21 March 2022
194-22

Supporting document 1: Nutrition assessment

Application A1230 – Very Low Energy Diets (VLED)

Executive summary

The purpose of this application is to amend the Australia New Zealand Food Standards Code (the Code) to permit Very Low Energy Diets (VLED) within Standard 2.9.5 – Foods for Special Medical Purposes (FSMP), in alignment with the Codex standard for 'Formula Foods for use in Very Low Energy Diets for Weight Reduction' (Codex STAN 203-1995).

This supporting document evaluates the nutrient composition requirements for setting an applicable food standard for VLED. The assessment evaluates the nutritional adequacy and safety of VLED currently on the Australian and New Zealand (ANZ) market that are formulated in alignment with Codex STAN 203-1995.

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 1: 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.

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Abbreviations and glossary

AI	Adequate Intake: the average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
ANZ	Australia and New Zealand
α-TE	Alpha-tocopherol equivalent
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
Codex	Refers to Codex Alimentarius
DFE	Dietary folate equivalents
DRV	Dietary reference value
EAR	Estimated average requirement
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FSMP	Food for Special Medical Purposes
MoH	Ministry of Health (New Zealand)
NE	Niacin equivalents
NHMRC	National Health and Medical Research Council (Australia)
NRV	Nutrient reference value established by NHMRC & MoH (2006)
N.S.	Not specified
PDCAAS	Protein digestibility-corrected amino acid score
RDI	Recommended Dietary Intake: the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97–98 per cent) healthy individuals in a particular life stage and gender group.
RE	Retinol equivalents
rNRV	Regulatory nutrient reference value
SD	Supporting document
The Code	Australia New Zealand Food Standards Code
UL	Upper Level of Intake: the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.
US	United States of America
US FDA	US Food and Drug Administration
VLED	Very Low Energy Diets
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

FSANZ received an application from Nestlé Australia Ltd. and Nestlé New Zealand Ltd. seeking to amend the Australia New Zealand Food Standards Code (the Code) to permit Very Low Energy Diets (VLED) within Standard 2.9.5 – Foods for Special Medical Purposes (FSMP), in alignment with the Codex standard for 'Formula Foods for use in Very Low Energy Diets for Weight Reduction' (Codex STAN 203-1995).

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

As VLED are used as total diet replacements their compositional requirements are explicitly defined by regulatory authorities. This assessment evaluates the nutrient composition of VLED specified by the Codex Stan 203-1995. This standard is specifically formulated to satisfy the daily nutritional requirements of overweight or obese adults in good health, in the context of energy-restricted diets for weight reduction. This includes requirements of the essential nutrients within 450-800 kilocalories (kcal) which represents the sole source of energy intake.

VLED are used as a total diet replacement for a prescribed duration, typically no longer than twelve weeks. The applicant's total diet replacement plans comprise three options: intensive level, active 2 level and active 1 level. The intensive level provides 800 kcal (3.35 megajoules (MJ)) or less per day, whilst consisting of sufficient protein, fatty acids, carbohydrates, vitamins and minerals for safe and fast weight loss. A daily intake typically consists of three VLED (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 drinks. VLED total diet replacement plans within the Australian and New Zealand (ANZ) market are typically quite similar in structure and prescription.

This variation to the Code seeks to 'codify' VLED currently in the ANZ marketplace in alignment with Codex STAN 203-1995.

1.1 Background

VLED have been in the ANZ market for over 20 years. VLED were initially included in FSANZ Proposal P242 – Foods for Special Medical Purposes, which commenced in 2000 and resulted in the establishment of Standard 2.9.5, but were omitted at the Final Assessment Report (FAR) in 2012.

The specific targeted and public consultation determined that the market for formulated foods used for weight reduction had evolved since 2000. This raised further issues as there was 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. In response to submissions received in 2010, FSANZ decided to exclude VLED from Proposal P242 and instead proposed a new project would be initiated to specifically investigate the most appropriate way to regulate VLED relative to all other formulated foods for weight reduction purposes. In the intervening years, this residual work has been ranked as a low priority on the FSANZ work plan and has not been further progressed.

In the interim VLED have been covered in New Zealand by Standard 2.9.6 — Transitional standard for special purpose foods (including amino acid modified foods), which has been used to regulate VLED as an interim measure in the absence of a binational standard. It was noted within the P242 FAR that the transitional standard would maintain as the status quo in regulating VLED manufactured in or imported into New Zealand until a binational standard was developed and implemented, following this the transitional standard would be repealed.

There is currently no standard regulating VLED manufactured or imported into Australia, which has left these products without an applicable food standard. VLED currently in the ANZ marketplace are aligned with the internationally recognised Codex STAN 203-1995. This application seeks regulatory clarity and certainty through development of an applicable standard that aligns with Codex STAN 203-1995.

1.2 International regulations

Due to the global nature of the VLED product market, there are number of international regulations that are of significance to the ANZ regulatory setting. These are:

- *Codex standards for 'Formula Foods for use in Very Low Energy Diets for Weight Reduction' (CODEX STAN 203-1995)*

The Codex Alimentarius Commission is an international intergovernmental body that is responsible for implementing the Food and Agriculture Organization (FAO) and World Health Organization (WHO) Food Standards Programme. Codex STAN 203-1995 sets out the essential composition of VLED, including recommended minimum and maximum nutrient amounts. This standard guides member countries when establishing the essential composition of VLED, and takes account of nutritional safety and adequacy. Codex STAN 203-1995 was established by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), based on advice from international scientific experts on VLED.

- *European Commission Directives on 'Foods Intended for Use in Energy-Restricted Diets for Weight Loss' (EU 2017/1798)*

The European Commission amended the EU 2017/1798 in 2017, and is based on the European Food Safety Authority (EFSA) Scientific Opinion on the essential composition of total diet replacements for weight control (2015). FSANZ notes the European Commission has received significant feedback on the ability for manufacturers to comply with the compositional requirements of EU 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.

- *Canadian Food and Drug Regulations 1954, Division 24 – Foods for Special Dietary Use, specifically regulations on 'Formulated Liquid Diets' (B.24 100 – 103) and 'Foods Represented for Use in Very Low Energy Diets' (B.24 300 – 306).*

- *UK Statuary Instruments 1997, 'The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations' (1997 no. 2182)*

1.3 P242 Previous Considerations

In 2010 FSANZ Proposal P242 sought stakeholder comments on the regulation of FSMP, which received numerous submissions. Table 1.3 lists issues raised during consultation that address the definition and nutrient composition of VLED, along with FSANZ responses.

Table 1.3 Summary of submitter comments to P242, regarding VLED

Issue	Submitters[1]	Submitter comments	FSANZ response / proposed option
Definition	3 (3I)	The definition of VLED needs further clarification.	FSANZ agrees that the definition for VLED needs to be further refined. The definition should acknowledge the products low energy range and that it can be a sole or primary source of nutrition. The definition for VLED is discussed in section 2.2.2.1 of the CFS.
Nutrient composition	2 (1I, 1HP)	Support received for the additional compositional requirements for VLED from several industry and health professional submitters.	FSANZ agrees that VLED require further compositional requirements in comparison to other FSMP. This was the basis of VLED being removed from P242.
	1 (1I)	Nutrient composition should also include permissions for vitamin K, chromium, and fluoride.	FSANZ has assessed these nutrients in section 5. FSANZ proposes to align with Codex STAN 203-1995 in not setting a permission for these nutrients.
	1 (1I)	*Maximums:* – Industry submitters questioned the maximum limits for certain nutrients, such as Vitamin E, Niacin and Magnesium.	FSANZ agrees that no maximums need to be set based on alignment with Codex STAN 208/1995. Further details can be found within sections 4 and 5.
	2 (1I, 1HPB)	*Minimums:* – An industry submitter stated that VLED should have a minimum daily amount set for micronutrients. – One Health Professional Body commented that VLED should be required to provide the recommended daily allowances of minerals, vitamins, trace elements, and fatty acids in a dose/serve.	FSANZ agrees that VLED should be required to provide the recommended daily allowances for all nutrients, in alignment with the ANZ NRVs. Micronutrients are assessed within section 4.

[1] Indicates number of submissions that commented on this issue; I = Industry, G = Government, HP = Health Professional, HPB = Health Professional Body

2 2021 Assessment

2.1 Objectives and Scope

The nutrition assessment evaluates the nutritional adequacy and safety of aligning with the Codex STAN 203-1995 nutrition composition in the context of the ANZ population. FSANZ is aware that due to the absence of standard for VLED within the Code, VLED on the ANZ market have been formulated to comply with Codex STAN 203-1995. The purpose of this application is to align with Codex STAN 203-1995 where appropriate to avoid reformulation of VLED on the ANZ market and increase international harmonisation to facilitate trade and exports.

The assessment evaluates the nutrient composition of VLED in the context the applicants intensive level total diet replacement plan and as a sole source of nutrition.

Codex STAN 203-1995 prescribes a range for energy and minimum amounts for nutrients per daily intake. The EU 2017/1798 prescribes a range for energy, protein and magnesium and minimum amounts for all other nutrients per daily intake. Both standards also regulate protein quality. The EU 2017/1798 prescribes a minimum for biotin, pantothenic acid, vitamin K, manganese, molybdenum, selenium and chloride, whereas Codex STAN 203-1995 does not include these nutrients.

The scope of the nutrition assessment covers all nutrients regulated in Codex STAN 203-1995, as well as nutrients included in EU 2017/1798 and the ANZ NRVs.

2.2 Approach

This supporting document is organised into two parts that discuss nutrients prescribed in Codex STAN 203-1995 and other nutrients prescribed in the EU 2017/1798 regulation or the ANZ NRVs, but not in Codex STAN 203-1995. Both sections assess the nutrient compositional issues for the following related nutrient groups: macronutrients and energy, micronutrients (vitamins and minerals) and other nutritive substances. For each nutrient, the value of the prescribed minimum and maximum, where applicable, is discussed and a regulatory option is proposed.

Part 1 of the nutrition assessment (sections 3 and 4 of this SD) follows an approach in which Codex STAN 203-1995 provisions for each nutrient were assessed against a set criteria. The assessment criteria were (where applicable):

1. estimation of daily intake according to intensive level total diet replacement plan and comparison with the adult ANZ NRVs (Reccomedned Dietary Intake (RDI), or Adequate Intake (AI) where RDI is unavailable) to determine nutritional adequacy (Nutritional adequacy assessment)
2. estimation of daily intake according to intensive level total diet replacement plan and comparison with the adult ANZ NRVs (Upper Level of Intake (UL)) to determine nutritional excess and safety (Nutritional safety assessment)
3. comparison against VLED product label declarations and Nutrition Information Panels (NIP) to determine consistency with ANZ market (ANZ market assessment)
4. consistency with current scientific knowledge
5. potential impacts on international trade
6. other relevant factors unique to the nutrient of interest such as the impact of manufacturing, nutrient bioavailability, history of apparent safe use, or the ANZ population.

Part 2 of the nutrition assessment (sections 5 of this SD) evaluates nutrients not regulated by Codex STAN 203-1995, but prescribed in the EU 2017/1798 or the ANZ NRVs the following assessment criteria was used (where applicable and NIP information allowed):

1. estimation of daily intake according to intensive level total diet replacement plan and comparison with the adult ANZ NRVs (RDI, or AI where RDI is unavailable) to determine nutritional adequacy
2. public health considerations
3. assessment of risk of inadequacy over life of product use (12 weeks maximum)
4. consistency with current scientific knowledge
5. potential impacts on international trade.

Where these was no clear trend between conclusions of the nutritional adequacy, safety and market assessment, FSANZ has further discussed other relevant factors to aid proposing a regulatory option.

2.3 Methods

Nutrition information for VLED in the ANZ market was collected through NIPs presented on company websites. NIPs were collected for shakes, bars, and soups. However, desserts were not included in this analysis as some brands did not have similar products. Nutritional values for products with comparable flavours within each category were collected to provide the amount of each nutrient reported to be present in a single serve. The single serve value was then multiplied by three to represent the amount consumed across a day if following the intensive total diet replacement plan, where three meals are replaced with VLED. Not all VLED reported amounts for all specified nutrients.

To assess nutritional adequacy the nutrition content range for each category was compared to the minimum amounts prescribed in Codex STAN 203-1995 and EU 2017/1798, and also further compared to the RDI, with the AI used when RDI was not available. RDI and AI values used are based on adults aged 19–50 years old. Separate values are provided for men and women where they do not align. To assess nutritional safety, the same process was followed. However, the comparisons were made against the UL where available (NHMRC and NZ MOH, 2006).

2.4 Assumptions

Unless otherwise specified, the current assessment assumes the following:

1. The nutrition assessment evaluates nutritional adequacy and safety based on adult ANZ NRVs. It is assumed that individuals who are using VLED are on average aged 19-50 years and are following the prescribed total diet replacement plan (sole source of nutrition) under medical supervision.
2. Individuals are consuming VLED as per the Total Diet Replacement Plan, for no longer than 12 weeks.
3. Where individuals vary from the Total Diet Replacement Plan, this is under medical supervision.
4. As VLED on the ANZ market aim to comply with the nutrient composition prescribed in Codex STAN 203-1995 comparing the intakes from these products against the ANZ NRV is a reflection of the Codex standard in force.

Assessment of nutrients prescribed in Codex STAN 203-1995

3 Macronutrient Assessment

3.1 Energy Range

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide, when prepared according to instructions, a daily energy intake of 450 - 800 kcal as the only source of energy. The EU 2017/1798 prescribes a higher energy range of 600 - 1200 kcal for the total daily ration.

We note that internationally kcal are used, however the Code reports energy in units of kilojoules (kJ). The assessment evaluates energy as kJ to reflect how it will eventually be prescribed within the Code. Codex STAN 203-1995 and EU 2017/1798 energy requirements have been converted to kJ, using the conversation factor of 4.18 listed in Schedule 11. The Codex STAN 203-1995 and EU 2017/1798 kJ equivalents are 1881 - 3344 kJ/day and 2508 - 5016 kJ/day, respectively.

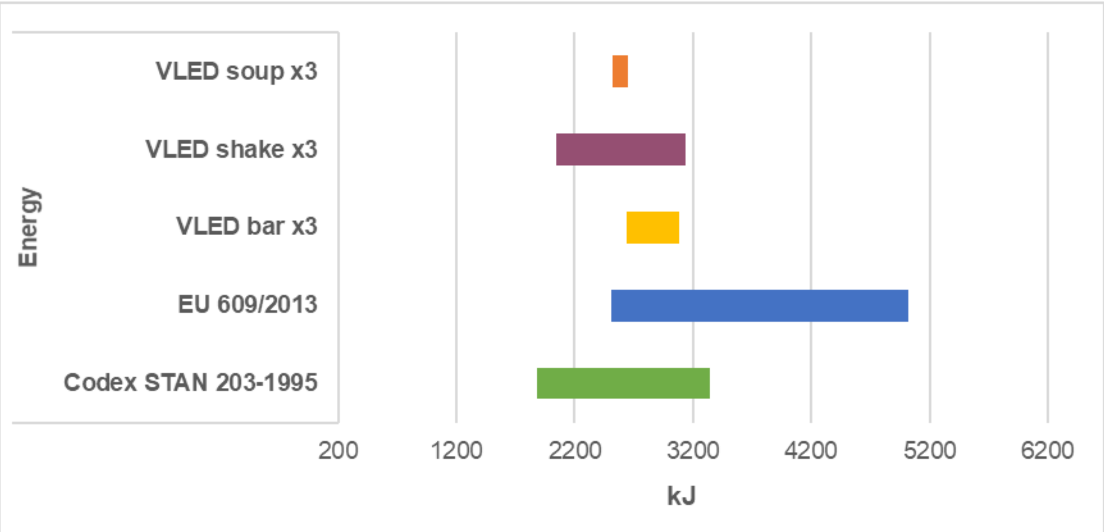


Figure 3.1 Reported energy content of VLED compared to international regulations

Nutritional adequacy and safety assessment

The nutritional adequacy and safety did not assess energy content of VLED as they are specifically formulated to provide very low levels of energy to create an energy deficit and assist with weight loss. Nutrient adequacy and safety are addressed via the products ability to supply macronutrient and micronutrients in sufficient levels within the discreet energy range. All other nutritional safety and adequacy concerns related to energy are addressed under medical supervision.

ANZ market assessment

The FSANZ 2021 label survey assessed energy content in VLED on the ANZ market (Figure 3.1). The survey found that energy content of VLED fell within the range of Codex STAN 203-1995. Most VLED categories complied with the lower end of EU 2017/1798 range.

If three VLED shakes were used in an intensive diet replacement plan the shakes would not meet the minimum energy level prescribed by EU 2017/1798. Some shake-based VLED programs provide only 2044 kJ/day.

Options and discussions

The EU 2017/1798 energy minimum is derived from the minimum macronutrient content of VLED daily intake; 75g protein, 30g carbohydrates and linoleic and α-linoleic acid in amounts which total around 20 g fat per day (EFSA 2015). EFSA (2015) also noted when setting the standard that from a scientific point of view there is no evidence to establish a threshold below which a diet could be considered to be very low in energy content.

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) set the Codex STAN 203-1995 standard. The energy range for VLED generated a wide variety of views, the Committee agreed that VLED would cover a daily energy intake of 1881 - 3344 kJ/day, instead of 2508 kJ, in order to avoid a gap in the daily energy intake across categories covered by other Codex standards. For example the Standard for Formula Foods for Use in Weight Control Diets applies to diets providing no less than 3344 kJ/day.

The intended purpose of VLED is to support weight loss in the treatment of overweight and obesity, to achieve this an energy deficit is required. Fast weight loss with the use of VLED has been shown to be an effective intervention for weight management (NHMRC, 2013).

In comparing Codex STAN 203-1995 and the EU 2017/1798 nutrient composition it is evident that the EU 2017/1798 energy range is higher and allows the majority of other macronutrient and micronutrient to have higher minimums within the regulation.

Proposed approach

Based on the above discussion and alignment with Codex STAN 203-1995, FSANZ proposes to adopt an energy intake range of 1881 - 3344 kJ/day, rounded to 1880 – 3345 kJ/day[1]. This is an amount manufacturers within the ANZ market are able to meet already. This proposed option is also consistent with P242 PFAR (page 39). The code will continue to use kJ as the unit of expression for energy content.

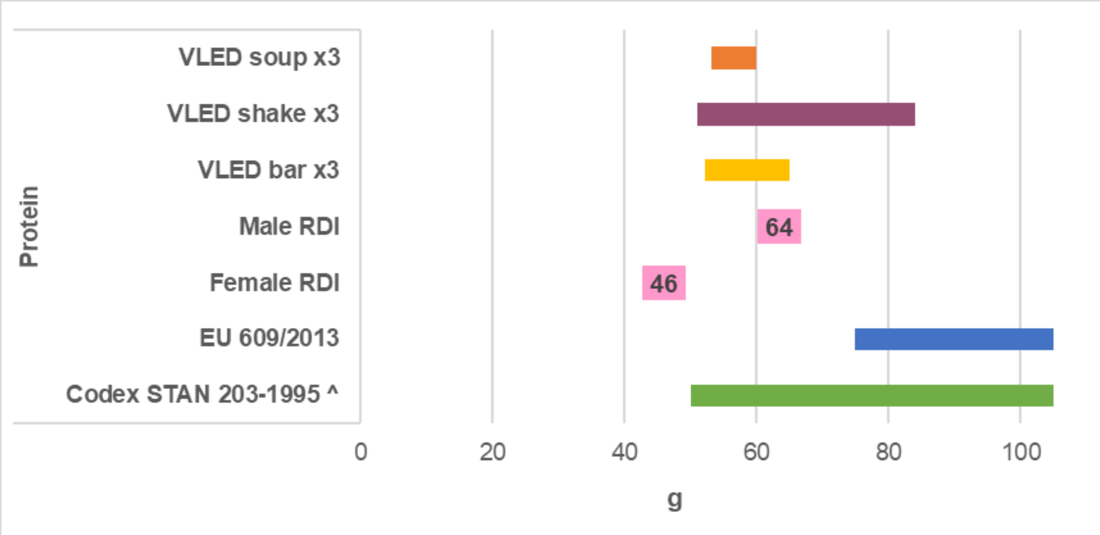
3.2 Protein

3.2.1 Protein minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a minimum of 50 g/day of protein. Codex STAN 203-1995 does not prescribe a maximum level. Whereas, the EU 2017/1798 prescribes very low energy diets shall provide a range of protein between 75g – 105g/day.

[1] The energy minimum was rounded down one kJ and energy maximum was rounded up one kJ to be fully inclusive of the Codex STAN 203-1995 energy range.



^ Codex specifies a minimum concentration of 50g/daily protein intake and does not specify a maximum permitted concentration.

Figure 3.2.1 Reported protein content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated protein content of VLED against the ANZ male and female RDI. Consumption of three VLED per day met the female RDI, however only the higher end of VLED bars and shakes met the male RDI of 64 g/day. Protein content of VLED on the ANZ market ranged from 52 - 70 g/day.

An additional 5 g/day is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan. The intensive level total diet replacement plan provides approximately 57 – 75 g/day of protein.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 protein minimum does not pose risk to nutritional adequacy for ANZ females and based on average intakes does not pose risk to ANZ males.

Nutritional safety assessment

The nutritional safety of protein content in VLED was unable to be assessed as there in no UL set due to insufficient evidence (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed protein content of VLED on the ANZ market (Figure 3.2.1). The survey found that protein content of VLED complied with the Codex STAN 203-1995 minimum, however the majority did not meet the EU 2017/1798 minimum. Figure 3.2.1 evidences that the EU 2017/1798 protein range is substantially higher than Codex STAN 203-1995 protein minimum and what is currently present on the ANZ market.

Options and discussions

The male RDI was not achieved through consumption of only VLED soups or the lower end of the VLED bars. However, consumption of only three VLED soups is assessed as worst case scenario as typically individuals would consume a mix of VLED products and would also consume the additional aspects of the total diet replacement plan. The male RDI is likely to be met and not pose nutritional inadequacy if consumers are directed to consume a mix of

VLED and abide by the total diet replacement plan for no longer than 12 weeks as directed under medical supervision.

The EU 2017/1798 protein range was based on a corrected Population Reference Intake (PRI) established for a normal-weight person by the quotient of the resting energy expenditure of overweight or obese individuals and the resting energy expenditure of a normal-weight reference subject. This correction translates into a minimum quantity of 75 g/day. EFSA (2015) notes that this is supported by results showing that protein turnover is either maintained or only slightly decreased during energy restriction provided a quantity of protein of between 50 g and 100 g/day is supplied in the diet. The Codex STAN 203-1995 protein minimum meets the lower end of this range to maintain protein turnover during energy restriction. The EU 2017/1798 protein maximum was not established based on known adverse effects, and is not an UL.

Proposed approach

Based on the above considerations, FSANZ proposes to align with the Codex STAN 203-1995 minimum of 50 g protein per day. This proposed option is also consistent with P242 PFAR (page 39).

3.2.2 Protein Quality

Current regulations

Codex STAN 203-1995 and the EU 2017/1798 prescribe that protein with a nutritional quality equivalent to a Protein Digestibility Corrected Amino Acid Score (PDCAAS) of 1 shall be present in the recommended daily intake of energy within very low energy diets. Both regulations allow addition of amino acids to improve protein quality, however only at amounts necessary for this purpose. Codex STAN 203-1995 prescribes that only L-forms of amino acids shall be used, except that DL-methionine.

Codex STAN 203-1995 also states, under section *3.3. Ingredients*, 'that VLED shall be prepared from protein constituents of animal and/or plant which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product'.

The applicant has not requested to align with Codex STAN 203-1995 protein quality prescription and suggests that specifying protein quality is unnecessary for VLED.

Nutritional adequacy assessment

The quantity and utilisation of indispensable amino acids is considered to be an indicator of the dietary protein quality, which is usually assessed via PDCAAS (EFSA 2015). High quality proteins are defined as a protein with a PDCAAS of 1.0, which includes common proteins such as casein, egg, milk, whey and soy (EFSA 2015, WHO/FAO/UNU 2007, Sarwar 1997).

The nutritional adequacy assessment evaluates the protein quality of VLED solely on the NIP and ingredient list. The addition of amino acids to VLED is not declared on the NIP and therefore a comprehensive assessment of PCDAAS was unable to be completed.

The majority of VLED on the ANZ market list high quality proteins as their base ingredients, such as milk protein, skimmed milk powder, casein and/or whole milk powder. This suggests that VLED on the ANZ markets have an approximated PDCAAS equivalent to 1.0.

VLED cereal bars did not include high quality protein sources as base ingredients but may have added amino acids.

Based on the above, FSANZ assumes that most VLED on the ANZ market have a PCDAAS of 1.0.

ANZ market assessment

The FSANZ 2021 label survey found that the majority of products on the ANZ market are compliant with Codex STAN 203-1995 and EU 2017/1798 protein quality standards. The label survey also found labelling claims such as 'high in protein', '40% more protein' and 'maintains muscles'. These claims could be misleading to consumers if the products are not compliant with the protein quality requirements.

Options and discussions

The applicant conducted an on-line search of OVID Medline, which supplied 11 studies on the relationship between the dietary management of overweight and obesity and protein quality (Alfenas 2010, Bowen 2006A, Bowen 2006B, Hall 2003, Leidy 2015, Macdonald 2015, Pesta 2014, Porter 2016, Veldhorst 2009A, Veldhorst 2009B, Veldhorst 2009C). Most of the studies did not assess diets of high quality protein against low quality protein and were unable to provide sound reasoning for excluding this permission.

The basis for the EU 2017/1798 protein quality prescription is that in 1970 prolonged consumption of VLED consisting largely of protein resulted in more than 60 deaths owing to cardiac complications (EFSA 2015; Sours 1981). These deaths were attributed to the low biological value of the protein products consumed at the time. Since then, the protein quality of VLED has drastically improved. However, nutritional quality equivalent to a PDCAAS of 1 is prescribed as a safety measure. As there is insufficient evidence to contend this FSANZ considers it appropriate to align with two safe and suitable international standards.

Infant formula products, like VLED, are intended for use as a sole source of nutrition. Because of this a full profile of essential amino acids should be provided to ensure nutritional adequacy. Standard 2.9.1 and Schedule 29, prescribe minimum amounts for each essential amino acids to ensure protein quality. This standard is much more comprehensive and less flexible than the protein quality requirements within Codex STAN 203-1995 and the EU 2017/1798.

FSANZ Application *A1175 – Rapeseed protein isolate as a novel food,* also assessed protein quality of rapeseed protein isolate via PDCAAS. The assessment found that rapeseed protein isolate has a PDCAAS equivalent to 1 and is comparable to that of the milk protein casein and slightly higher than that of soy protein isolates. The assessment concluded that based on PDCAAS the use of this protein did not raise nutritional concerns in relation to the protein adequacy (FSANZ, 2020).

If nutritional quality equivalent to a PDCAAS of 1 cannot be met via high-quality protein sources and addition of single amino acids, then FSANZ is of the view that the protein source should be assessed through a pre-market assessment for suitability for the intended product purpose. This approach provides a different pathway for innovation, while still ensuring nutritional adequacy and safety of unique protein sources within the ANZ food supply and consistency within the Code.

This proposed option does not limit innovation or diversity of protein sources. Plant based proteins can still be used within the Codex STAN 203-1995 and the EU 2017/1798, however addition of amino acids may be needed to meet protein quality requirements.

Further evidence would be required for FSANZ to justify a prescription that opposes two safe and suitable international regulations (Codex STAN 203-1995 and the EU 2017/1798). FSANZ also considers that misalignment with international standards will create future concerns regarding exports and trade.

Proposed approach

Based on the above discussion, FSANZ proposes the recommended daily intake of energy within very low energy diets must:

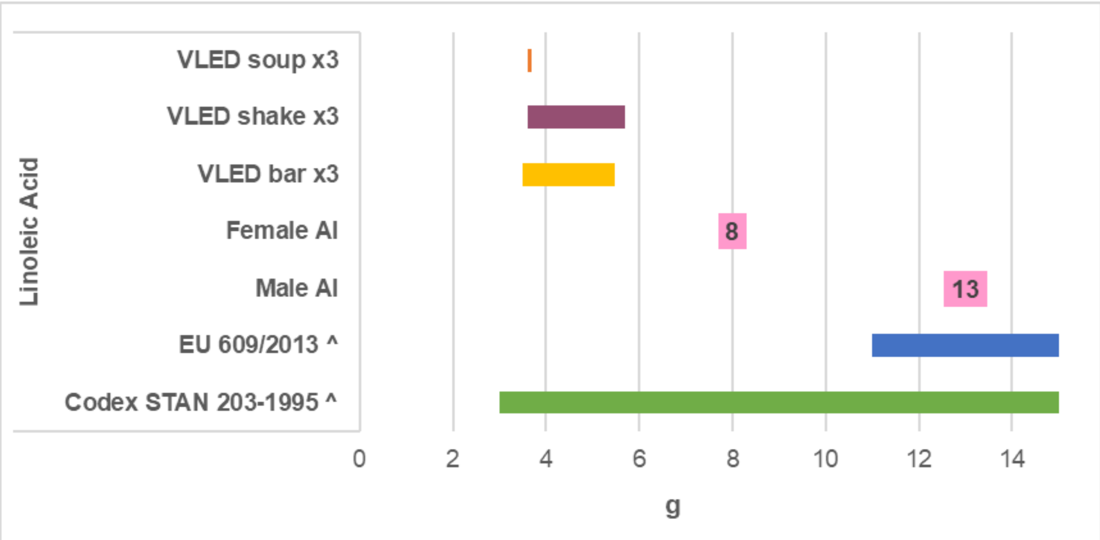
- have protein with a nutritional quality equivalent to a PDCAAS of 1, and
- amino acids may be added to improve protein quality only in amounts necessary for this purpose.

3.3 Fats

3.3.1 Linoleic acid minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a minimum of 3.0 g/day of linoleic acid. The EU 2017/1798 prescribes a much higher minimum of 11 g/day.



^ *Codex and the EU specify a minimum intake for LA and does not specify a maximum permitted concentration.*

Figure 3.3.1 Reported linoleic acid content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the linoleic acid content of VLED against the ANZ AI. Consumption of three VLED per day did not meet the male or female AI for linoleic acid.

In accordance with the intensive level total diet replacement plan an additional two cups of low starch vegetables and one teaspoon of vegetable oil can also be consumed per day. This accounts for an additional 2g of linoleic acid per day and brings the average intake to 5.6 – 7 g/day of linoleic acid. This is 1 g/day less than the female AI and 6 g/day less than the male AI.

Nutritional safety assessment

The nutritional safety of linoleic acid content in VLED was unable to be assessed as there in no UL set because there is no known level at which adverse effects may occur (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed linoleic acid content of VLED on the ANZ market (Figure 3.3.1). The survey found that linoleic acid content of VLED complied with the Codex STAN 203-1995 minimum, however did not meet the EU 2017/1798 linoleic acid minimum (11 g/day). Figure 3.2.1 evidences that EU 2017/1798 linoleic acid minimum is much higher than Codex STAN 203-1995 and what is currently present on the ANZ market.

Options and discussions

Levels of linoleic acid in VLED on the ANZ market did not meet the ANZ AI for males and females aged 19 years and above. However, an average intake of 5.6 – 7 g/day of linoleic acid is presented as a worst case scenario and is only prescribed for a maximum of 12 weeks. The ANZ AI used for assessment is based on median population intakes, which significantly deviates from the RDI. Because of this there is less risk associated with an AI not being met, in comparison to an RDI. It is also important to note that median population intakes will differ largely to nutrients supplied within the VLED as there is a substantially more discreet energy range in which these nutrients can be supplied.

Linoleic acid intake can also be increased through supplements. If this is a nutrient of concern for an individual using VLED under medical supervision, advice should be provided on other dietary management interventions, such as supplementation.

Based on the acute period of time and nutritional adequacy being compared to median population intakes, FSANZ considers that levels currently within VLED on the ANZ market, that are complaint with Codex STAN 203-1995, pose low risk to nutritional adequacy of VLED consumers. Any nutritional adequacy issues that appear within this acute period should be managed under medical supervision.

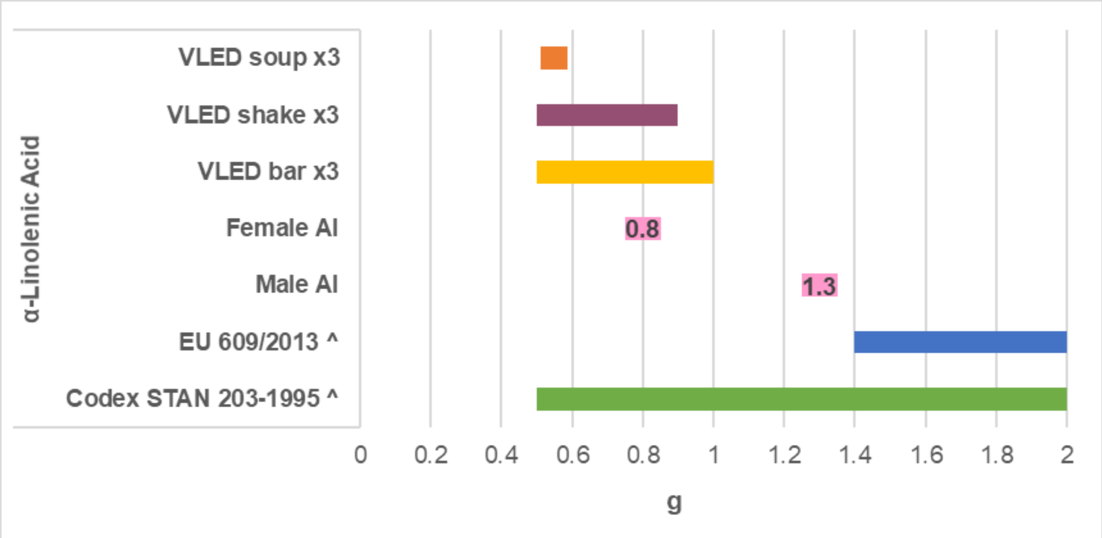
Proposed approach

Based on the above discussions, FSANZ proposes to adopt the Codex STAN 203-1995 linoleic acid minimum of 3 g/day. This prosed option is also consistent with P242 PFAR (page 39).

3.3.2 α-Linolenic acid minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a minimum of 0.5 g/day of α-linolenic acid. The EU 2017/1798 prescribes a much higher minimum of 1.4 g/day.



^ Codex and the EU specify a minimum intake for ALA and does not specify a maximum permitted concentration.

Figure 3.3.2 Reported α-linolenic acid content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated α-linolenic acid content of VLED against the ANZ male and female AI. Consumption of three VLED per day provided an average α-linolenic acid intake of approximately 0.5 – 0.8 g/day. An additional 0.5 g/day of α-linolenic acid is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average α-linolenic acid intake to approximately 1 – 1.3 g/day. This range exceeds the female AI, however only part of the range meets the male AI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 α-linolenic acid minimum does not pose risk to nutritional adequacy for females and poses low risk of nutritional adequacy for males.

Nutritional safety assessment

The nutritional safety of α-linolenic acid content in VLED was unable to be assessed as there in no UL set because there is no known level at which adverse effects may occur (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed α-linolenic acid content of VLED on the ANZ market (Figure 3.3.2). The survey found that α-linolenic acid content of VLED complied with the Codex STAN 203-1995 minimum, however did not meet the EU 2017/1798 α-linolenic acid minimum (1.4 g/day). Figure 3.2.1 evidences that EU 2017/1798 α-linolenic acid range is substantiality higher than Codex STAN 203-1995, the ANZ male and female AI and what is currently present on the ANZ market.

Options and discussions

As mentioned in section 3.3.1, AI values are based on median population intakes which tend to deviate significantly from and be numerically higher than an RDI if the RDI could be determined. Because of this there is less risk associated with an AI not being met. Any further risks associated with nutritional adequacy are prevented through the acute period these products serve as a sole source of nutrition. Nutritional adequacy is also further managed by risk management strategies noted on product labelling, within the total diet replacement plan and through medical supervision

Proposed approach

Based on the aim of the application, Codex STAN 203-1995 not posing risk to nutritional adequacy or safety, alignment with the ANZ market and further risk management strategies (such as the products being used under medical supervision) which ensure consumer safety, FSANZ proposes to adopt the Codex STAN 203-1995 α-linolenic acid minimum of 0.5 g/day. This proposed option is also consistent with P242 PFAR (page 39).

3.3.3 LA : ALA ratio

Current regulations

Codex STAN 203-1995 recommends the daily intake of linoleic acid to α-linolenic acid be in a ratio between 5 and 15. The EU 2017/1798 does not prescribe a set ratio for linoleic acid and α-linolenic acid.

Nutritional adequacy and safety assessment

Nutritional adequacy and safety elements of the Codex STAN 203-1995 minimums for linoleic acid and α-linolenic acid are addressed above in Section 3.3.1 and 3.3.2, respectively. The ratio prescribed by Codex STAN 203-1995 also further ensures nutritional safety.

ANZ market assessment

The FSANZ 2021 label survey assessed linoleic acid and α-linolenic acid content of VLED on the ANZ market, which reported that all product category averages satisfied the Codex STAN 203-1995 requirement that the ratio of linoleic acid to α–linolenic acid be between 5 and 15.

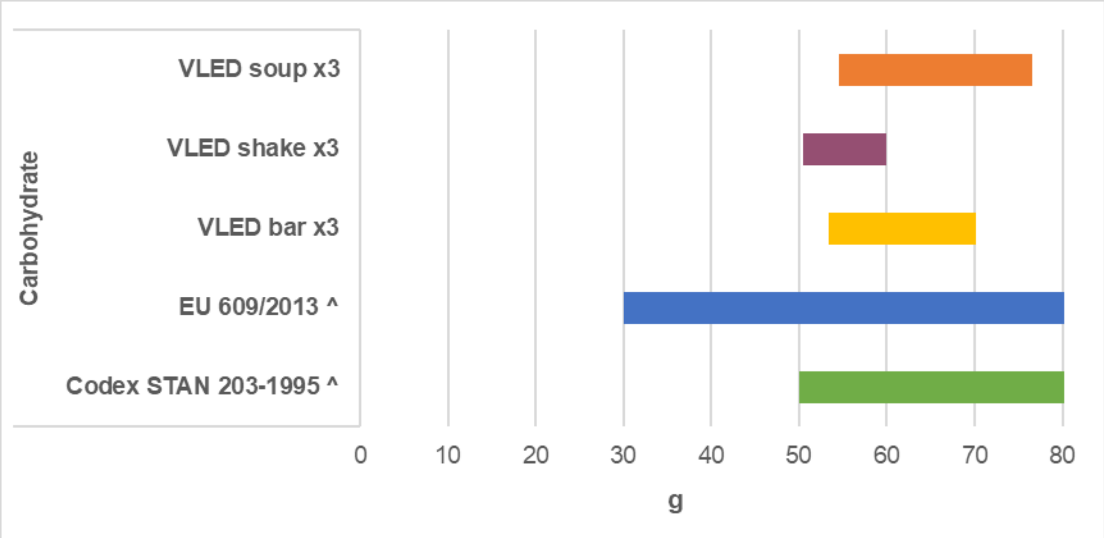
Proposed approach

Based on FSANZ proposing to adopt the Codex STAN 203-1995 minimum levels for linoleic acid and α-linolenic acid (noted in section 3.3.1 and 3.3.2), FSANZ proposes to align with the Codex STAN 203-1995 linoleic acid to α-linolenic acid ratio of 5 : 15.

3.4 Carbohydrate minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a minimum of 50 g of carbohydrate per day. Whereas, the EU 2017/1798 prescribes a lower minimum of 30 g/day.



^ Codex and the EU specify a minimum intake for Carbohydrates and does not specify a maximum permitted concentration.

Figure 3.4 Reported carbohydrate content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy of carbohydrate content within VLED was unable to be assessed as there is no EAR, RDI or AI set for most age and gender groups. This is due to limited data to base estimates of requirements on (NHMRC and NZ MOH, 2006).

Nutritional safety assessment

The nutritional safety of carbohydrate content in VLED was unable to be assessed in the absence of an UL. It was deemed inappropriate to set an upper level of intake for carbohydrates (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed carbohydrate content of VLED on the ANZ market (Figure 3.4). The survey found that carbohydrate content of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum. Figure 3.4 evidences that the EU 2017/1798 carbohydrate minimum sits approximately 20 g/day lower than the minimum amount found in VLED on the ANZ market.

Options and discussions

An additional 10 g/day of carbohydrates is also consumed in accordance with the intensive level of the total diet replacement plan.

Despite not being able to evaluate the nutritional adequacy and safety against the relevant NRVs, the adequacy and safety of VLED is ensured through medical supervsion. Carbohydrates are also not a nutrient of concern for over or under consumption in terms of deficiency or toxicity (NHMRC and NZ MOH, 2006).

Weight loss through very low energy diets is achieved by the restriction of both carbohydrate and total energy intake, which in turn achieves rapid weight loss and a mild ketosis that may suppress hunger. Diets containing 50-70 g of carbohydrate are generally considered low enough in carbohydrates to produce ketones (Gibson, A. 2015).

Proposed approach

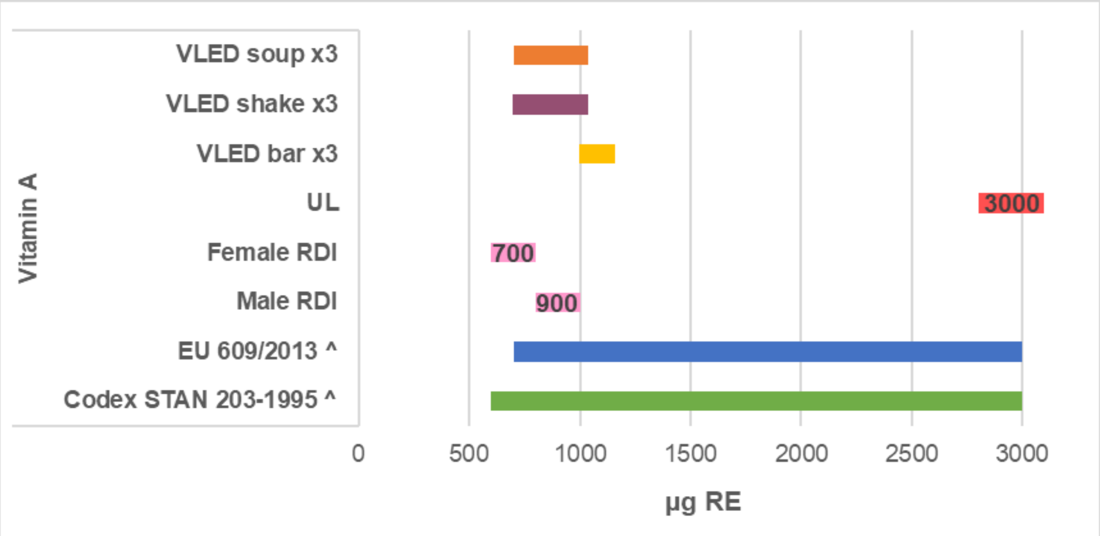
Based on the purpose of the application and international harmonisation, FSANZ proposes to adopt the Codex STAN 203-1995 carbohydrate minimum of 50 g/day.

4 Micronutrient Assessment

4.1 Vitamin A minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a vitamin A minimum of 600 µgRE/day. Whereas, the EU 2017/1798 prescribes a higher minimum of 700 µgRE/day.



^ *Codex and the EU specify a minimum intake for Vitamin A and does not specify a maximum permitted concentration.*

Figure 4.1 Reported vitamin A content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated vitamin A content of VLED against the ANZ female and male RDI. Consumption of three VLED per day provided an average vitamin A intake of approximately 800 - 1077 µgRE/day. An additional 154 µgRE/day of vitamin A is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average vitamin A intake to approximately 954 – 1231 µgRE/day. This level meets both the male and female ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 vitamin A minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the vitamin A content of VLED against the ANZ UL of 3000 µgRE/day. No VLED posed risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed vitamin A content of VLED on the ANZ market (Figure 4.1). The survey found that vitamin A content of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum.

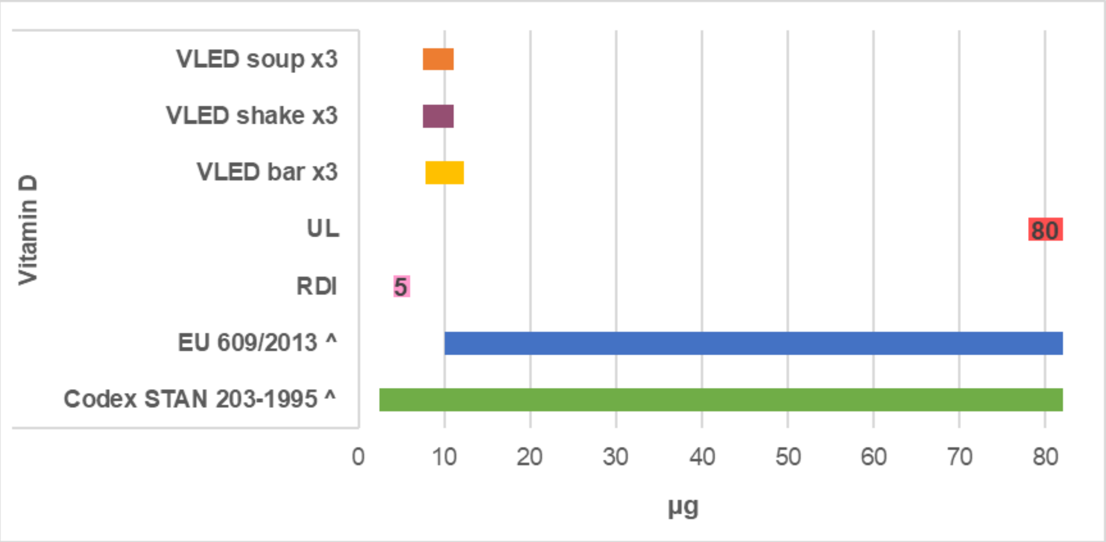
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessment, alignment with Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex vitamin A minimum of 600 µgRE/day.

4.2 Vitamin D minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a vitamin D minimum of 2.5 µg/day. Whereas, the EU 2017/1798 prescribes a higher minimum of 10 µg/day.



^ Codex and the EU specify a minimum intake for Vitamin D and does not specify a maximum permitted concentration.

Figure 4.2 Reported vitamin D content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated vitamin D content of VLED against the ANZ RDI. Consumption of three VLED per day provided an average vitamin D intake of approximately 7.6– 11.5 µg/day. An additional 1.1 µg/day of vitamin D is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average vitamin D intake to approximately 8.7 – 12.6 µg/day. This level meets the ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 vitamin D minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the vitamin D content of VLED against the ANZ UL of 80 µg/day. No VLED posed risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed vitamin D content of VLED on the ANZ market (Figure 4.2). The survey found that vitamin D content of VLED complied with the Codex STAN 203-1995 minimum. Only the upper end of vitamin D content for all VLED complied with the EU 2017/1798 minimum.

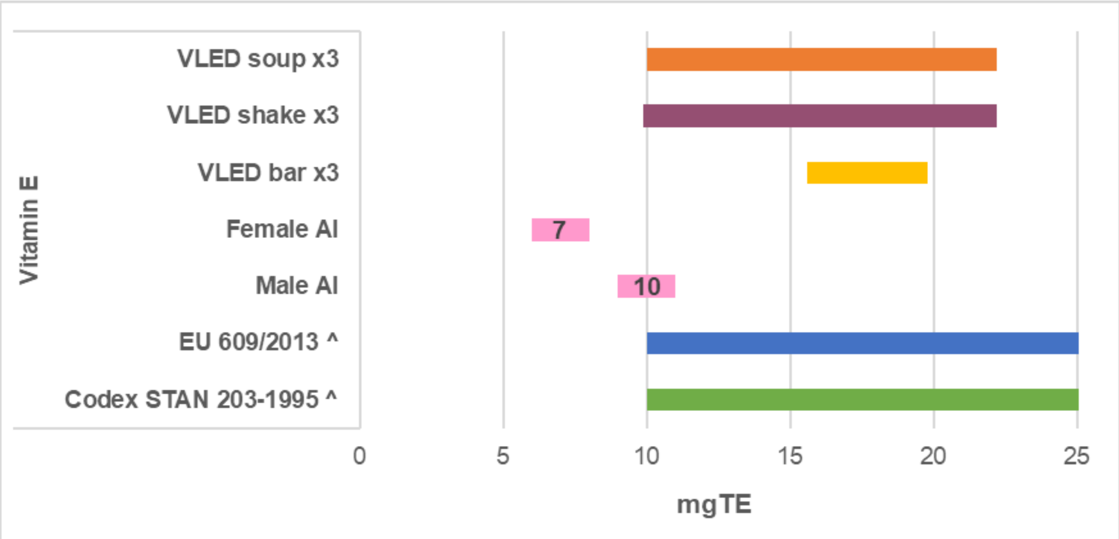
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessment, alignment with Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex vitamin D minimum of 2.5 µg/day.

4.3 Vitamin E minimum

Current regulations

Codex STAN 203-1995 and the EU 2017/1798 vitamin E minimums are aligned at 10 mgTE/day.



^ Codex and the EU specify a minimum intake for Vitamin E and does not specify a maximum permitted concentration.

Figure 4.3 Reported vitamin E content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated vitamin E content of VLED against the ANZ male and female AI. Consumption of three VLED per day provided an average vitamin E intake of approximately 11.8 – 21.4 mgTE/day. An additional 2.6 mgTE/day of vitamin E is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average vitamin E intake to approximately 14.4 – 24 mgTE/day. This level meets both the male and female ANZ AI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 vitamin E minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the vitamin E content of VLED against the ANZ

UL of 300 mgTE/day. No VLED posed risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed vitamin E content of VLED on the ANZ market (Figure 4.3). The survey found that vitamin E content of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum.

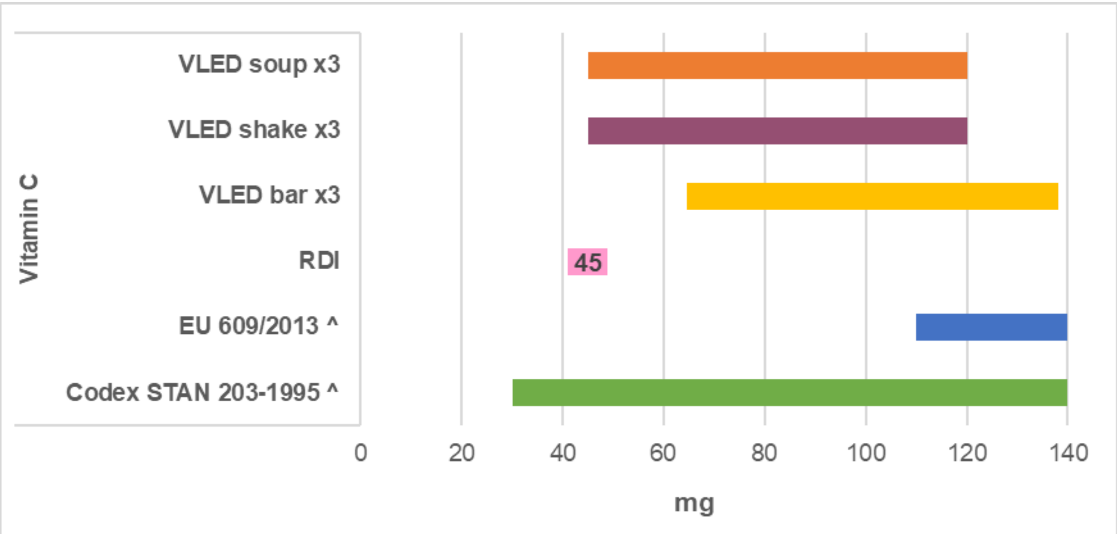
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessment, alignment between Codex STAN 203-1995, EU 2017/1798 and what is currently on the ANZ market, FSANZ proposes to adopt the vitamin E minimum of 10 mgTE/day.

4.4 Vitamin C minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a vitamin C minimum of 30 mg/day. Whereas, the EU 2017/1798 prescribes a higher minimum of 110 mg/day.



^ Codex and the EU specify a minimum intake for Vitamin C and does not specify a maximum permitted concentration.

Figure 4.4 Reported vitamin C content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated vitamin C content of VLED against the ANZ RDI. Consumption of three VLED per day provided an average vitamin C intake of approximately 51– 126 mg/day. An additional 50 mg/day of vitamin C is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average vitamin C intake to approximately 102 – 176 mg/day. This level meets the ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 vitamin C minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety of vitamin C content in VLED was unable to be assessed as there in no established UL. This is due to inconclusive evidence. However, expert bodies have suggested that no more than 1000 mg/day for adults should be consumed (NHMRC and NZ MOH, 2006). No VLED posed risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed vitamin C content of VLED on the ANZ market (Figure 4.4). The survey found that vitamin C content of VLED complied with the Codex STAN 203-1995 minimum. Only the upper end of vitamin C content of VLED complied with the EU 2017/1798 minimum.

Options and discussions

The EU 2017/1798 higher minimum is based on the EFSA (2015) opinion that VLED should provide vitamin C corresponding with the population reference intake (PRI) for adults. Within the ANZ population the RDI is lower at 45 mg/day, which is comparable to the Codex STAN 203-1995 minimum.

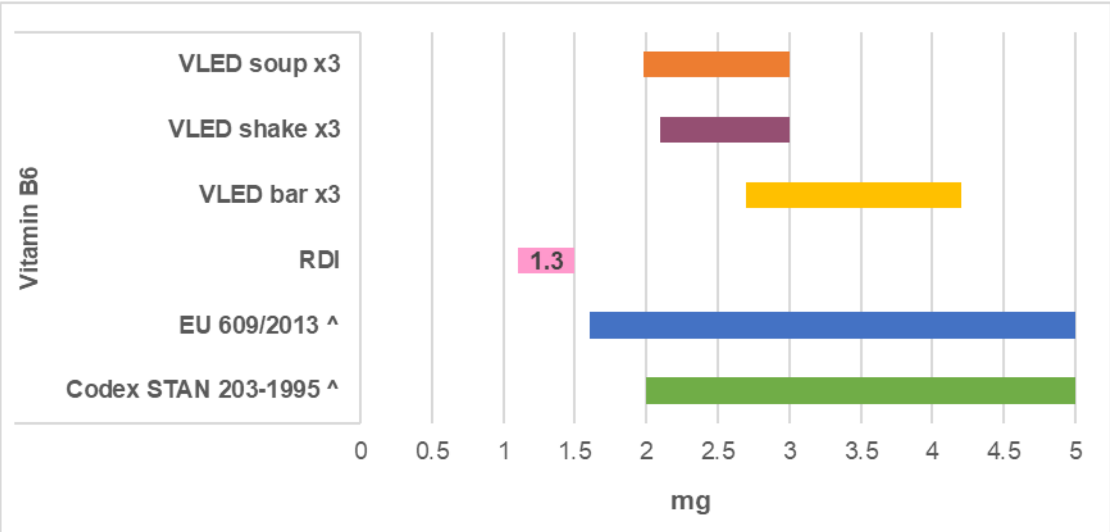
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessment, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex vitamin C minimum of 30 mg/day.

4.5 Vitamin B6 minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a vitamin B6 minimum of 2 mg/day. Whereas, the EU 2017/1798 prescribes a lower minimum of 1.6 mg/day.



^ *Codex and the EU specify a minimum intake for Vitamin B6 and does not specify a maximum permitted concentration.*

Figure 4.5 Reported vitamin B6 content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated vitamin B6 content of VLED against the ANZ RDI. Consumption of three VLED per day provided an average vitamin B6 intake of approximately 2.3 – 3.4 mg/day. An additional 1.0 mg/day of vitamin B6 is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average vitamin B6 intake to approximately 3.3 – 4.4 mg/day. This level meets the ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 vitamin B6 minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the vitamin B6 content of VLED against the ANZ UL of 50 mg/day. No VLED posed any risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed vitamin B6 content of VLED on the ANZ market (Figure 4.5). The survey found that vitamin B6 content of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum.

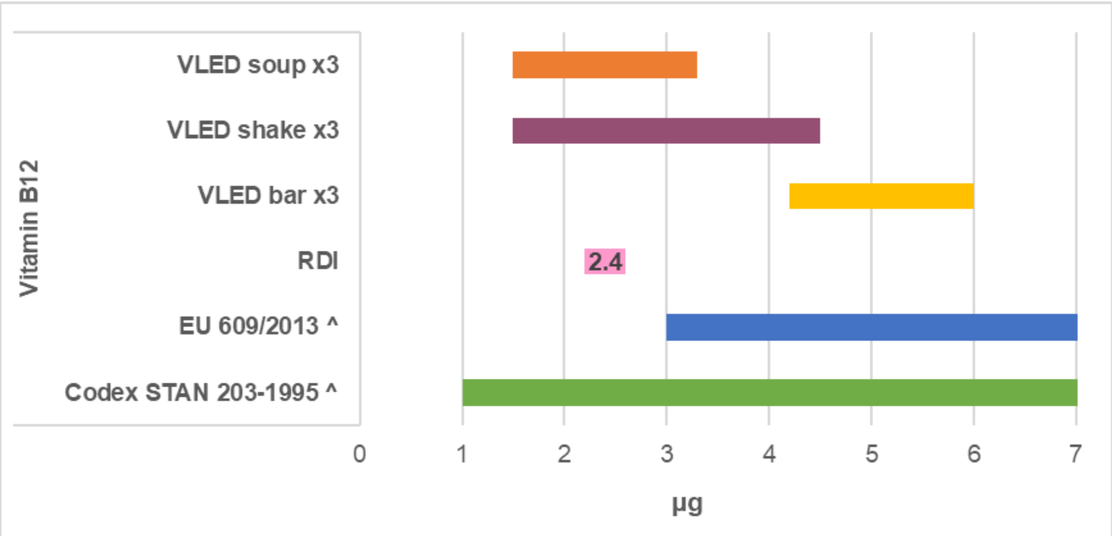
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessment, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex vitamin B6 minimum of 2 mg/day.

4.6 Vitamin B12 minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide a vitamin B12 minimum of 1 µg/day. Whereas, the EU 2017/1798 prescribes a higher minimum of 3 µg/day.



^ Codex and the EU specify a minimum intake for vitamin B12 and does not specify a maximum permitted concentration.

Figure 4.6 Reported vitamin B12 content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated vitamin B12 content of VLED against the ANZ RDI. Consumption of three VLED per day provided an average vitamin B12 intake of approximately 2.4 – 4.6 µg/day. This level meets the ANZ RDI. No additional vitamin B12 is provided through the low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 vitamin B12 minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety of vitamin B12 content in VLED was unable to be assessed as there in no UL set due to insufficient evidence that the current level of intake from foods and supplements represent a health risk (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed vitamin B12 content of VLED on the ANZ market (Figure 4.6). The survey found that vitamin B12 content of VLED complied with the Codex STAN 203-1995. The lower range of VLED vitamin B12 content did not comply with the EU 2017/1798 minimum. This was predominately evident in the VLED soup and shake products.

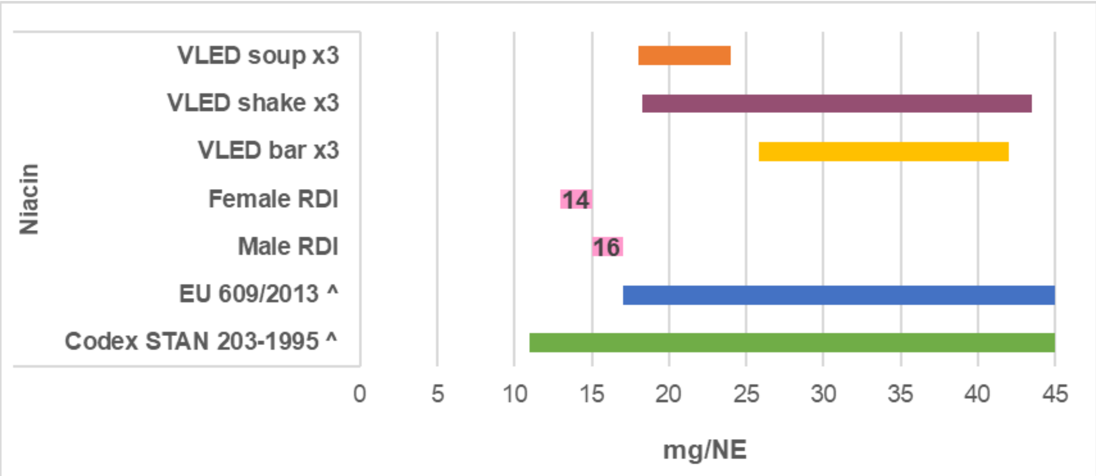
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessment, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex vitamin B12 minimum of 1 µg/day.

4.7 Niacin minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 11 mgNE/day of niacin. Whereas, the EU 2017/1798 prescribes a higher minimum of 17 mgNE/day. The RDI for niacin is 16 mgNE/day.



^ Codex and the EU specify a minimum intake for niacin and does not specify a maximum permitted concentration.

Figure 4.7 Reported niacin content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated niacin content of VLED against the male and female ANZ RDI. Consumption of three VLED per day provided an average niacin intake of approximately 20.7 – 36.5 mgNE/day. An additional 2.8 mgNE/day is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average niacin intake to approximately 23.5 – 39.3 mgTE/day. This level meets both the male and female ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 niacin minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the niacin content of VLED against the ANZ UL for nicotinamide of 900 mg/day (NHMRC and NZ MOH, 2006). No VLED posed risk of reaching this limit.

Niacin in the form of nicotinic acid has a lower UL of 35 mg/day (NHMRC and NZ MOH, 2006), however it is assumed that this form is not used in VLED, as its use would not allow individuals to meet the ANZ RDI given its lower UL.

ANZ market assessment

The FSANZ 2021 label survey assessed niacin content of VLED on the ANZ market (Figure 4.7). The survey found that niacin content of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum.

Options and discussions

FSANZ is aware that in most instances nicotinamide is the preferred form of niacin over nicotinic acid. This allows FSANZ to have confidence in VLED not meeting the UL. Niacin bioavailability, like many nutrients, varies according to the form of niacin and the food matrix. The nutrient status of an individual can also affect the response to dietary or supplemental niacin intake.

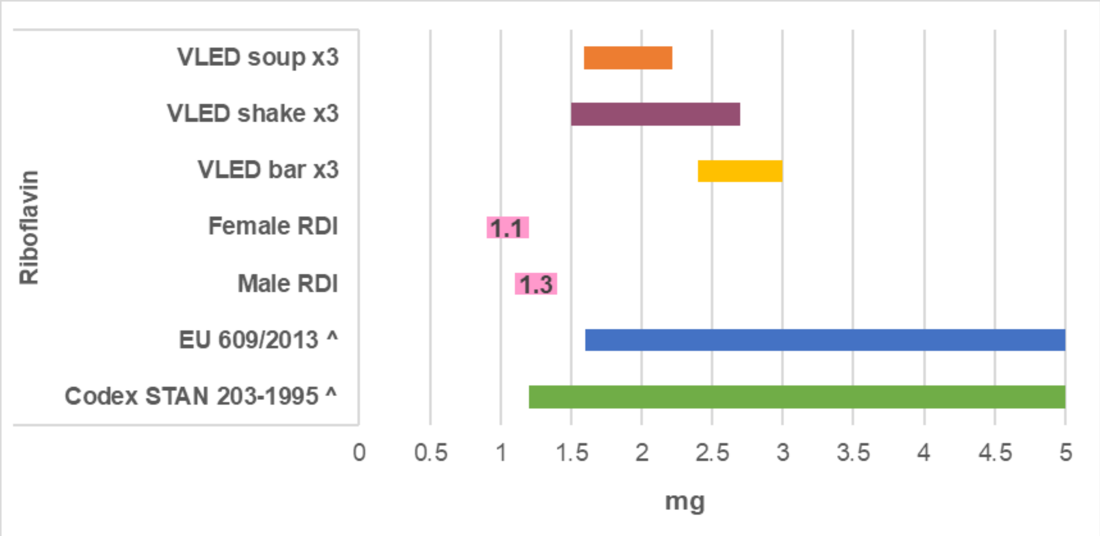
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessment, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex niacin minimum of 11 mgNE/day.

4.8 Riboflavin minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 1.2 mg/day of riboflavin. Whereas, the EU 2017/1798 prescribes a higher minimum of 1.6 mg/day.



^ Codex and the EU specify a minimum intake for riboflavin and does not specify a maximum permitted concentration.

Figure 4.8 Reported riboflavin content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the riboflavin content of VLED against the ANZ male and female RDI. Consumption of three VLED per day provided an average intake of 1.8 – 2.6 mg/day of riboflavin and met both ANZ RDIs. Minimal riboflavin (0.1 mg/day) is provided through the low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 riboflavin minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety of riboflavin content in VLED was unable to be assessed as there in no UL set due to insufficient evidence (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed riboflavin content of VLED on the ANZ market (Figure 4.8). The survey found that riboflavin content of VLED complied with the Codex STAN 203-1995 minimum, however if a VLED was made up of only shakes a small portion of the riboflavin nutrient content did not meet the EU 2017/1798 minimum.

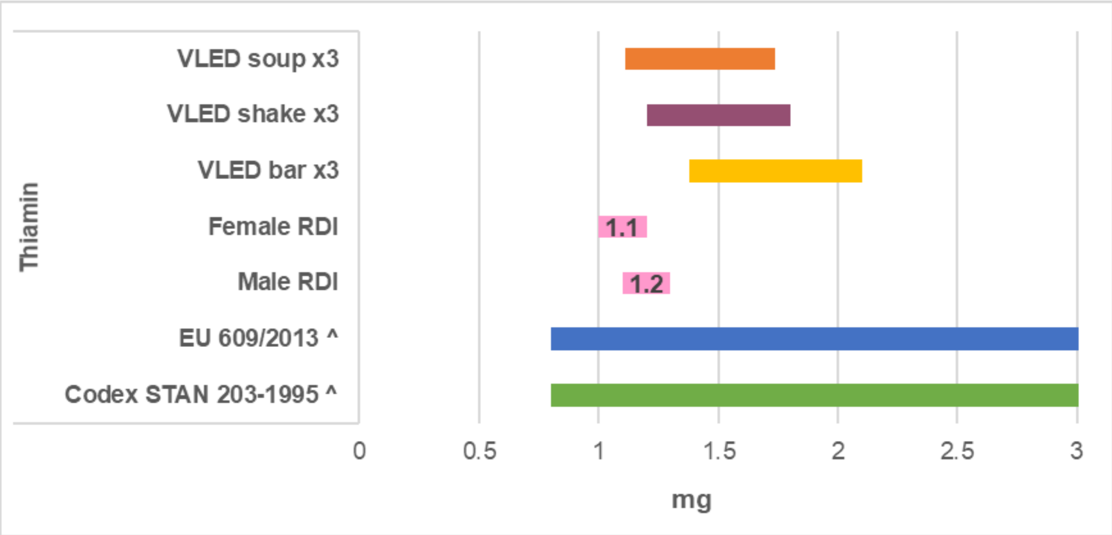
Proposed approach

Based on the conclusions of the nutritional adequacy assessment, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex riboflavin minimum of 1.2 mg/day.

4.9 Thiamin minimum

Current regulations

Both Codex STAN 203-1995 and EU 2017/1798 prescribe very low energy diets shall provide at least 0.8 mg/day of thiamin.



^ Codex and the EU specify a minimum intake for thiamin and does not specify a maximum permitted concentration.

Figure 4.9 Reported thiamin content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the thiamin content of VLED against the ANZ male and female RDI. Consumption of three VLED per day provided an average intake of 1.2 – 1.8 mg/day of riboflavin and met both ANZ RDIs. Minimal thiamine (0.1 mg/day) is provided through the low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 thiamin minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety of thiamin content in VLED was unable to be assessed as there in no UL set due to insufficient evidence (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed thiamin content of VLED on the ANZ market (Figure 4.9). The survey found that thiamin content of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum.

Proposed approach

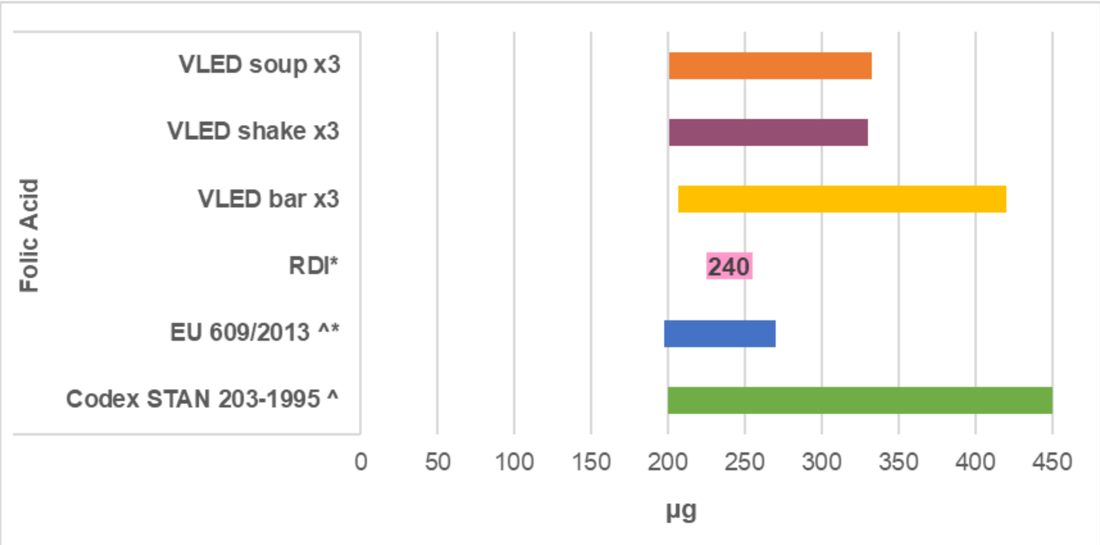
As there is already harmonisation between two internationally recognised standards, which have proven to be safe and suitable, FSANZ does not believe there are any concerns in adopting a thiamine minimum of 0.8 mg/day within the context of the ANZ population and market.

Based on above, FSANZ proposes to adopt the thiamin minimum of 0.8 mg/day.

4.10 Folic Acid minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 200 µg/day of folic acid (as monoglutamate). Whereas, the EU 2017/1798 prescribes a minimum of 330 µg/day of Dietary Folate Equivalents (DFE). The ANZ RDI for folate is 400 µg/day of DFE.



^ Codex and the EU specify a minimum intake for folic acid and does not specify a maximum permitted concentration.
** The EU 2017/1798 and ANZ RDI have been converted from DFE to units of folic acid for ease of comparison.*

Figure 4.10 Reported folic acid content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the folic acid content of VLED against the ANZ RDI. The ANZ population has an EAR of 320 µg/day and a RDI of 400 µg/day of DFE. 1 µg of DFE is equivalent to 1 µg food folate, 0.5 µg folic acid on an empty stomach and/or 0.6 µg folic acid with meals or as a fortified food (NHMRC and NZ MOH, 2006).

Standard equivalence factors provide an internationally recognised approach for addressing this conversion. Therefore the evidence demonstrating DFE as a bioavailable form of folic acid sufficiently upholds the principle of nutritional equivalence. Based on the above, the ANZ population has an RDI equivalent to 240 µg/day for folic acid.

Consumption of three VLED per day provided an average of 200 - 360 µg/day of folic acid, which meets the folic acid equivalent of the ANZ RDI. An additional 60 µg/day of folic acid is provided through the low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, increasing the average folic acid intake of 260 - 420 µg/day.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 folic acid minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the folic acid content of VLED against the ANZ UL of 1000 µg/day (NHMRC and NZ MOH, 2006). No VLED posed risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed folic acid content of VLED on the ANZ market (Figure 4.10). The survey found that folic acid content of VLED complied with the Codex STAN 203-1995 minimum. Due to the difference in units between what is declared on ANZ VLED and the EU 2017/1798, there seems to be misalignment between the two. However, once conversions are factored in products on the ANZ market do meet the folic acid equivalent of the EU 2017/1798 (198 µg/day).

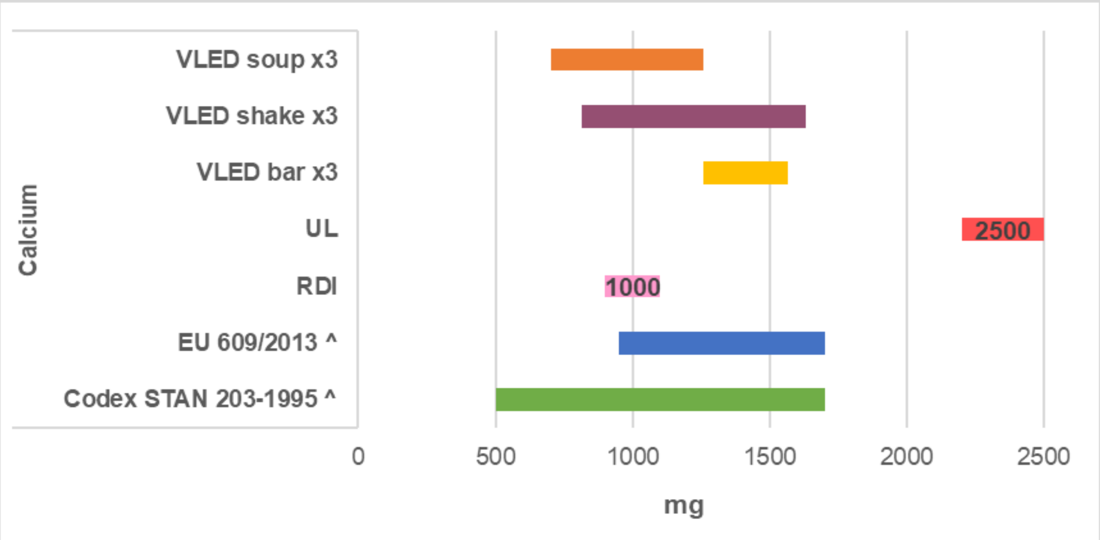
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessments, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 folic acid minimum of 200 µg/day. FSANZ also proposes that folic acid will used as the unit of expression.

4.11 Calcium minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 500 mg/day of calcium. Whereas, the EU 2017/1798 prescribes a higher minimum of 950 mg/day.



^ *Codex and the EU specify a minimum intake for calcium and does not specify a maximum permitted concentration.*

Figure 4.11 Reported calcium content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated calcium content of VLED against the ANZ RDI. Consumption of three VLED per day provided an average calcium intake of approximately 926 – 1485 mg/day. An additional 84 mg/day of calcium is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average calcium intake to approximately 1000 – 1500 mg/day. This level meets the ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 calcium minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the calcium content of VLED against the ANZ UL of 2500 mg/day (NHMRC and NZ MOH, 2006). VLED did not pose risk of reaching this limit. The calcium UL is set conservatively at 2500 mg/day due to the relatively common occurrence of kidney stones in the ANZ population.

Based on the above, the nutritional safety assessment considers that the use of the Codex STAN 203-1995 calcium minimum does not pose risk to nutritional safety.

ANZ market assessment

The FSANZ 2021 label survey assessed calcium content of VLED on the ANZ market (Figure 4.11). The survey found that calcium content of the majority of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum. The lower range of VLED soups and shakes did not comply with the EU 2017/1798 minimum.

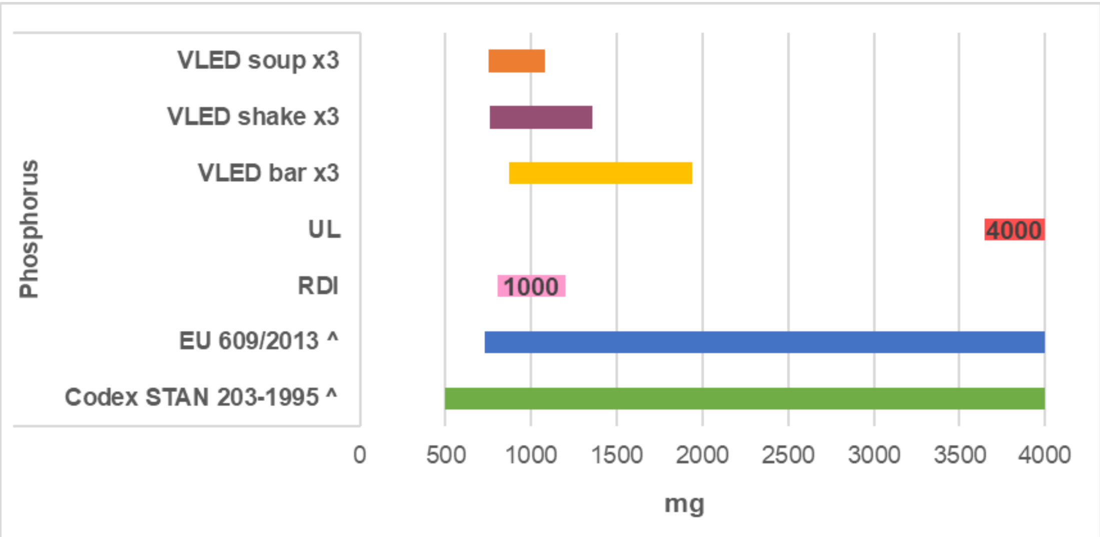
Proposed approach

Based on the conclusions of the nutritional adequacy assessment, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 calcium minimum of 500 mg/day.

4.12 Phosphorus minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 500 mg/day of phosphorus. Whereas, the EU 2017/1798 prescribes a higher minimum of 730 mg/day.



^ Codex and the EU specify a minimum intake for Phosphorus and does not specify a maximum permitted concentration.

Figure 4.12 Reported phosphorous content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the phosphorus content of VLED against the ANZ RDI. Consumption of three VLED per day provided an average phosphorus intake of 800 – 1460 mg/day. An additional 155 mg/day of phosphorus is provided through the low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, bringing the total phosphorus intake to 955 – 1615 mg/day. This level meets the ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 phosphorous minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the phosphorus content of VLED against the ANZ UL of 4000 mg/day (NHMRC and NZ MOH, 2006). VLED did not pose risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed phosphorus content of VLED on the ANZ market (Figure 4.12). The survey found that phosphorus content of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum.

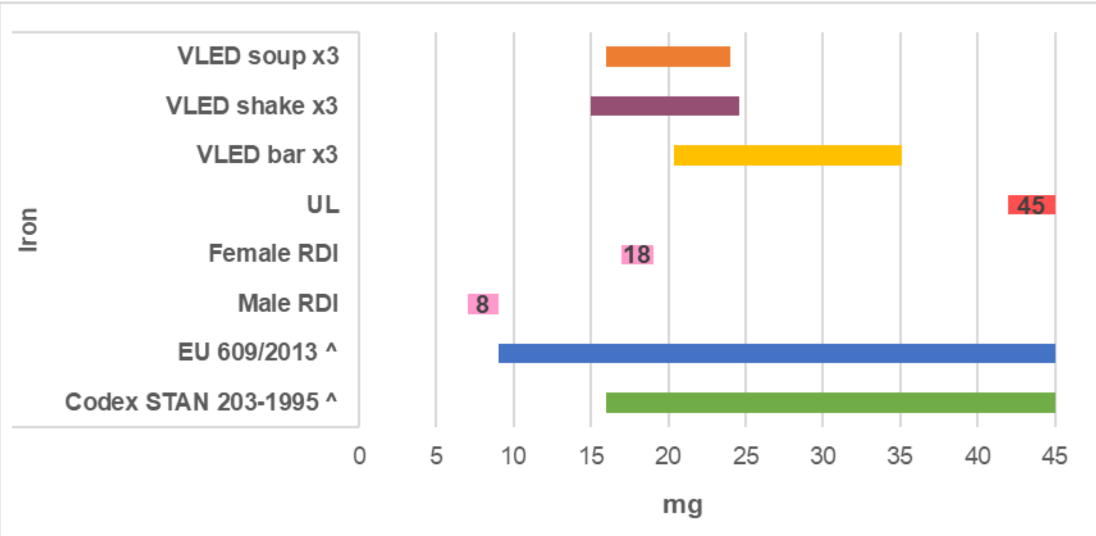
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessments, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 phosphorus minimum of 500 mg/day.

4.13 Iron minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 16 mg/day of iron. Whereas, the EU 2017/1798 prescribes a lower minimum of 9 mg/day.



^ Codex and the EU specify a minimum intake for iron and does not specify a maximum permitted concentration.

Figure 4.13 Reported iron content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the iron content of VLED against the ANZ male and female RDI. Consumption of three VLED per day provided an average iron intake of 20 – 30 mg/day, which meets the ANZ male and female RDI. An additional 2.4 mg/day of iron is provided through low starch vegetables and vegetable oil prescribed in the total diet replacement plan.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 iron minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the iron content of VLED against the ANZ UL of 45 mg/day (NHMRC and NZ MOH, 2006). No VLED reached the UL. The highest iron contributor, was VLED bars. Consumption of three VLED bars provides 35 mg/day of iron, which is relatively close to the UL.

ANZ market assessment

The FSANZ 2021 label survey assessed iron content of VLED on the ANZ market (Figure 4.13). The survey found that iron content in the majority of VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum. The lower bound level of a VLED consisting of three shakes (15 mg/day) did not meet the Codex STAN 203-1995 minimum (16 mg/day).

Options and discussions

The nutritional safety assessment notes that VLED bars are the highest contributor to iron in the intensive level total diet replacement plan. The treating medical professional holds the responsibility of managing this nutrient. The total diet replacement plan recommends consuming a mix of VLED, so it is highly unlikely that an individual would consume only three VLED bars per day on an ongoing basis.

Despite this, within the ANZ population the Codex STAN 203-1995 minimum is more appropriate as it ensures that the female RDI for iron is met. This is nutrient of concern within the female population as there is variability of iron loss during menstruation (NHMRC and NZ MOH, 2006). The lower EU 2017/1798 minimum (9 mg/day) would not ensure that the ANZ female RDI is met.

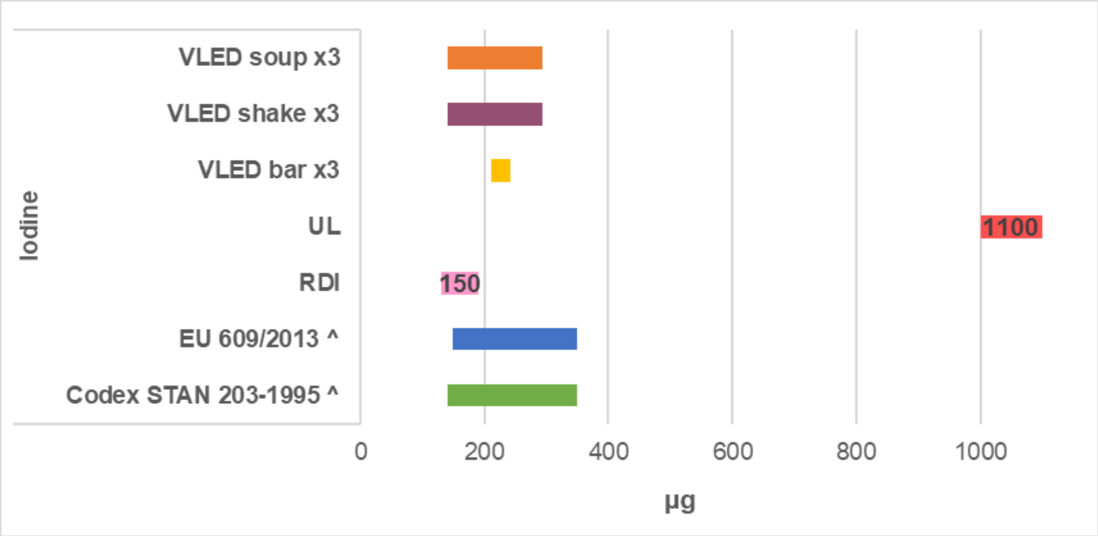
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessments, appropriateness within the ANZ population and alignment between Codex STAN 203-1995, FSANZ proposes to adopt the Codex STAN 203-1995 iron minimum of 16 mg/day.

4.14 Iodine minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 140 µg/day of iodine. Whereas, the EU 2017/1798 prescribes a higher minimum of 150 µg/day.



^ Codex and the EU specify a minimum intake for iodine and does not specify a maximum permitted concentration.

Figure 4.14 Reported iodine content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the iodine content of VLED against the ANZ RDI. Consumption of three VLED per day provided an average iodine intake of approximately 165 – 280 µg/day, which meets the ANZ RDI. An additional 2.5 µg/day of iodine is provided through the low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 iodine minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated the iodine content of VLED against the ANZ UL of 1100 µg/day (NHMRC and NZ MOH, 2006). VLED did not pose risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed iodine content of VLED on the ANZ market (Figure 4.14). The survey found that iodine content in the VLED complied with the Codex STAN 203-1995 and EU 2017/1798 minimum.

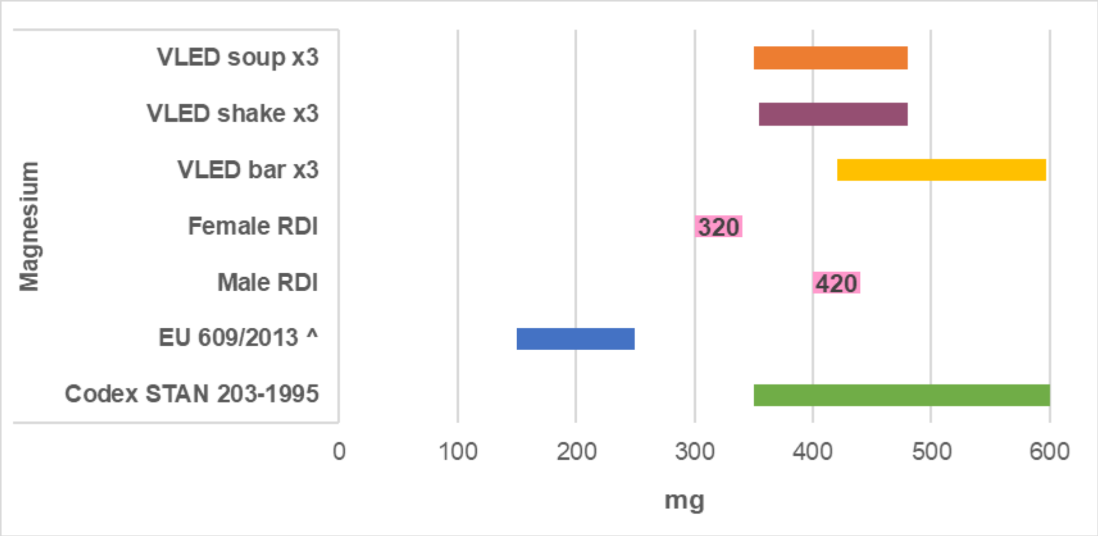
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessments, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 iodine minimum of 140 µg/day.

4.15 Magnesium minimum and maximum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 350 mg/day of magnesium. Whereas, the EU 2017/1798 prescribes a range of 150 – 250 mg/day.



^ Codex and the EU specify a minimum intake for magnesium and does not specify a maximum permitted concentration.

Figure 4.15 Reported magnesium content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated the magnesium content of VLED against the ANZ male and female RDI. Consumption of three VLED per day provided an average magnesium intake of approximately 375 – 520 mg/day. An additional 53 mg/day of magnesium is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average magnesium intake to approximately 430 – 570 mg/day. This level meets both the male and female ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 magnesium minimum does not pose risk to nutritional adequacy.

The EU 2017/1798 prescribed range of 150 – 250 mg/day does not allow the male or female ANZ RDI to be met. The EU 2017/1798 magnesium maximum is likely to pose risk to nutritional adequacy of the ANZ population.

Nutritional safety assessment

The nutritional safety of magnesium content in VLED was unable to be assessed because there is no UL (NHMRC and NZ MOH, 2006).

Magnesium as a supplement has an UL of 350mg/day (NHMRC and NZ MOH, 2006). There is limited evidence in support of setting ULs for magnesium as it has not been shown to produce toxic effect when ingested as naturally occurring magnesium in food (NHMRC and NZ MOH, 2006). This UL is specific to supplemented therapeutic magnesium intake, does not apply to intakes from food or account for the interactions of food matrices. Because of this the UL is not applicable to VLED and the nutritional safety assessment considers that the Codex STAN 203-1995 magnesium minimum does not pose risk to safety.

ANZ market assessment

The FSANZ 2021 label survey assessed magnesium content of VLED on the ANZ market (Figure 4.15). The survey found that magnesium content in the VLED assessed complied with the Codex STAN 203-1995 minimum. VLED on the ANZ market complied with the EU 2017/1798 magnesium range.

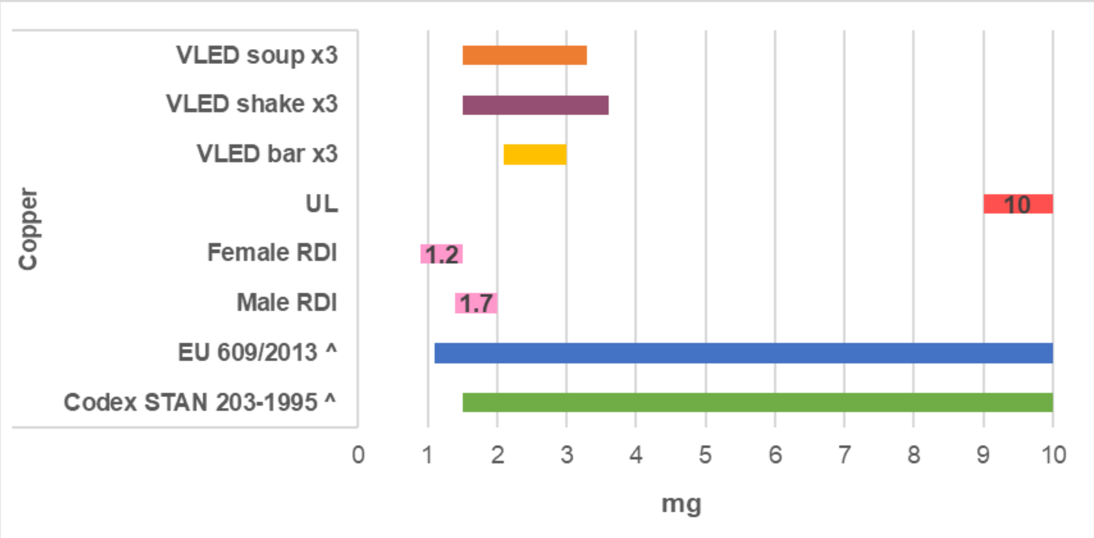
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessments, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 magnesium minimum of 350 mg/day. In the absence of an UL, FSANZ does not propose to set a maximum level for magnesium.

4.16 Copper minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 1.5 mg/day of copper. Whereas, the EU 2017/1798 prescribes a lower minimum of 1.1 mg/day.



^ Codex and the EU specify a minimum intake for copper and does not specify a maximum permitted concentration.

Figure 4.16 Reported copper content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated copper content of VLED against the ANZ male and female RDI. Consumption of three VLED per day provided an average copper intake of approximately 1.7 – 3.3 mg/day. An additional 0.5 mg/day of copper is provided through low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average copper intake to approximately 2.2 – 3.3 mg/day. This level meets both the male and female ANZ RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 copper minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety assessment evaluated copper content of VLED against the ANZ UL of 10 mg/day (NHMRC and NZ MOH, 2006). VLED did not pose risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed copper content of VLED on the ANZ market (Figure 4.16). The survey found that copper content of VLED assessed complied with the

Codex STAN 203-1995 and EU 2017/1798 copper minimum.

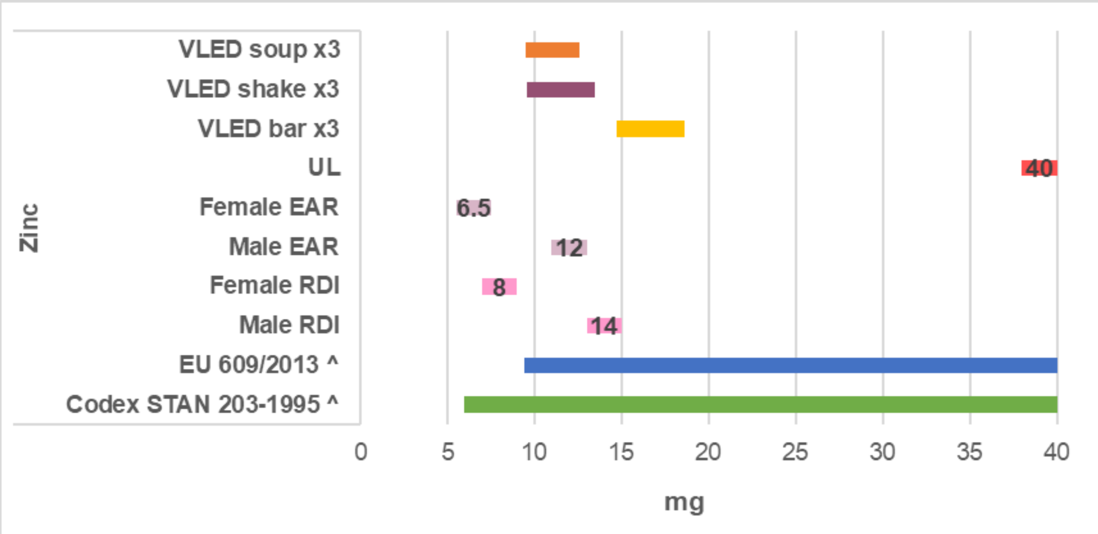
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessments, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 copper minimum of 1.5 mg/day.

4.17 Zinc minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 6 mg/day of zinc. Whereas, the EU 2017/1798 prescribes a higher minimum of 9.4 mg/day.



^ Codex and the EU specify a minimum intake for zinc and does not specify a maximum permitted concentration.

Figure 4.17 Reported zinc content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated zinc content of VLED against the ANZ EAR and RDI, for males and females. Consumption of three VLED per day provided an average zinc intake of approximately 11.5 – 15 mg/day. An additional 1.1 mg/day of zinc is provided via low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average zinc intake to approximately 12.5 – 16 mg/day. This range exceeds the ANZ EAR and RDI for females, however only part of the range meets the ANZ EAR and RDI for males.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 zinc minimum does not pose risk to nutritional adequacy for females and poses low risk of nutritional adequacy for males.

Nutritional safety assessment

The nutritional safety assessment evaluated zinc content of VLED against the ANZ UL of 40 mg/day (NHMRC and NZ MOH, 2006). No VLED posed risk of reaching this limit.

ANZ market assessment

The FSANZ 2021 label survey assessed zinc content of VLED on the ANZ market (Figure 4.17). The survey found that VLED complied with the Codex STAN 203-1995 and EU 2017/1798 zinc minimum.

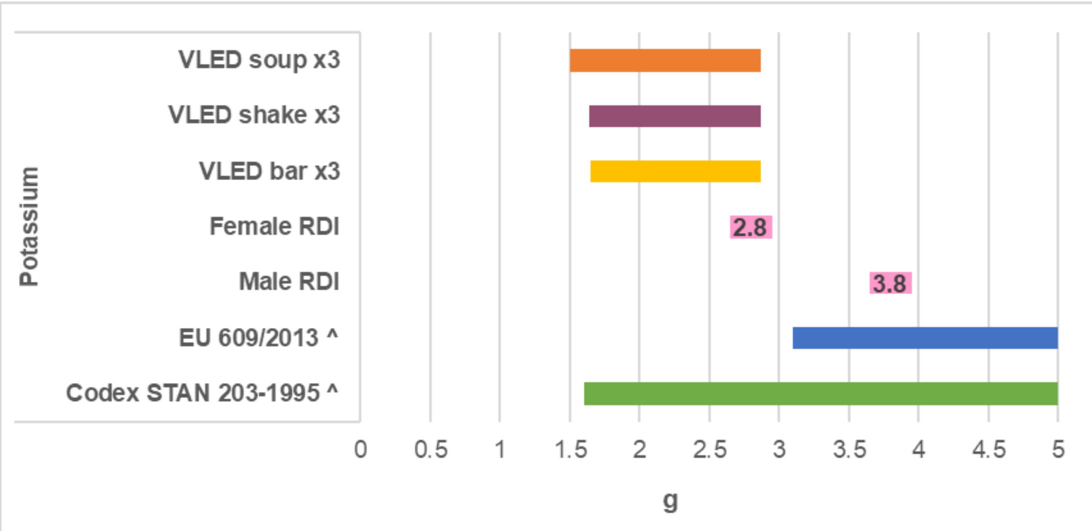
Proposed approach

Based on the conclusions of the nutritional adequacy and safety assessments, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 zinc minimum of 6 mg/day.

4.18 Potassium minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 1.6 g/day of potassium. Whereas, the EU 2017/1798 prescribes a higher minimum of 3.1 g/day.



^ Codex and the EU specify a minimum intake for potassium and does not specify a maximum permitted concentration.

Figure 4.18 Reported potassium content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated potassium content of VLED against the ANZ male and female RDI. Consumption of three VLED per day provided an average potassium intake of approximately 1.6 – 1.9 g/day. An additional 0.9 g/day of potassium is provided via low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average potassium intake to approximately 2.5 – 3.8 g/day. This majority of this range exceeds the ANZ RDI for females, however only does not satisfy the male RDI.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 potassium minimum does not pose risk to nutritional adequacy for females.

In the context of the intensive level total diet replacement plan, the nutritional adequacy assessment considers that the Codex STAN 203-1995 potassium minimum poses low risk of nutritional adequacy for males given the acute period of use.

Nutritional safety assessment

The nutritional safety of potassium content in VLED was unable to be assessed as there is no UL set for potassium from dietary sources (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed potassium content of VLED on the ANZ market (Figure 4.18). The survey found that the majority of VLED complied with the Codex STAN 203-1995 minimum. The lower end of VLED comprised of three soups (1.5 g/day) did not meet the Codex STAN 203-1995 minimum. No VLED on the ANZ market complied with the EU 2017/1798 potassium minimum.

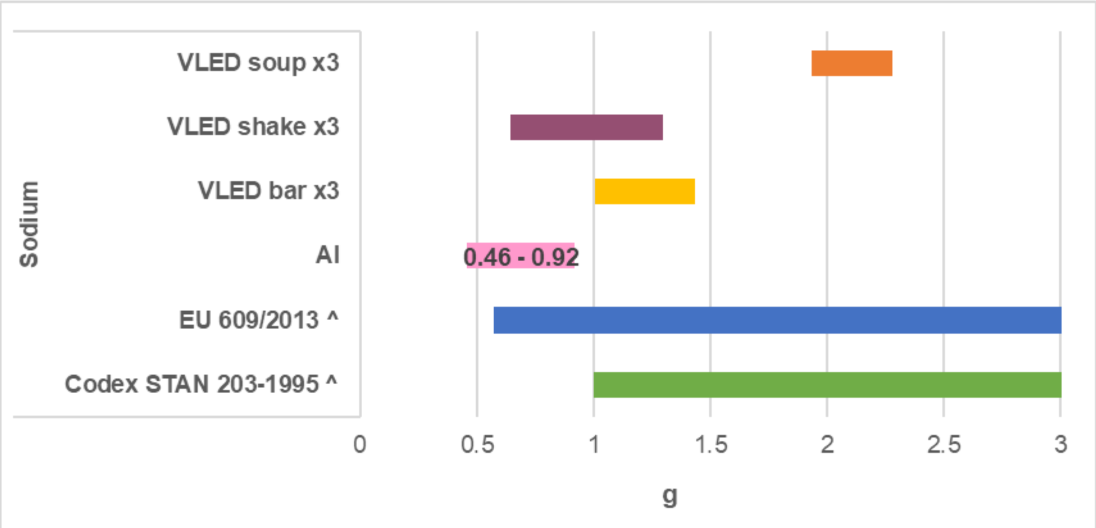
Proposed approach

Based on the conclusion of the nutritional adequacy assessment, alignment between Codex STAN 203-1995 and what is currently on the ANZ market, FSANZ proposes to adopt the Codex STAN 203-1995 potassium minimum of 1.6 g/day.

4.19 Sodium minimum

Current regulations

Codex STAN 203-1995 prescribes very low energy diets shall provide at least 1 g/day of sodium. Whereas, the EU 2017/1798 prescribes a lower minimum of 0.575 g/day.



^ Codex and the EU specify a minimum intake for sodium and does not specify a maximum permitted concentration.

Figure 4.19 Reported sodium content of VLED compared to international regulations and ANZ NRVs

Nutritional adequacy assessment

The nutritional adequacy assessment evaluated sodium content of VLED against the ANZ AI of 0.46 – 0.92 g/day. Consumption of three VLED per day provided an average sodium intake of approximately 1.2 – 1.7 g/day. An additional 0.1 g/day of sodium is provided through the low starch vegetables and vegetable oil prescribed in the intensive level total diet replacement plan, which brings the average sodium intake to approximately 1.3 – 1.8 g/day. This range meets the ANZ AI.

The ANZ AI for sodium also accounts for the maintenance of sodium balance within hot climates.

Based on the above, the nutritional adequacy assessment considers that the use of the Codex STAN 203-1995 sodium minimum does not pose risk to nutritional adequacy.

Nutritional safety assessment

The nutritional safety of sodium content in VLED was unable to be assessed as the UL for sodium is unable to be determined for ANZ adults (NHMRC and NZ MOH, 2006).

ANZ market assessment

The FSANZ 2021 label survey assessed sodium content of VLED on the ANZ market (Figure 4.19). The survey found that the majority of VLED complied with the Codex STAN 203-1995 minimum, expect for the lower end of VLED comprising of three shakes (0.6 g/day). VLED on the ANZ market complied with the EU 2017/1798 sodium minimum.

Proposed approach

Based on the conclusion of the nutritional adequacy assessment and appropriateness in meeting the ANZ AI, FSANZ proposes to adopt the Codex STAN 203-1995 sodium minimum of 1 g/day.

5 Additional nutrient composition, not prescribed in Codex STAN 203-1995

Codex STAN 203-1995 does not prescribe minimums or maximums for any of the following nutrients. The EU 2017/1798 minimums and ANZ NRVs are noted below in Table 6.1.

Table 5.1 EU 2017/1798, ANZ NRVs and dietary intake of nutrients not prescribed in Codex STAN 203-1995

Nutrient	Unit	EU 2017/1798	ANZ NRV[1]	Dietary Intake[2]
Biotin	µg	40	25 – 30	50
Pantothenic Acid	mg	5	4 – 6	6
Vitamin K	µg	70	60 – 70	91
Manganese	mg	3	5 – 5.5	2
Chromium	µg	NA	25 – 35	59
Molybdenum	µg	65	45^	80
Selenium	µg	70	60 – 70^	73
Chloride	mg	830	NA	1198
Choline	mg	400	425 – 550	*
Dietary Fibre	g	NA	25 – 30	16
Fluoride	mg	NA	3 – 4	1

[1] ANZ NRVs: the AI was used in most cases, the RDI used when AI was not available. The ANZ NRV ranges note the female NRV as the lower value and the male NRV as the higher value.
[2] Dietary Intake: refers to intake from 3 VLED, 2 cups of low starch vegetables and 1 teaspoon vegetable oil as per the intensive level of the total diet replacement plan.
^ ANZ RDI
** Unable to collect information*
NA = No minimum set

VLED on the ANZ market do not pose risk to nutritional adequacy or safety in relation to the following nutrients; biotin, pantothenic acid, vitamin K, chromium, molybdenum, selenium and chloride. These nutrients met the relevant ANZ NRV and/or the relevant EU 2017/1798 minimum. Based on the above, there are no further considerations. FSANZ proposes to align with Codex STAN 203-1995 and not set any nutrient composition requirements for these nutrients.

5.1 Manganese

2 mg/day of manganese is provided through intake according to the intensive level total diet replacement plan. This intake does not meet the EU 2017/1798 minimum of 3mg/day or the ANZ AI of 5 – 5.5 mg/day for females and males, respectively. Despite not meeting the AI, nutritional adequacy is not of concern as the manganese AI is based on median population intakes and the total diet replacement plan encourages consumption of low energy drinks, such as tea which is a major contributor of manganese intake (NHMRC and NZ MOH, 2006). Tea consumption was not factored into assessment of dietary intake noted in Table 6.1.

Based on the above, FSANZ proposes to align with Codex STAN 203-1995 and not prescribe a minimum for manganese.

5.2 Choline

The nutritional adequacy of choline was unable to be assessed as VLED on the ANZ market do not list choline on the NIP and the AUSNUT (2011-13) food nutrient database does not report on choline content of foods within the ANZ market (FSANZ 2014). EFSA (2015) reported that most studies assessing the effects of VLED do not mentioned if and how much choline was provided by the diets.

Despite being unable to assess choline content of the intensive level total diet replacement plan, it is known that choline is widely distributed throughout the food supply and can also be produced endogenously within the body (NHMRC and NZ MOH, 2006). Milk is a particularly good source of choline, supplying 43 mg through 1 cup of 1% fat milk (U.S. Department of Agriculture, 2019). Choline sourced naturally from vegetables will also increase intake, as prescribed within the intensive level total diet replacement plan.

As discussed in section 4.2.2 Protein Quality, VLED are predominately based on milk, with milk protein, skimmed milk powder, casein and/or whole milk powder as the top ingredients in the products. It is assumed that inclusions of these ingredients within VLED will further increase incidental levels of choline within the products, despite not being declared on the NIP. Choline content is also dependant on the protein and fat sources, as animal derived sources typically contain higher amounts of choline (EFSA, 2015). Within section 4.2.2 Protein Quality, FSANZ has proposed that high quality proteins are used within VLED to achieved PDCAAS equivalent to 1. This further ensures use of animal protein sources continue to be used in VLED.

Addition of choline to VLED can also pose challenges for manufacturers as the taste profile of choline is quite unpalatable and reduces the shelf life of products. Consumer compliance to VLED is a critical aspect in the dietary management of overweight and obesity, which could be affect by the above factors. As very low energy diets do not represent a permeant diet regime, it is expected that choline stores would be present within the body prior to commencing the intensive diet phase and would also be restored when normal dietary intake is resumed.

Although choline is essential, data within the ANZ population shows that there appear to be no reports of deficiency within the general population (NHMRC and NZ MOH, 2006). Any nutritional adequacy concerns related to choline should be addressed under medical supervision.

Based on the above, FSANZ considers it appropriate to align with Codex STAN 203-1995 in prescribing no set nutrient composition for choline.

5.3 Dietary Fibre

16 g/day of dietary fibre is provided through intake according to the intensive level total diet replacement plan. This intake does not meet the ANZ AI of 25 – 30 g/day for females and males, respectively. The EU 2017/1798 does not prescribe a minimum for dietary fibre.

Resources used by medical professionals also encourage the intake of water and including a fibre supplement or psyllium husk to help reduce constipation and increase feeling of fullness (Baker Heart and Diabetes Institute, 2020). This diet intervention would support individuals to meet the ANZ AI for dietary fibre.

Based on neither the EU 2017/1798 or Codex STAN 203-1995 prescribing a minimum for dietary fibre within very low energy diets, FSANZ proposes to align with this approach. Any nutritional adequacy concerns related to dietary fibre should be addressed under medical supervision.

5.4 Fluoride

1 mg/day of fluoride is provided by three VLED, two cups of low starch vegetables and one teaspoon vegetable oil in accordance with the intensive level of the total diet replacement plan. This intake does not meet the ANZ AI of 3 – 4 mg/day for females and males, respectively. The EU 2017/1798 does not prescribe a minimum for fluoride.

The intensive level total diet replacement plan also recommends consumption of an additional two litres of water per day. This recommendation was not factored into the original dietary intake assessment as water does not typically increase nutrient intake. Australian drinking water supplies are fluoridated within the range of 0.6 – 1.1 mg/L (NHMRC, 2017) and New Zealand drinking water supplies are fluoridated within a similar range of 0.7 – 1.0 mg/L (MOH, 2018). Two litres of drinking water within ANZ provides an additional 1.2 – 2.2 mg/day of fluoride.

On average total fluoride intake would range between approximately 2.2 – 3.2 mg/day. This level satisfies the female AI and is 0.8 mg/day lower than the male AI (3 mg/day). However, this level could be easily achieved with increase fluid intake. As individuals using VLED are under medical supervision the risk associated with this is minimal. It is also important to note that there is less certainty surrounding AI levels and these are typically based on median population intakes.

Fluoride is also not a recognised mineral in the Code, as it is added to water supplies in most capital cities and is available in supplement form.

Based on the above, FSANZ does not consider that there are nutritional adequacy or safety concerns surrounding fluoride intake of VLED consumers. FSANZ proposes to align with the EU 2017/1798 and Codex STAN 203-1995 by not prescribing a minimum or maximum for fluoride in very low energy diets.

6 References

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Appendix 1 - Nutrient composition summary table

FSANZ proposes to align with Codex STAN 203-1995, for all nutrients listed below. This table includes minimums only, there are no maximum levels prescribed in Codex STAN 203-1995.

Nutrient	Unit	Codex STAN 203-1995	EU 2017/1798	A1230
Macronutrient				
Energy	kJ/day	1881 - 3344	2508 - 5016	1880 – 3345
Protein	g/day	50	75 - 105	50
Protein Quality	PDCAAS	1*	1*	1*
LA	g/day	3	11	3
ALA	g/day	0.5	1.4	0.5
LA:ALA	ratio	5 : 15	NS	5 :15
Carbohydrate	g/day	50	30	50
Micronutrient				
Vitamin A	µg retinol equivalents/day	600	700	600
Vitamin D	µg/day	2.5	10	2.5
Vitamin E	mgTE/day	10	10	10
Vitamin C	mg/day	30	110	30
Vitamin B_6	mg/day	2	1.6	2
Vitamin B_{12}	µg/day	1	3	1
Niacin	mgNE/day	11	17	11
Riboflavin	mg/day	1.2	1.6	1.2
Thiamin	mg/day	0.8	0.8	0.8
Folic Acid	µg/day	200	330 (DFE)	200
Calcium	mg/day	500	950	500
Phosphorus	mg/day	500	730	500
Iron	mg/day	16	9	16
Iodine	µg/day	140	150	140
Magnesium	mg/day	350	150 - 250	350
Copper	mg/day	1.5	1.1	1.5
Zinc	mg/day	6	9.4	6
Potassium	g/day	1.6	3.1	1.6
Sodium	g/day	1	0.575	1
Nutrients not included within Codex STAN 203-1995				
Biotin	µg/day	NS	40	FSANZ proposes to align with Codex STAN 203-1995 and not set any permissions for the
Pantothenic Acid	mg/day	NS	5	
Vitamin K	µg/day	NS	70	
Manganese	mg/day	NS	3	
Chromium	µg/day	NS	NS	
Molybdenum	µg/day	NS	65	
Selenium	µg/day	NS	70	

Chloride	mg/day	NS	830	following nutrients.
Choline	mg/day	NS	400	
Dietary Fibre	g/day	NS	NS	
Fluoride	mg/day	NS	NS	

** Essential amino acids may be added to improve protein quality only in amounts necessary for this purposes*
NS: Not Specified