body weight/day. (Gibson, A. A., et al., 2016). Furthermore, protein has been shown to reduce feelings of hunger, which can assist with compliance whilst on an energy restricted diet. A minimum level of 50g of protein per day is required to ensure that adequate protein is consumed to assist in the maintenance of muscle loss.

Protein quality

The Applicant suggests that specifying protein quality is unnecessary for VLEDs for the following reasons:

- There is limited evidence that protein quality is relevant for management of the condition of overweight and obesity. (Refer to Appendix 3 for further information).
- Apart from Infant Formula Products, no other categories are regulated in this way. The Infant formula products Standard regulates protein quality through minimum essential amino acids. It is important to note that Infant Formula Products are the primary source of nutrition for an extended period of time for newborns and infants.
- Not mandating protein quality will enable future Innovation in terms of the diversity of protein sources (e.g. plant based, and other vegan suitable products), to meet evolving market and consumer requirements. The current specification constrains formulating with mainly dairy proteins.

Carbohydrates

Advantages of VLEDs include the motivating effect of rapid weight loss and a mild ketosis that may suppress hunger. (National Health and Medical Research Council, 2013). Weight loss with a VLED is achieved by the restriction of both carbohydrate and total energy intake. A low carbohydrate intake enables the body to use its body fat stores for energy via a metabolic process called ketosis. A diet containing 50-70g of carbohydrate is generally considered low enough in carbohydrates to produce ketones. In addition, ketosis has been suggested to suppress appetite, therefore assisting in compliance whilst on an energy restricted diet. (Gibson, A. A., et al., 2015).

Linoleic acid & Alpha-linolenic acid

Linoleic acid (LA) & alpha-linolenic acid (ALA) are essential fatty acids, meaning that they must be supplied in the diet. They are then converted into polyunsaturated fatty acids in the body, which are essential for maintaining a healthy body, and have been associated with improving cholesterol levels, and therefore lowering the risk of heart disease (NHMRC www.nrv.gov.au, and de Lorgeril, M & Salen, P., 2004).

The World Health Organisation (WHO) has suggested an LA to ALA ratio of between 5:1 and 10:1 due to their competing biological roles. The minimum quantities specified in Table 1 provide an LA to ALA ratio of 6:1, so are within the WHO guidelines (FAO and WHO: Fats and oils in human nutrition, 1994). VLED products must provide the consumer with nutrients such as essential fatty acids to support a healthy body while they lose weight.

Micronutrient composition - minimum values

The Applicant asks that minimum micronutrient values are derived from CODEX standard (STAN 203-1995) for the following reasons:

- This Standard is internationally recognised, having been developed using the CODEX international consensus building process.
- The Applicant's VLED products have been specifically formulated to meet the CODEX standard CODEX (STAN 203-1995), and these products are currently sold in many countries around the world. These markets are provided with harmonised recipes, based on the Codex Standard. The markets and regulators have been satisfied with the current formulation.
- It follows that aligning with the Codex Standard supports continuity of supply and avoids significant disruption and costs that would arise from the need to change product formulations and specifications.
- FSANZ has already completed safety assessments for VLED composition as detailed in the FSANZ Proposal P242 PFAR (2010). Using this existing, peer-reviewed data will facilitate this Application, avoiding a new or revised risk assessment.
- Harmonisation plays an important role in international trade for VLED products. Moving away to a new composition specifically for the ANZ market would be problematic in terms of trade and economics. ANZ is a relatively small volume market, and the costs and logistics of producing a unique product for this market would be prohibitive.

Table 2: Proposed micronutrient levels for food for special medical purposes for Very Low Energy Diet (VLED) products - contains the proposed micronutrient levels expressed per day and per serve, derived from CODEX STAN 203-1995.

The Applicant notes that:

- The CODEX STAN 203-1995 micronutrient values are minimum values.

- They are expressed as a total daily 'ration'.
- The Applicants VLED program requires consumption of 3 serves of product each day for a total diet replacement.
- The micronutrient values have been expressed on a 'per serve' basis by dividing the daily ration by 3 (noting the recommended consumption of 3 VLED products (serves) per day).
- Following the recommended VLED programs will ensure adequate nutrition.

Table 2: Proposed micronutrient levels for food for special medical purposes for Very Low Energy Diet (VLED) products

Table 2 - Proposed micronutrient levels for Very Low Energy Diet (VLED) products			
Nutrient	**Units**	**Minimum daily ration from CODEX STAN 203-1995**	**Minimum requirement per serve (Daily ration/3)**
Vitamins			
Vitamin A	µg retinol equivalents	600	200
Thiamin	mg	0.8	0.3
Riboflavin	mg	1.2	0.4
Niacin	mg niacin equivalents	11	3.7
Vitamin B_6	mg	2	0.7
Folate	µg	200	67
Vitamin B_{12}	µg	1	0.3
Vitamin C	mg	30	10
Vitamin D	µg	2.5	0.8
Vitamin E	alpha-tocopherol equivale	10	3.3
Biotin	µg	No minimum set	No minimum set
Pantothenic Acid	mg	No minimum set	No minimum set
Vitamin K	µg	No minimum set	No minimum set
Minerals			
Calcium	mg	500	167
Magnesium	mg	350	117
Iron	mg	16	5.3
Phosphorus	mg	500	167
Zinc	mg	6	2.0
Manganese	mg	No minimum set	No minimum set
Copper	mg	1.5	0.5
Iodine	µg	140	47
Chromium	µg	No minimum set	No minimum set
Molybdenum	µg	No minimum set	No minimum set
Selenium	µg	No minimum set	No minimum set
Electrolytes			
Sodium	mg	1000	333
Potassium	mg	1600	533
Chloride	mg	No minimum set	No minimum set

Note: VLED programs typically specify 3 VLED products should be consumed as the total dietary requirement during the first or 'intensive' phase.

Nutritive or health-related function(s) of the substance at the proposed level in the relevant food product(s) – MICRONUTRIENTS

Vitamins, minerals and electrolytes as detailed in Table 2 are essential components of dietary intake. As VLED products are used as part of a total diet replacement, it is essential that the products provide the consumer with their daily nutrient requirements to support a healthy body while they lose weight.

The continuing evolution of reference values

Reference values continue to evolve as nutritional science evolves. However, noting that the current products are based on CODEX STAN 203-1995, it could be problematic should new reference values be introduced for a product standard sought by this specific Application, without mitigation of impacts on manufacturers and marketers.

The Applicant is supportive of the ongoing improvement of nutritional goals through managed change in reference values and standards development where this is undertaken in a separate and deliberate process. The Applicant is willing to participate in such a process.

A.3 Information related to the safety of the proposed compositional change

*The application **must** include information related to the safety of a food additive, processing aid, novel food or novel food ingredient, or nutritive substance for the target population (Information to demonstrate safety is also requested elsewhere in Part 3).*

Introduction

Very Low Energy Diets (VLED) have been used for many years to assist with weight management and therefore improve health conditions for people with obesity. They have been proven to be safe and effective for rapid weight loss. (Delbridge, E. and J. Proietto, 2006; Mustajoki, P. and T. Pekkarinen, 2001). Formulations contain all essential nutrients to ensure that VLED products can be used as a total diet replacement, however nutrient compositions will differ dependent on the brand, timing of the research, and country. Nevertheless, research shows that VLEDs which contain all nutrients for a total diet replacement are safe and effective for rapid weight loss for people who are obese.

VLED products provide sufficient protein, carbohydrates, fatty acids, vitamins and minerals to ensure safe and rapid weight loss whilst replacing 3 meals per day.

The Applicant considers that consumption of the VLED products can be 'considered safe and suitable' when used as directed, noting that the recommended 'use under the supervision of a health care professional' provides an additional level of safety and risk management.

Safety – macronutrient-composition

The proposed macronutrient composition is based on CODEX STAN 203-1995. This Standard has been pre-market assessed to be safe, and products based on that standard have been on the market for many years with no evidence of market failure or safety concerns. The Applicant considers the CODEX STAN 203-1995 to reflect satisfying the Application requirement for information relating to safety, in relation to all the ingredients (used for nutritional purpose), used in a VLED product.

Average daily energy content provided by 3 VLED products on a total diet replacement program is 2.66 MJ, with 63 g of protein, 56 g of carbohydrate, 3.6 g of linoleic acid, 0.58 g of alpha linolenic acid and a linoleic/alpha-linolenic ratio of 6.2, meeting the proposed regulatory requirements.

Nutritive substance and micronutrient source permissions

Permissions for nutritive substances, micronutrients, processing aids, food additives and their permitted forms to be used in VLED products are covered by existing permissions in the horizontal chapters of the Code plus those permitted by Standard 2.9.5 of the Code. These substances have already been pre-market assessed as safe by FSANZ. The Applicant is not seeking any addition or variation to the Code in this regard. The Applicant considers the existing permissions to satisfy the Application requirement for information relating to safety, in relation to all nutritive substance and micronutrient source permissions.

Safety – micronutrient minimum and maximum values

The safety and suitability of micronutrient composition (profile and levels) is covered in detail in section B2. The assessment indicates that the VLED products align well with the proposed VLED regulatory requirements.

The Applicant notes that the proposed composition including macro and micronutrients is aligned with the **pre-market assessed**, internationally recognised CODEX Standard that has been in general consumption across many countries without any systemic concerns regarding its safety or suitability. The Applicant considers the alignment with existing reference values to satisfy the Application requirement for information relating to safety, in relation to all micronutrients.

A.4 Information related to the nutritional impact or performance impact of the proposed compositional change

This demonstrates how the compositional change would contribute to achieving the intended purpose of the special purpose food.

*The application **must** include clinical studies that examine the nutritional suitability of the food, for the target population.*

The role of VLEDs in management of overweight and obesity

Very Low Energy Diets (VLEDs) have become widely recognised consumer products. They are characterised by their low energy content (450- 800 kCal or 1.88-3.35 MJ per day), low carbohydrate (but not less than 50g per day), a prescribed minimum protein content (at least 50g per day) together with an extensive range of micronutrients to maintain health. VLEDs are formulated as a total diet replacement to be used under supervision of a recognised healthcare professional.

Reducing energy intake to less than 800 kcal (3.35MJ) is designed to incur an energy deficit, and together with reducing carbohydrate intake induces a mild ketosis resulting in body fat / lipid stores being utilised as the major source of energy. Advantages of VLEDs include the motivating effect of rapid weight loss and a mild ketosis that may suppress hunger. (Delbridge and Proietto, 2006). They have also been associated with improvements in insulin sensitivity, blood pressure, serum triglycerides, sleep apnoea and glycaemic control in adults with Type 2 diabetes. (Mustajoki, P. and T. Pekkarinen, 2001).

VLEDs are intended for use as part of the management of overweight and obesity, particularly when there is an associated secondary pathology e.g. type 2 diabetes, hypertension, osteoarthritis, gynaecological disorders, dyslipidaemia, where obesity is an impediment to surgery or where more conservative approaches to weight loss have been unsuccessful.

NHMRC recognises Very Low Energy Diets as one of a number of intensive interventions, as the following extract from NHMRC publication discusses. (NHMRC Clinical Practice Guidelines for the Management of overweight and obesity in adults, adolescents and children in Australia, 2013, *(Sec 6 and 6.2.1))*.

> *'More intensive weight management interventions—such as very low-energy diets, weight loss medication and bariatric surgery may need to be considered as adjuncts to lifestyle approaches, especially when a person is obese and/or has risk factors or comorbidities, or has been unsuccessful reducing weight using lifestyle approaches. The decision to use intensive weight loss interventions is made based on the individual situation.*
> *Advantages of very low-energy diets include the motivating effect of rapid weight loss and a mild ketosis that may suppress hunger (Delbridge & Proietto 2006). Very low-energy diets have been associated with weight loss (Nield et al. 2007; Norris et al. 2005b; Tuomilehto et al. 2009), improvements in sleep apnoea (Tuomilehto et al. 2009) and improved glycaemic control in adults with type 2 diabetes (Nield et al. 2007; Norris et al. 2005b). They are commonly used in medically supervised weight reduction programs for people with BMI > 30 kg/m2 (or > 27 kg/m2 with obesity related comorbidities), or for whom rapid weight loss is necessary (Sumithran & Proietto 2008).'*

Weight loss
Very Low Energy Diets have been shown to be very effective in the management of obesity, with weight losses averaging approximately 1.0-2.5kg per week, providing greater initial weight loss than other forms of calorie restriction. (Delbridge, E. and Proietto, J., 2006; Mustajoki, P. and T. Pekkarinen 2001.) They are commonly used in medically supervised weight reduction programs for people with BMI >30kg/m2 (or >27kg/m2 with obesity-related co-morbidities), or for whom rapid weight loss is necessary. (NHMRC, 2013). Sustained weight loss requires a balanced and disciplined approach to diet and nutrition, exercise and lifestyle. That is, VLEDs cannot be expected to be a complete solution on their own.

Long-term weight loss
Reports on long-term weight loss maintenance over a 1–2-year period have been variable. A 2013 review supports the evidence that weight loss over 1-2 years averages 0-14kg and that success is more likely when behavioural or drug therapy was used in follow up. (Asher, R.C.Z., T.L. Burrows, and C.E. Collins, 2013.) This review also highlights that lean body mass was not compromised by VLED use with a 2 year follow up.

Contrary to popular belief, rapid weight loss has been shown to lead to greater weight loss in the long-term, even taking into account weight regain post diet. Post hoc analyses of weight loss intervention studies show that a greater initial weight loss, usually achieved in the first 2-4 weeks of commencing the program, is associated with a better long-term outcome, i.e., a sustained weight loss 1-5 years later (see Table 3 below). (Delbridge, E. and Proietto, J., 2006).

Table 3: VLED vs Non-VLED weight losses - initial and long term
(Delbridge, E. and Proietto, J., 2006).

	End of Program Weight Loss	Weight Loss at 1-2 Years
VLED	9.2-19.3kg	7.2-12.9kg
Non-VLED	6.2-14.3kg	5.7-9.5kg

A trial conducted by Purcell et al. randomised 200 participants to either a 36-week gradual weight loss group or a 12-week rapid loss group using a VLED. Participants that lost 12.5% of their initial weight loss from both groups were then placed onto a 144-week weight maintenance group. It was found that the amount of weight regain was similar in both groups. The author's conclusion was that the rate of weight loss does not affect the proportion of weight regained within 144 weeks. (Purcell, K., et al, 2014.)

The role of VLEDs in other health outcomes

Health outcomes and metabolic indicators
A systematic review of the impact of obesity and weight gain on diabetes risk and coronary heart disease (CHD) has shown that obesity and weight gain can increase diabetes risk by greater than ninetyfold and CHD by sixfold. (Anderson, J.W, 2003).

In conjunction with weight loss, energy restriction has also been found to improve a wide range of health-related outcomes and metabolic indicators such as improvements in insulin sensitivity, decrease fasting plasma glucose, lowering of blood pressure and lowering of serum triglyceride values. (Mustajoki, P. and T. Pekkarinen, 2001; Anderson, J.W, et al., 2003; Drawert, S. et al., 1996). VLEDs may be considered in the management of overweight and obesity in patients presenting with co-morbidities.

Table 4: Metabolic outcomes after energy restriction**
(Anderson, J.W, et al., 2003)

Risk Factors	% Change from Baseline
Plasma glucose	25.7% ↓
Serum cholesterol	9.2% ↓
Serum triglyceride	26.7% ↓
Systolic Blood Pressure	8.1% ↓
Diastolic Blood Pressure	8.6% ↓

** Larger weight losses were associated with larger reductions in these values. Energy restriction was achieved through VLEDs and Low Energy Diets.

Weight loss with use of VLEDs has also shown to benefit symptom control in patients with osteoarthritis and improve obstructive sleep apnoea in 80% of cases. (Johansson, K., et al, 2009; Riecke, B.F., et al, 2010).

Table 4 summarises some of the effects of weight loss with energy restriction on metabolic outcomes. VLEDs may be considered in the management of people who are overweight and obese presenting with co-morbidities.

Benefits of pre-surgical weight loss

Preoperative weight loss is generally recommended to optimise the safety of surgery in patients who are obese. (Pekkarinen, T. and P. Mustajoki, 1997). Most studies have shown weight loss prior to bariatric surgery decreases operating time complications, blood loss during surgery and post-surgery hospital stays. (Alami, R.S., et al, 2007; Tarnoff, M. et al, 2008)

VLEDs have often been prescribed pre-surgery when rapid weight loss is indicated and to assist in reducing liver volume. A reduction in liver volume improves abdominal access for the surgeon and reduces the risk of conversion from laparoscopic to an open procedure. (Colles, S. et al. 2006.)

Some of the complexities of bariatric surgery may be overcome with weight reduction prior to surgery. Pre-surgical weight loss may be recommended to all patients with morbid obesity (BMI ≥40kg/m2) and for individuals with a BMI >35kg/m2 as they can often suffer from fatty liver, poor blood glucose level control and sleep apnoea. (Pekkarinen, T. and P. Mustajoki, 1997).

The following points highlight the benefits of pre-surgical weight loss.

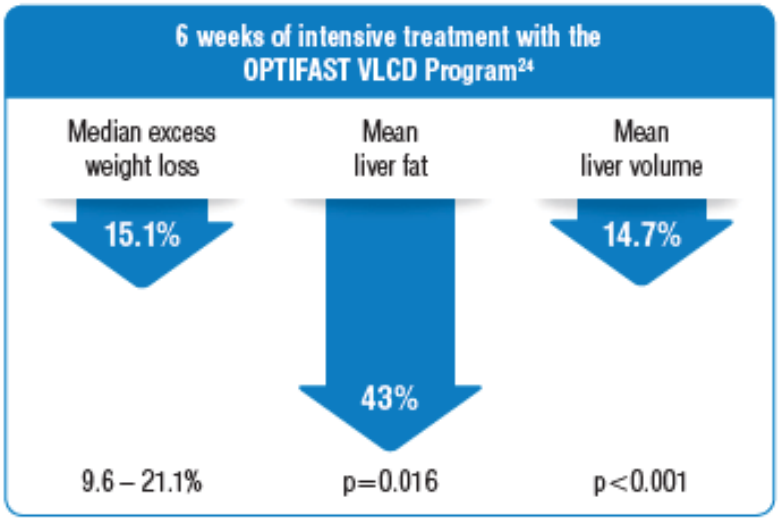
Reduced visceral fat levels and liver size

Weight loss prior to bariatric surgery can effectively reduce visceral fat levels and liver size, leading to greater access for the surgeon and less chance of conversion from laparoscopic to open procedure. Australian researchers have shown that hepatomegaly or excessive visceral fat are the most common reasons for conversion from laparoscopic to open surgical procedures. (O'Brien, P.E., et al 2002).

Following are two studies that demonstrate the effectiveness of the OPTIFAST VLCD Program in patients prior to bariatric surgery.

Study 1: 18 morbidly-obese patients underwent MRI and spectroscopy to measure liver size and fat content before and after 6 weeks of intensive treatment with the OPTIFAST VLCD Program. (Lewis et al., 2006). Significant results were achieved in the reduction of liver fat and volume, as seen in Figure 2 below.

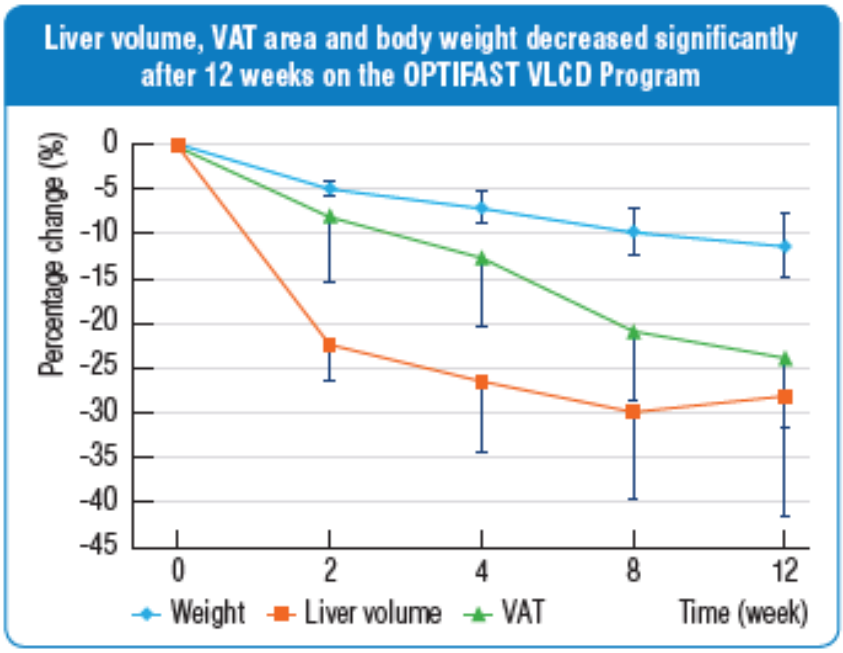
Figure 2: Results (weight loss, liver markers) of 6 weeks Intensive Level Optifast VLCD program. (Lewis et al., 2006)



'The reduction in liver fat and volume likely accounts for the perceived improved operability in patients undergoing LAGB. (Lewis et al., 2006).

Study 2: 32 morbidly-obese patients followed the OPTIFAST VLCD Program for 12 weeks with measurements including changes in liver volume and visceral/subcutaneous adipose tissue (VAT/SAT) taken at baseline and weeks 2, 4, 8 and 12. The most significant improvement in liver volume is seen after 2 weeks, as can be seen in Figure 3 below. A 6-week duration of the OPTIFAST VLCD Program was recommended to achieve maximal liver volume reduction. (Colles at al., 2006).

Figure 3: Results (weight loss, liver markers) of 6 weeks Intensive Level Optifast VLED program. Adapted from Colles, S. et al. 20



p≤0.001 for all three measures at week 12 vs. baseline.

Continuing research

Research into VLEDs continues. A recent paper (Brown, A. and Leeds, A.R., 2019) observes:

> *'The use of formula VLEDs and LEDs (Low Energy Diets) has been shown to effectively produce clinically significant weight loss of between 10% and 15% bodyweight for up to 12 months, and when combined with weight loss maintenance strategies can aid long-term weight maintenance for up to 4 years. Evidence has also grown for their effective use in obesity-related comorbidities, particularly OSA (obstructive sleep apnoea) and OA (osteoarthritis). Recent data showing that T2D (type 2 diabetes) can be put into remission using a formula LED in up to 46% of people may well change the landscape of T2D treatment in the coming few years*.'

Summary

There is strong body of evidence that VLEDs are considered to be an effective component in management of severe overweight and obesity. There is also significant evidence that co-morbidities such as type 2 diabetes, obstructive sleep apnoea and hypertension are often seen to improve with sustained loss in weight, and that VLEDs can play a vital role in achieving weight management goals.

VLEDs can also contribute to risk reduction for surgical procedures, by using them in preparation for bariatric surgery or other surgeries where obesity complications are present.

There is recognition and support from Australian clinicians for the role of VLEDs in addressing overweight and obesity – that is, the research findings are being 'backed-up' by real-world practise and experience, all pointing to the conclusion that VLEDs are a legitimate, effective and appropriate element of weight management programs and also where pre-surgery risk reduction is indicated.

B. Information related to the dietary intake or dietary exposure

B.1 Data on the recommended level of consumption of the special purpose food for the target population

Information relating to the recommended number of serves per day and the size of each recommended serve should be provided for relevant special purpose foods for the target population

VLED program overview

The Applicant's VLED program, intended for use as a total diet replacement (replacing normal food intake), is a flexible approach to managing overweight and obesity. The Applicant has a variety of VLED/VLCD products including shakes, soups, desserts and bars from which participants can choose.

Participants are advised that whilst on the program, it is important to each day take an additional 2 litres of calorie-free fluids, preferably water plus at least 2 cups of low starch vegetables. Regular exercise is encouraged to enhance well-being and likelihood of weight loss success.

The program is structured into 4 levels: 3 levels for active weight loss, and 1 level for weight maintenance. The first phase (Intensive Level) of the very low energy diet program uses 3 VLED products as a total diet replacement each day and achieves the fastest rate of weight loss, after which the rest of the program can be followed, replacing 1 or 2 VLED products each day with a low-calorie meal(s) for graduated weight loss.

This approach is designed to transition program participants, over the short term, from a very low energy diet to a more typical dietary pattern. These stages continue under the guidance of a health care professional. (Refer Table 5: Example VLED weight management program).

Once the desired weight loss is achieved, the participant can move onto the Maintenance Level where no VLED products are used and a nutritionally balanced calorie-controlled meal plan is followed.

The VLED weight loss program

Table 5: Example VLED weight management program

Intensive Level (daily intake)	Active 2 Level (daily intake)	Active 1 Level (daily intake)	Maintenance Level (daily intake)
VLED 1	VLED 1	VLED 1	Low calorie meal 1
VLED 2	VLED 2	Low calorie meal 1	Low calorie meal 2
VLED 3	Low calorie meal 1	Low calorie meal 2	Low calorie meal 3
2 cups of low carbohydrate vegetables	2 cups of low carbohydrate vegetables	2 cups of low carbohydrate vegetables	2 cups of low carbohydrate vegetables
2 litres of water	2 litres of water	2 litres of water	2 litres of water
1 teaspoon vegetable oil (recommended)	1 serve of dairy	1 serve of dairy	1 serve of dairy
	1 serve of fruit	2 serves of fruit	2 serves of fruit

Note: i) The Intensive level can be followed for up to 12 weeks, or at the discretion of the healthcare professional.
ii) Active 2 and Active 1 are typically of shorter duration, guided by the healthcare professional.
ii) Each VLED product can be chosen from the range of shakes, soups, desserts and bars, in a range of flavours.
iii) The gradual introduction of low calorie meals supports program participants to transition from a very low energy diet to a more regular dietary pattern.

Intensive Level: Program participants generally start at the Intensive Level to achieve early, rapid weight loss. At the Intensive Level, the very low energy diet program uses 3 VLED products as a total diet replacement, together with 2 cups of low carbohydrate vegetables and a teaspoon of vegetable oil (recommended) each day. The addition of vegetables assists in providing fibre and can also assist in the social aspects of eating.

Generally, an individual can stay on the Intensive Level for up to 12 weeks, however this period is variable and depends on weight loss goals and their response to the VLED program. Participants may continue on the Intensive Level for longer than the 12 weeks at the discretion of their healthcare professional who will monitor and supervise during this period. The total calorie intake during this level is less than 800 kcal (3.35MJ) per day.

Sample meal plan

Sample meal plans are offered to assist program participants. An example of a sample meal plan is included in Figure 5**:** VLCD Sample Meal Plan for the Intensive Level.

Figure 4: VLCD Sample Meal Plan for the Intensive Level
(Source: Applicant's internal document)[1]

Meals	Sample Meal Plan 1	Sample Meal Plan 2	Sample Meal Plan 3
Breakfast	1 OPTIFAST VLCD Shake	1 OPTIFAST VLCD Shake	1 OPTIFAST VLCD ProteinPlus Shake
Morning Tea	½ OPTIFAST VLCD Bar Tea/coffee (either black or with up to 30mL of skim milk and no sugar)	Tea/coffee (either black or with up to 30mL of skim milk and no sugar)	Tea/coffee (either black or with up to 30mL of skim milk and no sugar)
Lunch	1 OPTIFAST VLCD Soup	1 OPTIFAST VLCD Shake	1 OPTIFAST VLCD Bar
Afternoon Tea	½ OPTIFAST VLCD Bar Tea/coffee (either black or with up to 30mL of skim milk and no sugar)	Vegetable sticks	1 cup of low starch vegetables
Dinner	2 cups of low starch salad or vegetables with 1 tsp of vegetable oil and other allowed condiments	2 cups of low starch salad or vegetables with 1 tsp of vegetable oil and other allowed condiments	1 OPTIFAST VLCD Soup plus 1 cup of low starch vegetables with 1 tsp of vegetable oil
Supper	Herbal tea 125mL of diet jelly	1 OPTIFAST VLCD Dessert	Herbal tea
Total Nutrient Intake	753 calories 64.2g protein 68.5g carbohydrate	744 calories 65g protein 65g carbohydrate	793 calories 73g protein 66g carbohydrate

Key points advised to participants/clients for the Intensive Level of the VLCD Program:

1. Importance of following the Intensive Level exactly as prescribed in order to achieve mild ketosis. This is associated with control of appetite and burning of fat stores.
2. The use of all 3 VLED products, plus at least 2 cups of low starch vegetables and additional fluids, each day.
3. Addition of a small amount of lipid each day (e.g. 1 teaspoon vegetable oil on salad or vegetables) to maintain gall bladder function.
4. The need for active supervision by a healthcare professional during the Intensive Level and supervised progression on to Active 2 and Active 1 Levels to achieve long-term weight loss and Maintenance.

Active 2 Level: The Active 2 Level follows the Intensive Level**.** During the Active 2 Level, one VLED product is replaced with the re-introduction of one low-calorie meal of approximately 350 kcal (1.47MJ). This ensures a gradual and controlled re-introduction to a regular diet. Two cups of low

[1] This sample mean plan can also be found at web location: *Sample Meal Plan – Optifast*

starch vegetables and 2 litres of water are continued, and 1 serve of fruit (around 70 kcal) and 1 serve of dairy (around 100 kcal) are introduced. The Active 2 level provides approximately 1000 kcal (4.19 MJ) per day.

Active 1 Level: The Active 1 Level follows the Active 2 Level. During the Active 1 Level one further VLED product is replaced with another low-calorie meal and a second serve of fruit is introduced. The additional vegetables, water, and dairy are followed, as with Active 2 Level. The Active 1 level provides approximately 1200 kcal (5.02MJ) per day.

Maintenance Level: The Maintenance Level is the last stage, where all VLED products are eliminated. It is designed to help maintain a long-term focus on maintaining weight loss. At Maintenance Level the daily dietary intake consists of three low-calorie meals (approximately 350 kcal (1.47MJ) each), two serves of fruit and one serve of dairy, plus low starch vegetables and water. The nutrition component of the Maintenance Level requires ongoing monitoring for meal plan adjustments and education to ensure long-term weight management. The Maintenance level provides approximately 1500 kcal (6.28 MJ) per day.

B.2 Data to enable the dietary exposure of the target population to be estimated

Estimated daily intake for dietary exposure assessment – Intensive Level

The average daily intake of key macronutrients and micronutrients was calculated using the number (quantity) of each VLED products indicated on the 3-day sample meal plan (Figure 5), multiplied by the declared nutrient values for each VLED product. The 3-day totals (i.e. 9 VLED products) for each nutrient were divided by 3 to get a daily-average-ration for each nutrient.

The Intensive Level was used as it utilises the most VLED products and provides the greatest dietary exposure. Table 6 - Daily nutrient intake averaged over 3 days of following sample meal planner (declared values)) sets out the average daily calculated intake of a wide range of macro and micro nutrients using the Applicant's recommended VLED program. The nutrient intake is listed (compared) with

i) Proposed macronutrient recommendations. (Refer Table 1).
ii) Proposed minimum regulatory levels for micronutrients. (Refer Table 2).

Notes:

- Table 6 does not include nutrition intake arising from the recommended 2 cups of 'low starch' vegetables.
- There is an e-version of the spreadsheet used to calculate nutrient intake presented in Table 6 accompanying this Application (refer Appendix 2).
- **Confidential commercial information** (CCI) status is claimed for this data. (Refer Attachment 4).

Discussion nutrient intake – dietary exposure:

Table 6) shows the daily nutrient intake at the Intensive Level of the VLED program, averaged over the 3-day meal planner. The VLED diet provides a comprehensive range of macro and micronutrient intakes well aligned with the proposed regulatory values.

Average daily energy content for the Intensive Level program is 2.66 MJ, with daily intakes of 63g of protein, 56g of carbohydrate, 3.6 g of linoleic acid, 0.58 g of linolenic acid and a linoleic/alpha linolenic ratio of 6.2. These values are within the proposed CODEX parameters.

Table 6: Daily nutrient intake averaged over 3 days of following sample meal planner (declared values)

Table 6 - Daily nutrient intake averaged over 3 days of following sample meal planner (declared values)			
VLED NUTRITION INFORMATION	Units	Daily nutrient intake averaged over 3 days (from meal planner)	Macronutrient and minimum micronutrient values from CODEX STAN 203-1995
Energy	kJ	2663	1880-3350
	kcal	637	450-800
Protein	g	63	not less than 50
Fat, total	g	16	
- Saturated	g	4.5	
- Linoleic acid	g	3.6	not less than 3
- α-Linolenic acid	mg	584	not less than 500
Carbohydrate	g	56	not less than 50
- Sugars	g	24	
- Lactose	g	18	
Dietary Fibre	g	12	
Sodium	mg	1263	1000
Vitamin A	µg RE	1021	600
Thiamin (B1)	mg	1.7	0.8
Riboflavin (B2)	mg	2.3	1.2
Niacin	mg NE	29	11
Pantothenic Acid	mg	8.1	
Vitamin B6	mg	3.0	2
Biotin	µg	47	
Folic Acid	µg	344	200
Vitamin B12	µg	3.6	1
Vitamin C	mg	119	30
Vitamin D	µg	10	2.5
Vitamin E	mg TE	21	10
Vitamin K	µg	96	
Calcium	mg	1303	500
Chromium	µg	34	
Copper	mg	2.9	1.5
Fluoride	µg	684	
Iodine	µg	270	140
Iron	mg	23	16
Magnesium	mg	462	350
Manganese	mg	2.7	
Molybdenum	µg	47	
Phosphorus	mg	1144	500
Selenium	µg	106	
Zinc	mg	13	6
Potassium	mg	2705	1600
Chloride	mg	1067	

Vitamin and mineral intakes will adequately meet the CODEX based minimum daily requirements for CODEX listed micronutrients, as proposed.

Overall, consumption of the VLED products can be 'considered safe and suitable' when used as directed, noting the recommendation that program participation is under the supervision of a health care professional.

Further detail can be found in Appendix 2: Dietary Exposure Spreadsheet- (Commercial in confidence).

C. Information related to labelling requirements under Part 2.9 of the Code

The application **must** contain the following information if it relates to a change to labelling requirements:

General Changes to Standard 2.9.5

Amendment to definition Standard 2.9.5.-2(2)

The Applicant notes that Standard 2.9.5 –2 (2)a should be amended to remove the phrase that defines that a product 'which is formulated for the dietary management of obesity or overweight is not a food for special medical purposes'

Division 3 Composition Clause 2.9.5

The following should **not** apply:

Division 3 Composition Clause 2.9.5 – 7 Compositional requirements for food represented as being suitable for use as sole source of nutrition.

The proposed amended requirements are suggested in Part III A of this Application.

C.1 Information related to safety or nutritional impact of the proposed labelling change

This includes information to support the proposed labelling change e.g. the inclusion of (or change to) a warning or advisory statement, directions for use, or claim conditions.

The Applicant recognises the importance of labelling and the expected requirement to Include clauses within FSC 2.9.5 specifically for VLED products, noting:

1. The applicability of Standard 2.9.5 - Section 3(b)

and the following:

2. A statement to the effect that a VLED is a nutritionally complete formula presented for use in energy restricted diets for the dietary management of obesity
3. Division 4 Labelling, Section 8 and Section 9 - no change
4. Division 4, Labelling, Section 10 Mandatory statements and declarations sets out labelling requirements for FSMP. These general requirements are applicable to VLED products. The

Applicant supports continuation of these requirements, with the exception of 2.9.5-10 (1)(f) & (g) as these subclauses are not relevant to VLED products.

5. Division 4 Labelling: Additional, specific **labelling** for VLED products **should** apply. These should include the following advisory statements:
    a. A statement to the effect that the product is for the dietary management of obesity (non-prescribed wording);
    b. Reference to the importance of maintaining an adequate daily fluid intake;
    c. A statement that the product may not be suitable for use by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except where medically indicated; and
    d. A statement on the recommended daily quantity of the product to be consumed, with the quantity to be established by the manufacturer.

The suggestions above (5a-5d) are consistent with the recommendations contained in the PFAR of proposal P242 and the Applicant is supportive of those recommendations. The Applicant notes continued support for recommendation 5d, which was omitted from PFAR P242, as it provides important information to VLED consumers.

- The Applicant notes that suggestions 2 and 5(a)- (d) are more specific than the general requirements set out in Section 10 (1) b-f, but believes that the additional detail is relevant and helpful to consumers, and addresses some concerns raised during Proposal P242, such as the inappropriate consumption of VLEDS by non-target consumers. Labelling can play a role in addressing that risk.

Adequacy of consideration of labelling

The Applicant notes that FSANZ gives wide-ranging consideration to proposed labelling changes and specifically notes the comprehensive consideration and pre-market assessment of labelling requirements as set out in P242 PFAR and FAR for Foods for Special Medical Purposes and in particular VLED products.

C.2 Information to demonstrate that the proposed labelling change will be understood and will assist consumers, if applicable

This includes consumer research information to demonstrate the anticipated consumer response to the proposed change, or data obtained from an overseas market where the proposed labelling is in place.

For example, information to demonstrate how the proposed label change will assist consumer understanding of the specific nature of the food, the intended population group or the intended special purpose of the food

Labelling proposed is consistent with current long-standing national and international practice

The Applicant has not undertaken specific consumer research data on labelling of VLED products, however the Applicant considers these proposed additional labelling elements were pre-market assessed by FSANZ in P242. Notwithstanding the absence of a Standard, VLED products in the marketplace have generally been aligned with these requirements.

The Applicant also notes that the suggested labelling requirements are consistent with international norms such as those that already apply in the and US markets, and have done so in these markets for many years. There has been no change to VLED specific labelling requirements in this time, reflecting adequacy of VLED labelling.

Similarly, the Applicant's VLED products, with labelling consistent with the above recommendations (4a-4d), have been in the Australia New Zealand marketplace for more than 20 years. The Applicant is unaware of any substantive issues of health and safety, or consumer confusion attributable to labelling raised by consumers or jurisdictions over that time, and notwithstanding the absence of a specific VLED standard.

Market response to current labelling

The Applicant is not aware of any current concerns over labelling of FSMP or VLED products in the ANZ market.

When FSANZ was considering Proposal P242, among the reasons for excluding VLED products from Proposal P242 were concerns that some consumers, seeking to reduce weight, would confuse FMRs and VLED products, despite the many, clear differences in labelling. (Refer P242 PFAR sec 5.2.1.2). At the time there was little qualitative or quantitative evidence supporting this concern and few jurisdictions had reported adverse events.

Following completion of P242 in 2012, VLED products have remained in the market, unregulated, with no reported concerns (potential or actual) as noted above, coming to the attention of the Applicant. That is, the potential concerns have not been realised, leading to a possible conclusion that current labelling and advertising practice has not resulted in consumer confusion or detriment, with implication that current labelling is providing sufficient relevant information to consumers.

The proposed variation to Standard 2.9.5 is **supportive** of current labelling conditions of that Standard, together with a number of recommendations for specific labelling for VLED products. These additional recommendations are strongly aligned with those presented in PFAR for P242.

C.3 Additional risk management measures

There is more to risk management than labelling: It is important to note that VLED specific labelling is utilised as one component of risk management responses. Other measures include:

1. *Restricted retail outlets*: In Standard 2.9.5: restricting the person and premises of sales together with a number of more general labelling requirements contained in 2.9.5-10.
2. *Collateral information:* The Applicant (and other VLED manufacturers) have highly informative dedicated web sites, include leaflets on VLED programs with the product and include commercial materials that advise among other matters that VLED products should be used under supervision of a health care professional.
3. *Training of health care professionals:* Training of retail staff at medical practices, pharmacies or similar responsible institutions is undertaken to ensure that retail staff understand the VLED program, the differences between VLED products and FMRs, and essential advice regarding use of the product under supervision of a healthcare professional.
4. *Customer support*: Provision of customer call centre (Refer Figure 5) for providing support and advice to VLED consumers.

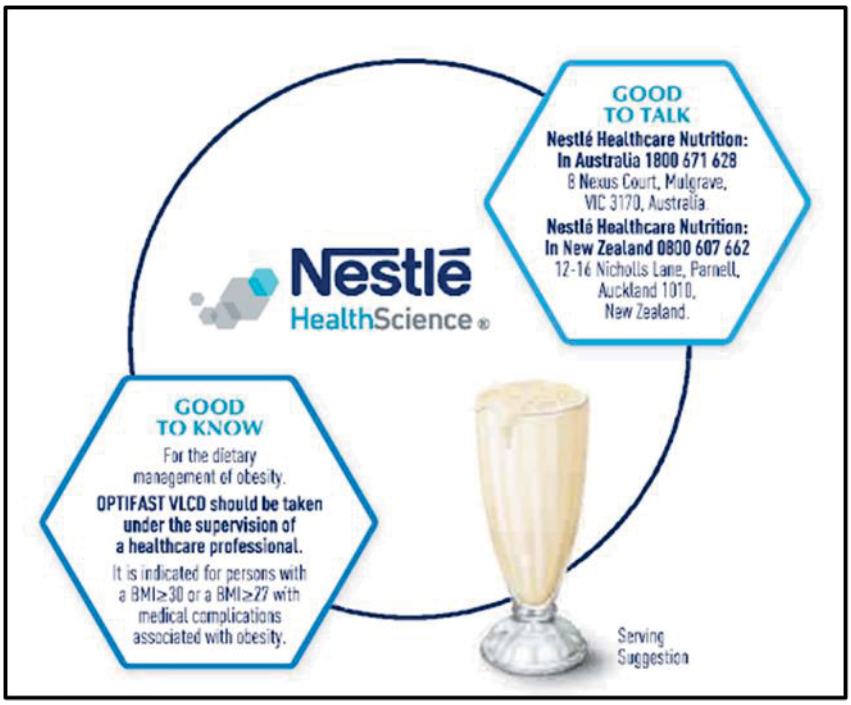


Figure 5: Consumer contact number (1800...) for consumer support (image from rear of Vanilla Shake product pack).

Summary
In summary, the Applicant believes that the **labelling** of FSMP, and VLED products in particular, as proposed, is providing an acceptable level of consumer information, and the above labelling recommendations are fully appropriate.

Further, the additional risk management measures outlined above provide additional constructive information and support for retailers and consumers.

D. Information related to internationally recognised codes of practice and guidelines

*The application **must** contain information demonstrating the extent to which the application is consistent with internationally recognised standards and codes of practices. These include Codex and the WHO recommendations and guidelines, relating to the composition and labelling of special purpose foods*.

This element has already been covered in Part III, Sections A2 and A3 of the Application.

E. Further information: Consistency with Policy Guideline - Intent of Part 2.9 - Special Purpose Foods.

Applicants are advised to consider relevant Policy Guidelines from the Australia New Zealand Ministerial Forum for Food Regulation (formerly the Australia New Zealand Ministerial Council for Food Regulation). The relevant guideline is Policy Guideline - Intent of Part 2.9 – Special Purpose Foods. The development of a VLED standard in the Code is aligned with the Guideline, as follows:

Policy element: Scope/Aim:

Very Low Energy Diet products are consistent with the scope and aim, being formulated for people who are overweight and obese whose physical and physiological conditions require nutrition with altered (reduced) energy intake (dot point #2).

Policy element: High order policy principles

Development of a standard for VLED products is consistent with high order policy principles as follows:

a) *protection of public health and safety* – through scientifically developed compositional requirements and proposed alignment with CODEX STAN 203-1995 which has been pre-market assessed during a CODEX development process, and the range and volume of products marketed and consumed in the ensuing 25 years and applying this Standard,

b) *provision of adequate information relating to food to enable consumers to make informed choices* - through adopting measures already codified in Standard 2.9.5 of the Code, and supporting substantive measures proposed in PFAR to P242 Foods for Special Medical Purposes,

c) *prevention of misleading and deceptive conduct* - through appropriate labelling as noted in (b) above, and also noting that there is no record of substantive issues, raised by consumers or jurisdictions, of consumer concern or confusion attributable to labelling of current VLED products in the current marketplace.

The development of a VLED standard meets principle 2a of the high order principles being based on sound scientific evidence and substantially aligned with CODEX. Establishing a standard that is consistent with international norms and that enables international trade meets principles 2b – 2d as it permits both local manufacture and importation thus promoting fair trade. The absence of a standard is now seen to be inhibiting to international trade, and is contrary to 2c-2d and the additional policy guidance relating to WTO TBT requirements.

Policy element: Specific order policy principles

The proposed standard for VLED products is consistent with specific order policy principles as follows:

- *Targeting*: The products are clearly marketed and labelled to be consumed by people who are overweight and obese and with obesity-related medical conditions,
- *Composition*: Composition is specifically developed as a complete diet (total diet replacement) for people who are overweight and obese,
- *Labelling* and information for safety: Consumers have access to product labelling and point-of-sale material that clarifies the purpose and relevant indications for use. The labels and other information also state that use of VLED nutritional products should be subject to medical supervision. This is further reinforced at point of sale, and on dedicated product-brand web sites. The purpose of this information is to achieve the desired outcome of consumer safety and safely-managed weight loss.

Policy element: Additional policy guidance

The Application is aligned with internationally recognised guidance and standards including CODEX STAN 203-1995 (CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction) and dietary reference values including NHMRC Nutrient Reference Values.

Overall, the development of a VLED standard in the Code is aligned with the Aim, Higher Order Policy Principles, Specific Policy Principles and the additional Policy Guidance set out in Australia New Zealand Food Regulation Ministerial Council Policy Guideline - Intent of Part 2.9 – Special Purpose Foods.

F. References

1) Alami, R.S., et al., Is there a benefit to preoperative weight loss in gastric bypass patients? A prospective randomized trial. Surg Obes Relat Dis, 2007. 3(2): p. 141-5; discussion 145-6.

2) Anderson, J.W., Kendall, C.W.C., and Jenkins, D.J.A., Importance of Weight Management in Type 2 Diabetes: Review with Meta-analysis of Clinical Studies. Journal of the American College of Nutrition, 2003. 22(5): p. 331-339.

3) Asher, R.C.Z., Burrows, T.L., and Collins, C.E., Very low-energy diets for weight loss in adults: A review. Nutrition & Dietetics, 2013. 70(2): p. 101-112.

4) Australian Institute of Health and Welfare, Snapshots, Overweight and Obesity, July 2020. https://www.aihw.gov.au/reports/australias-health/overweight-and-obesity.

5) Brown, A., and Leeds, A.R., *Very low-energy and low-energy formula diets: Effects on weight loss, obesity co-morbidities and type 2 diabetes remission – an update on the evidence for their use in clinical practice.* Nutrition Bulletin published by John Wiley & Sons Ltd on behalf of British Nutrition Foundation Nutrition Bulletin, 2019. 44, 7–24.

6) Colles, S., et al., *Preoperative weight loss with a very low energy diet: quantitation of changes in liver and abdominal fat by serial imaging.* Am J Clin Nutr, 2006. 84: p. 304-311.

7) Delbridge, E. and Proietto, J., *State of the science: VLED (Very Low Energy Diet) for obesity.* Asia Pacific Journal Clinical Nutrition, 2006. 15 (Suppl): p. 49-54.

8) de Lorgeril, M. & Salen, P., Alpha-linolenic acid and coronary heart disease. Nutrition, Metabolism, Cardiovascular Diseases (2004) 14:162-169).

9) Drawert, S., Bedford, K., and Largent, D., Change in Glucose, Blood Pressure, and Cholesterol with weight loss in Medically Obese Patients. Obesity Research, 1996. 4(Suppl.1): p. 67S.

10) FAO & WHO: Fats and oils in human nutrition, 1994. (General conclusions and recommendations, Essential fatty acids, Report of a Joint FAO/WHO Expert Consultation, Rome, Italy, 19-26 October 1993.) http://www.fao.org/3/V4700E/V4700E00.htm

11) Gibson, A. A., et al., *Do ketogenic diets really suppress appetite? A systematic review and meta-analysis.* Obes Rev, 2015. **16**(1): p. 64-76.

12) Gibson, A. A., et al., *Comparison of Very Low Energy Diet Products Available in Australia and How to Tailor Them to Optimise Protein Content for Younger and Older Adult Men and Women.* Healthcare (Basel), 2016. 4(3).

13) Johansson, K., et al., Effect of a very low energy diet on moderate and severe obstructive sleep apnoea in obese men: a randomised controlled trial. BMJ, 2009. 339: p. b4609.

14) Lewis, M.C., et al., *Change in liver size and fat content after treatment with Optifast very low calorie diet.* Obes Surg, 2006. **16**(6): p. 697-701.

15) Mustajoki, P. and Pekkarinen, T*., Very low energy diets in the treatment of obesity. Obesity Reviews, 2001. 2: p. 61-72.*

16) NHMRC, Clinical Practice Guidelines for the Management of overweight and obesity in adults, adolescents and children in Australia, National Health and Medical Research Council, 2013. (Document (pdf) included in references).

17) NHMRC, Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes 2006, Version 1.2 Updated September 2017. https://www.nrv.gov.au/

18) O'Brien, P.E., et al., The laparoscopic adjustable gastric band (Lap-Band): a prospective study of medium-term effects on weight, health and quality of life. Obes Surg, 2002. **12**(5): p. 652-60.

19) Pekkarinen, T. and Mustajoki, P., Use of Very Low-Calorie Diet in Preoperative Weight Loss: Efficacy and Safety. Obesity Research, 1997, 5(6): p. 595-602.

20) Pi-Sunyer, X., The Medical Risk of Obesity. Postgrad Med. 2009 Nov; 121(6): 21–33.

21) Purcell, K., et al., The effect of rate of weight loss on long-term weight management: a randomised controlled trial. The Lancet Diabetes & Endocrinology, 2014. 2(12): p. 954-962.

22) Rajan, T.M., and Menon, V., Psychiatric disorders and obesity: A review of association studies. J Postgrad Med. 2017, Jul-Sep; 63(3): 182–190.

23) Riecke, B.F., et al., Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese patients: a pragmatic randomized clinical trial. Osteoarthritis Cartilage, 2010. 18(6): p. 746-54.

24) Simon, G.E., et al., Association Between Obesity and Psychiatric Disorders in The US Adult Population, Arch Gen Psychiatry. 2006 Jul; 63(7): 824–830.

25) Tarnoff, M., Kaplan, L.M., and Shikora, S., An evidenced-based assessment of preoperative weight loss in bariatric surgery. Obes Surg, 2008. 18(9): p. 1059-61.

PART IV: Accompanying material

Attachment 1: Checklist for General requirements

This Checklist will assist you in determining if you have met the mandatory format and information requirements as detailed in Guideline 3.1.1 – General requirements. All applications **must** include this Checklist.

General requirements (3.1.1)		
Check	**Page No.**	**Mandatory requirements**
		A Form of application
☐		*Application in English*
	3	☐ *Executive Summary (separated from main application electronically)*
☐		☐ *Relevant sections of Part 3 clearly identified* **Refer to Table of Contents Part II and Part III**
		☐ *Pages sequentially numbered*
		☐ *Electronic copy (searchable)*
		☐ *All references provided*
☐	4	B Applicant details
☐	5	C Purpose of the application
	6	D Justification for the application
☐	9	☐ *Regulatory impact information*
	10	☐ *Impact on international trade*
		E Information to support the application
☐	10	☐ *Data requirements, also in Application: Part III Special purpose foods – Other foods (3.6.3)* **(refer Attachment 2).**
		F Assessment procedure
	10	☐ *General*
☐		☐ *Major*
		☐ *Minor*
		☐ *High level health claim variation*

☒	11	G Confidential commercial information ☒ *CCI material separated from other application material* ☒ *Formal request including reasons* ***Refer: Attachment 4 – pg 42*** ☒ *Non-confidential summary provided* ***Refer: Attachment 4 – pg 42***
☒	11	H Other confidential information **Not required** ☐ *Confidential material separated from other application material* ☐ *Formal request including reasons*
☒	11	I Exclusive Capturable Commercial Benefit **Not required** ☐ *Justification provided*
☒	12	J International and other national standards ☒ *International standards* ☒ *Other national standards*
☒		K Statutory Declaration
☒		L Checklist/s provided with application ☒ *3.1.1 Checklist* ☒ *All page number references from application included* ☒ *Any other relevant checklists for Chapters 3.2–3.7*

Attachment 2: Checklist for applications for special purpose foods and standardised foods

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guidelines 3.6.1–3.6.3.

Special purpose foods – Other foods (3.6.3)		
Check	**Page No.**	**Mandatory requirements**
☐	14	A.1 Identity and need of target population
☐	15	A.2 Purpose of compositional change
☐	20	A.3 Safety of proposed compositional change
☐	21	A.4 Nutritional or performance impact
☐	26	B.1 Dietary exposure data
☐	29	B.2 Level of consumption
☐	31	C.1 Safety and nutritional impact of labelling change
☐	32	C.2 Demonstrated consumer understanding of labelling change
☐	33	**C.3 Additional risk management measures** (Additional material)
☐	34	D Internationally recognised codes of practice and guidelines
☐	34	E **Further information: Consistency with Policy Guideline - Intent of Part 2.9 - Special Purpose Foods** (Additional material)

Attachment 3: List of Appendices

Appendix 1: Examples of Optifast VLED product packaging.

Appendix 2: VLED Nutrient compositional information, reference values and data enabling assessment of dietary exposure – a spreadsheet - CONFIDENTIAL COMMERCIAL INFORMATION (CCI).

Appendix 3: Information informing protein quality discussion – 'Relevance of protein quality in VLED products'.

Attachment 4: Summary of information contained in Appendices for which confidentiality (Commercial Confidential Information status) is claimed.

Appendix 2: *VLED Nutrient compositional information, reference values and data enabling assessment of dietary exposure – a spreadsheet*

The spreadsheet contains extensive product data and calculations that enable assessment of dietary intake across a wide range of nutrients. An excerpt of this data is found in Table 6 - Daily nutrient intake averaged over 3 days of following meal planner (declared values). This data is intended for use as an input to dietary exposure assessment.

Reason for Confidential Commercial Information (CCI) status:

The Applicant asks for *VLED Nutrient compositional information, reference values and data enabling assessment of dietary exposure – a spreadsheet* to be considered **Confidential commercial information (CCI).** The information has commercial significance as it contains extensive product technical data that would be of commercial interest to competitors.

Attachment 5: List of Tables and Figures

List of tables **Page**

List of figures