Submission

Application A1230

VERY LOW ENERGY DIETS

[redacted]

KCL
Law 1981–2021
CELEBRATING 40 YEARS

[redacted]

17 December 2021

[redacted]

Email: [redacted]

[redacted]

Our client: Opti-Pharm Pty Ltd
Re: Application A1230

1. We refer to:-

   (a) Your Final Assessment Report on Proposal P242, Food for Special Medical Purposes ("**FSPM**") dated 2 May 2012("**P242 FAR**");

   (b) Standard 2.9.5 of the *Australia New Zealand Food Standards Code* ("**the Code**");

   (c) Nestlé Australia Ltd and Nestlé New Zealand Ltd's (collectively referred to as "**Nestle**" or "**the Applicant**") Application A1230 to vary Standard 2.9.5 to include Very Low Energy Diet ("**VLED**") products ("**Application**"); and

   (d) FSANZ's call for Submissions on Application A1230 dated 19 November 2021 ("**Call for Submissions**").

2. We make this submission on behalf of Opti-Pharm Pty Ltd ("**Opti-Pharm**"). The submission addresses:-

   (a) The P242 FAR;

   (b) the Application made by the Applicant;

   (c) the Food Standards Australia New Zealand ("**FSANZ**") initial assessment of the Application;

[redacted]

(d) Opti-Pharm's submissions in opposition to the Application, alternatively its submissions for changes to the Application. Specifically, if the Application is granted over Opti-Pharm's and other party's objections then the proposed variations to 2.9.5 need to be amended before they are adopted by FSANZ and suggest that a second round of public consultation and call for further submissions is made.

3. It is Opti-Pharm's position that:-

(a) the Application is unnecessary and the case for justification is weak;

(b) if FSANZ's wishes to take action in relation to VLED products, then proper industry and consumer consultation is necessary so that when a standard is adopted for an enactment, it has been properly considered and drafted with due consideration for the issues which are uniquely related to VLEDs. They have, in our respectful submission, not been properly addressed by Nestle in its Application nor by FSANZ in its initial assessment which has been hastily prepared especially when considered in light of FSANZ's prior deliberations regarding P242 FAR and its decision to exclude VLEDs from standard 2.9.5;

(c) the objectives in section 18 of the *Food Standards Australia New Zealand Act 1991* (Cth)("**FSANZ Act**") for developing or reviewing food regulatory measures and variations of food regulatory measures have not been satisfied.

P242 FAR and FSANZ's Decision to Exclude VLEDs from 2.9.5

4. VLEDs, also known as VLCD – Very Low-Calorie Diet, have been on the Australian and New Zealand ("**ANZ**") markets for many years as a food product, albeit possibly not being categorised within *Australia New Zealand Food Standards Code* ("**ANZFSC**" also referred to as "**the Code**"), but not being explicitly prohibited by any authority. In about 2010, FSANZ undertook a consultation process to determine industry position on whether VLEDs should be included in Standard 2.9.5 of the Code as a FSPM.

5. Following that consultation and as set out in the Report and Call for Submissions:-

(a) FSANZ decided to exclude VLEDs from P242 FAR and Standard 2.9.5.[1]

(b) It was considered that a new project would need to be initiated to investigate the most appropriate way to regulate VLEDs relative to all other formulated foods for weight reduction.[2]

(c) FSANZ was concerned that two different regulatory arrangements could have developed for products that would be sold and used in a similar manner if VLEDs remained in Proposal P242, thus proposed a new project for VLEDs providing a *clear differentiation between VLEDs and other meal replacement products*.[3]

6. FSANZ is, however, now proposing to include VLEDs in Standard 2.9.5, having accepted the Application by Nestle on the basis it warrants a variation to Standard 2.9.5, rather than dealing with VLEDs independently.

1 P242 FAR at page iii; page 8 [2.1.1].
2 P242 FAR at page 8 [2.1.1].
3 Consultation paper dated 15 December 2010, page 4.

7. Various submissions were made prior to 2012 containing opinions on whether VLEDs were suitable for inclusion in Standard 2.9.5. FSANZ decided to exclude them based on submissions that provided (inter alia):-

   (a) VLEDs differ from other FSMP and require specific nutritional composition and other labelling elements that were not captured by Standard 2.9.5.[4]

   (b) There is a potential for misuse of VLEDs.[5]

   (c) A separate definition and set of regulatory measures should be developed for VLEDs, to prevent misuse.[6]

   (d) There are different risks between FSMPs and VLEDs.[7]

   (e) There is an overlap between VLED products and other types of formulated food used for weight reduction, both in presentation of the two food categories and the way in which the products are used.[8]

   (f) The definition of VLED needed clarification, as VLEDs could be used as a supplement and result in a daily energy intake greater than 3350kJ.[9]

   (g) VLEDs should be treated separately for advertising and advertising would need monitoring.[10]

   (h) The proposed compositional requirements at Draft Assessment would result in reformulation of some VLED products, resulting in additional costs to those manufacturing the product.[11]

   (i) Additional compositional requirements for VLEDs was supported; VLEDs should include permissions for vitamin K, chromium and fluoride.[12]

   (j) There was uncertainty around maximum limits for nutrients such as vitamin E, niacin, magnesium.[13]

   (k) There should be a requirement that VLEDs provide recommended daily allowances of minerals, vitamins, trace elements and fatty acids in a dose/serve.[14]

   (l) There should be a minimum amount set for micronutrients of VLEDs.[15]

   (m) Mandatory warnings and advisory statements for VLEDs are necessary, including in relation to pregnant, nursing or lactating women or by infants, children, adolescents or elderly.[16] Although, this was opposed by some submitters because those classes can be obese and medical professionals may treat with VLEDs,

4 Call for Submissions, page 7.
5 P242 FAR at page 63.
6 P242 FAR at page 63.
7 Human Services SA, Submissions on P242 dated 12 February 2003; P242 FAR at page 71.
8 P242 FAR at page 8.
9 Australia New Zealand Enteral Nutrition Manufacturers Association Submissions on P242 dated March 2003.
10 Dietitians Association of Australia Submissions on P242 dated March 2003; New Zealand Dietetic Association Submissions on P242 (undated); P242 FAR at page 74.
11 OFRAM Pty Ltd Submissions on P242 dated 3 February 2003; P242 FAR at page 76.
12 Australia New Zealand Enteral Nutrition Manufacturers Association Submissions on P242 dated March 2003; P242 FAR at page 77.
13 P242 FAR at page 77.
14 Dietitians Association of Australia Submissions on P242 dated March 2003; P242 FAR at page 77.
15 Australian Food and Grocery Council Submissions on P242 dated February 2003; P242 FAR at page 77.
16 New Zealand Dietetic Association Submissions on P242 (undated); P242 FAR at page 80.

which could cause anxiety and confusion to those advised to take VLEDs and then reading the warnings.

(n) VLEDs should be labelled with a statement '*health hazard'*, whereas labelling FSMP as a health hazard may not be true because they can rarely be classified as a health hazard.[17]

(o) Labelling VLEDs with a reference to the condition, disease or disorder for which a FSMP has been designed could lead to self-diagnosis.[18]

(p) The composition requirements of VLEDs were not clear, whether calorie or joule could be substituted for energy.[19]

(q) There were no provisions for omega-3 fatty acids (other than a-linolenic acid).[20] The requirement of 0.5g/day does not take into account alternative sources of omega-3 fatty acid.

(r) Unsupervised and non-prescribed meal replacements and VLED products being used interchangeably can be hazardous for vulnerable groups.[21]

8. Notwithstanding the above, FSANZ has now stated:-

(a) It considers that Standard 2.9.5 is the most appropriate standard within the Code to regulate VLED products due to the significant risk management strategies embedded in the standard. Although, VLEDs were specifically excluded from Standard 2.9.5 due to the requirement for specific risk management strategies that were not in Standard 2.9.5.

(b) It considers VLEDs are appropriately represented by the definition of FSMP, but for paragraph 2.9.5 2(2)(a), and therefore proposes to remove '*a food is not FSMP if it is formulated and represented as being for dietary management of obesity and or overweight'* from the definition.

(c) It considers existing risk management strategies are suitable in informing and protecting consumers of VLEDs (i.e. leaflets).[22]

(d) Additional intake information is detailed in leaflets, so adequate intake of essential nutrients such as vitamin K and essential fatty acids, and dietary fibre are dealt with that way, although submitters in 2012 took issue with compositional requirements for VLED and vitamin K not being captured in Standard 2.9.5.

This is not dealt with in Nestle's Application as no minimum nutrients have been proposed for some of the micronutrients (i.e. Vitamin K): see Table 2 on page 18 of the Application.[23]

It has sought to *align* labelling requirements for VLEDs where appropriate with *existing labelling requirements for FSMP*, even though this was a specific reason for VLEDs exclusion from the definition of FSMP in the first place and VLEDs

17 Dietitians Associate of Australia Submissions on P242 dated March 2003; P242 FAR at page 81.
18 Human Services Submissions on P242 dated 12 February 2003; P242 FAR at page 82.
19 Food Liaison Submissions; P242 FAR at page 88.
20 Pharmacy Health Solutions; P242 FAR at page 90.
21 Health Professionals; P242 FAR at page 95.
22 Call for Submissions, page 9 [2.2.2.4].
23 We also refer to ANZ Enteral Nutrition Manufacturers Position Statement on Draft Proposal P242 dated 25 March 2003 and in particular pages 8 and 9.

being excluded from Standard 2.9.5.

We acknowledge that FSANZ has listed the specific labelling requirements at page 11 of its Call for Submissions, but included in that list is *"statement indicating the medical purpose of the food, which may include any disease, disorder or medical condition for which the food has been formulated",* which was originally raised as a concern by a submitter because of the potential for self-diagnosis. We are instructed that using any disease or medical term is strictly against all previous FSANZ requirements and principles.

(e) It does not propose labelling requirements for mandatory warning and advisory statements,[24] and Opti-Pharm agrees with this position.

(f) There is no clarification in the definition of VLEDs and the compositional requirements for VLEDs regarding if someone uses VLEDs as a partial replacement and not for all meals. If used as a supplement, then it is possible VLEDs will result in daily intake in excess of 3345kJ/day so there may be need for specification of use as a sole source of nutrition.

9. It appears that, rather than initiating a new project for regulation of VLEDs and the associated risks as intended in 2012, FSANZ are content for Standard 2.9.5 to incorporate VLEDs, despite excluding it originally because of the complexities and risks, particularly with advertising.

10. We do not consider that:-

(a) the Application properly deals with and addresses all reasons VLEDs were excluded from Standard 2.9.5 in the first place so relevant risk management has not been addressed.

(b) the Application and proposal by FSANZ properly deals with the objectives in the FSANZ Act.

Advertising

11. It was proposed in Proposal P242 that there be a restriction on advertising of FSMPs to manage potential health and safety risks associated with unsupervised and inappropriate use of FSMP, *in particular VLED products*. However, submitters disagreed that there was evidence of any risk from FSMP to public health and safety and it was suitable to reconsider restrictions on advertising *because VLED products were removed from Proposal P242.*[25]

12. After consultation, FSANZ removed restrictions on advertising of FSMPs to allow direct advertising to the general public, because VLED products were removed from P242 FAR. The risks of inappropriate use of FSMP as a result of advertising were considered low in the Report, because of the removal of VLED products from P242 FAR.[26]

13. Paragraph 2.2.2.2 of the Call for Submissions states:-

> *"FSANZ is of the opinion that as Standard 2.9.5 is reflective of the intended purpose of VLED as a sole source of nutrition, states the products are intended for use under the supervision of a medical professional and has specific sale and*

24 Call for Submissions, page 12 [2.2.3.4].
25 P242 FAR at page 16 [6.4.1].
26 Ibid [6.4.2].

advertising restrictions, it is the most appropriate and safe standard for VLED to be integrated into".[27]

However, P242 FAR does not deal with advertising for VLEDs, it was not considered necessary because VLEDs were excluded from Standard 2.9.5. The primary objective under the FSANZ Act is for the protection of public health and safety,[28] and a secondary objective is for provision of adequate information relating to food to enable consumers to make informed choices.[29] The amendments do not address this and whilst Nestle say that concerns raised in 2012 have not been realised, leading to a conclusion that current practice has not resulted in consumer confusion or detriment, and an implication sufficient information is available – it is speculative, identified as mere 'possibility' and it is not stated whether Nestle carried out any research or consultation to support the statement.

14. Finally, the proposed inclusion of VLEDs does not provide a clear differentiation between VLEDs and other meal replacement products, rather it includes VLEDs as a FSMP, notwithstanding FSANZ's original intention to ensure regulatory framework dealt with them separately.[30]

Opti-Pharm's submissions

15. We are instructed to reiterate the submissions made by [redacted], Managing Director of Opti-Pharm, on 1 October 2021. To ensure they are properly considered by FSANZ, we repeat them herein (omitting highlighting from original):-

[redacted]

27 Call for Submissions, page 8 [2.2.2.2].
28 FSANZ Act s 18(1)(a).
29 Ibid s 18(1)(b).
30 Consultation paper dated 15 December 2010, page 4.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Food Standards Australia New Zealand Act

16. When assessing the Application, FSANZ must have regard to the objectives in section 18 of the FSANZ Act, as well as assessment requirements in section 29 of the FSANZ Act, being:-

> *"(a) Whether the costs that would arise from a good regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to*

> *the community, Government or industry that would arise from the development or variation of the food regulatory measure;*
>
> *(b) Whether other measures (whether available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application…".*[31]

17. It is proposed that medical guidance and information be provided in a leaflet, which is the current health information already provided to consumers. Further, the available evidence does not indicate that the benefit would outweigh the costs. In assessing the Application, FSANZ ought to consider that other measures, such as the CODEX standard, would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.[32] In its Application, Nestle says current VLED products on the market are formulated to meet the CODEX standard,[33] rendering the Application nugatory. The current position on VLEDs in ANZ, as supported in the Application and Opti-Pharm's submissions, is sufficient; there is no evidence that regulation in 2.9.5 would be better to the public and no evidence that the current position in relation to VLEDs causes harm to the public.[34] Instead, codifying VLEDs in Standard 2.9.5 will create confusion and risk, as set out by FSANZ in 2012, in P242 FAR, when it opted to exclude VLEDs from Standard 2.9.5.

18. In addition, FSANZ has sought to adopt CODEX nutrient information, but has not adopted similar wording enabling essential nutrients to be added to products. At present, despite the proposal to adopt the CODEX standard, no permissions are allowed for nutrients (ie. biotin, vitamin K). There is no flexibility for manufacturers of VLEDs that otherwise exists under the CODEX standard.

19. In *Will Studd Enterprizes Pty Ltd v Food Standards Australia*,[35] the Administrative Appeals Tribunal upheld a decision of FSANZ to reject an application to vary Standards 2.5.4 and 1.6.2 on the basis (inter alia) that the applicant:-

> *"failed to produce evidence that would warrant a change to or reconsideration of the risk assessment and management conclusions stated in the approved reports"*.[36]

It is Opti-Pharm's position that Nestle has similarly failed to produce evidence warranting the change to risk assessment and risk management conclusions stated in P242 FAR, which unequivocally determined VLEDs should be excluded from Standard 2.9.5.

20. Nestle fails to discharge its burden of demonstrating that the incorrect decision was made in 2012 when P242 FAR determined VLEDs should be excluded from Standard 2.9.5.[37]

The Case for Justification is Weak

21. The case made for justification of the Application is weak and unpersuasive. It is clear that in 2012 FSANZ specifically decided after careful and extensive deliberation over

31 Food Standards Australia New Zealand Act 1991 (Cth)("**FSANZ Act**") s 29.
32 FSANZ Act, s 29(1)(b).
33 Application, page 8 at [C].
34 *Distilled Spirits Industry Council of Australia Inc v Food Standards Australia New Zealand* (2003) 133 FCR 19: the FSANZ Act is primarily aimed at public health protection [77] cited in *Axiome Pty Ltd (on behalf of Cognis GMHB) v Food Standards Australia New Zealand*.
35 [2001] AATA 3080.
36 *Will Studd Enterprizes Pty Ltd v Food Standards Australia* [2020] AATA 3080. We acknowledge that the decision in that case ultimately turned on the relevant standards no longer having effect, but the same principles ought to apply when considering a variation.
37 Submissions of the Authority in *Will Studd Enterprizes Pty Ltd v Food Standards Australia* [2020] AATA 3080.

numerous years to exclude VLEDs from Standard 2.9.5. In doing so FSANZ recognised the intrinsic difference between VLEDs and FSMPs. Its position was the correct one, and was backed by the South Australian Department of Human Services, as well as others, who recognised the clear distinction between VLEDs and FSMPs.[38]

22. The Application repeatedly notes that VLEDs have been sold safely for more than 20 years in Australia. It cites no evidence of any health issues which have arisen in relation to the use by VLEDs by consumers in Australia. Rather, the Application repeatedly emphasises the benefits of VLEDs to consumers in Australia, particularly for the treatment of weight loss and obesity. VLED products are specifically designed to deal with the issues of weight loss and obesity, and Nestle seeks to put VLEDs in a category for FSMPs supposedly to give greater certainty and clarity to consumers. But there is no evidence that any such clarity or certainty is needed, nor is there any evidence from a health-based perspective that certainty or clarity is needed.

23. Indeed, the emphasis by Nestle in its Application on the safety of VLEDs and their use for over 20 years calls into question the whole purpose of the Application. Whilst it endorses certainty and clarity, the Application and FSANZ readily acknowledge that there are different standards governing VLEDs in the European Union than the one proposed in Australia. Neither Nestle nor FSANZ urge an adoption of the EU standard, and Opti-Pharm agrees with this but points out the inconsistency in the Application and FSANZ's assessment. It also refers to the abovementioned failure by FSANZ to include in the proposed standard an allowance for flexibility and permissions for other essential nutrients to be added to VLED products.

24. P242 FAR noted that FSANZ intended to embark on a project to deal with a special standard for VLEDs given the complexities related to these products. Such complexities arise because a prescription is not required nor is a prescription being suggested in the Application. The use of VLEDs and their sale through pharmacies and online throughout Australia is clear evidence that they are being used by persons for various uses with only some people using them as a complete meal replacement for what has been referred to as the "intensive" phase, i.e. three VLEDs a day. Even then, the Applicant rightly notes that VLEDs are <u>not the sole source</u> of nutrition for consumers, a point which seems to have been lost upon FSANZ based upon comments made in the initial assessment which incorrectly referred to VLEDs as the sole source of nutrition.

25. Nestle also acknowledges that most users will reduce the use of VLEDs over time, and usually within the 12-week period, by dropping down to two VLEDs, then one VLED, and then none. This gradual and expected reduction in the use of VLEDs makes it difficult to classify them as an FSMP. Whilst there is force in the argument that when VLEDs are used three times a day with no other meals and only some low starch vegetables, as recommended by Nestle and Opti-Pharm, that argument loses force when VLEDs are consumed twice a day; only once a day; or occasionally as part of a healthy weight loss program.

26. Importantly, the Applicant and Opti-Pharm both include in the packaging and in their advertising recommendations that consumers consult a health care professional about the use and consumption of the VLEDs. This is sufficient, in Opti-Pharm's submission, but classifying VLEDs as FSMPs means that the sale of them could be greatly limited under the proposed variations to Standard 2.9.5.

27. The variations drafted by the Applicant and proposed by FSANZ do not deal with online sales of VLEDs. However, both the Applicant and Opti-Pharm sell VLEDs online and this

38 P242 FAR at page 71.

issue has been completely ignored by the Applicant and FSANZ. Online sales of VLEDs, much like everything else in Australia (and worldwide), have increased since P242 FAR was published. The COVID-19 pandemic has accelerated the use and adoption of online purchasing as a primary means for many consumers to buy goods, including VLEDs and especially in regional Australia. The standard as drafted is simply unworkable for VLEDs in the current climate, and in the "*real world*" where consumers are buying VLEDs online, similarly to other products available at pharmacies, like prescription medication.

28. Standard 2.9.5 limits the places in which VLEDs will be able to be sold, and hence will limit where consumers have access to purchase them. The standard does not appear to include online sales, which is likely to lead to a reduction in the consumption of VLEDs, and the diminishment of the health benefits associated with them. Those health benefits have been used by the Applicant as a basis for supporting the Application, but in Opti-Pharm's submission, work against the Application. In addition, the variations add a cost to consumers in the form of travel expenses and time particularly for consumers in regional Australia. Separately, there is an adverse environmental impact in the form of greenhouse gasses.

Nutritional Requirements

29. VLEDs were included in FSANZ Proposal P242 in 2012 but were abandoned by FSANZ due to industry response to Proposal P242. It is noted that FSANZ and its predecessors have previously included several Standards into ANZFSC after food products have been implicitly permitted to be marketed and sold without issue for many years in ANZ, but which did not comply with any ANZFSC Standard.

30. Some examples are:

    (i) Standard 2.9.3 – Formulated Supplementary Foods was designed to suit the popular fortified Chocolate milk drink powders, such as "Milo" and "Ovaltine" which had respectively been manufactured or imported for many years.

    (ii) Standard 2.6.4 - Formulated Caffeinated Beverages was designed to suit Australian manufacture of "Red Bull" drink which was originally a fully imported product, through New Zealand and the Trans-Tasman Mutual Recognition Arrangement.

    (iii) Standard 2.9.5 – Food for Special Medical Purposes which had been imported from overseas for many years and still are.

    (iv) A Standard, similar to the New Zealand Food Regulations 2015 has been proposed and then abandoned by FSANZ on several occasions and to-date products legitimately manufactured and sold in New Zealand are still freely available in Australia without actual compliance with any Standard in ANZFSC.

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31. The following points are not in any order of priority but generally follow the order of the proposed Draft Standard and the various documents associated with A1230.

32. Initially, it is strongly suggested that VLED and Very Low Energy Food ("**VLEF**") be the subject of a new and separate Standard (as originally proposed in P242 FAR), possibly to be referenced as Standard 2.9.7, i.e. as part of Special Purpose Foods, or Standard 2.9.3

(discussed below) but not included in Standard 2.9.5. There are several reasons accompanying this suggestion set out below.

33. The basis for this discussion is the proposed changes listed in the Schedule included in FSANZ document "Call for Submissions – Application A1230" of 19 November 2021, unless otherwise referenced. Reference is made using the same numbering system as used in the Schedule.

    (a) [1.1] Subsection 1.1.2-5(2); the definition for VLED states that this regime will "provide the sole source of nutrition…".

        The terms 'sole' and 'nutrition' are not defined within ANZFSC and thus reliance is based on an accepted resource "Macquarie Dictionary, Sixth Edition" where "sole" includes 'being the only one of the kind', 'unique', 'exclusive', etc. "Nutrition" includes 'food nutriment' and 'nutriment' includes 'any matter that that taken into a living organism, serves to sustain it in its existence'.

        A simple interpretation of "sole nutrition" would exclude any other foods, including water.

        Both major companies who offer VLEDs as part of the initial 12-week VLED regime also include other foods, such as low starch vegetables, vegetable oil and water. Therefore, VLED does not provide the 'sole nutrition' for any participant in a VLED.

    (b) It was noted that FSANZ cites the contribution of 'low starch vegetables and vegetable oil' in calculating the Micronutrient Assessment of some Vitamins, such as Vitamin A, Vitamin D, Vitamin E, Vitamin B6, Vitamin C, etc. and Minerals, such as Phosphorous, Iron, Magnesium, Copper, etc. – refer Supporting Document 1 - "Nutrition assessment" of 19 November 202, Section 4.

    (c) The current Standard 2.9.5- Food for Special Medical Purposes (FSMP) includes Standard 2.9.5-7 – '*Compositional requirements for food represented as being suitable for use as sole source of nutrition* and has the associated Schedule 29-21.

        The Schedule in A1230 does not make any reference to 2.9.5.7 and therefore it may be assumed that VLED and VLEF are meant to be included in 2.9.5.7 if the 'sole nutrition' definition is to be retained.

33.2 [2.2] The term 'Sole nutrition' is also included in Note 4 following Section 2.9.5-2.

33.3 [2.7] Division 5, Standard 2.9.5-18(1)(a) states that the maximum energy level of VLED is 3345kJ. Standard 1.2.8-7(3) requires the use of 'not more than 3 significant figures' when expressing the average energy content. Therefore, the proposed new section should read either 3340kJ or 3350kJ. Using the conversion factor in Schedule S11-2(4) of 4.18Cal = 1kJ, then 3345kJ = 800.2 Cal, 3340kJ = 799.0kJ and 3350kJ = 801.4kJ. To maintain consistency with the meaning of Codex Standard CXS 203-1995, the maximum value for VLED in A1230 probably should be 3340kJ for ANZ.

33.4 [2.7] Proposed new Standard 2.9.5-18(1)(c) and 2.8.5-18 (3) discuss the Protein content of VLED as having a Protein Digestibility Corrected Amino Acid Score ("**PDCAAS**") of 1.

    (a) Market acceptable VLEFs with a PDCAAS of 1 can be achieved with certain dairy-based protein isolates/concentrates and soy-based isolate/concentrate.

(b) Egg and possibly some meat-derived proteins may also have PDCAAS of 1 but are difficult and expensive to be used as the basis for a powder or reasonably easily accessible form for consumers. Organoleptic properties, short shelf-life and many other reasons exist to not use these protein sources.

(c) For future innovation, including a growing consumer base who prefer plant-based, vegan, vegetarian based diets, it is considered that although there are several/many viable protein sources, including cereal-based, pea, Fava beans, hemp, etc. which have a PDCAAS less than 1, that fortification with individual amino acids should not be mandated.

(d) Voluntary fortification with amino acids may be an option.

(e) In the Supporting Document 1 - "Nutrition assessment" of 19 November 2021, FSANZ cites the use of Rapeseed Protein Isolate as a possible source of protein with a PDCAAS of 1. This protein was recently included in ANZFSC, Schedule 25-Permitted Novel Foods in 2021.

(f) As the current VLEDs and VLEFs have been consumed for many years in ANZ, neither FSANZ, the Applicant for A1230 nor other major sellers can provide any evidence in ANZ of any detrimental health effects related to VLED and their protein contents. Further, both the Applicant and FSANZ acknowledge that VLEDs are not intended to be the sole source of nutrients as low starch vegetables are recommended.[39]

(g) In the Supporting Document 1 - "Nutrition assessment" of 19 November 2021, FSANZ mentions "in 1970 prolonged consumption of VLED consisting largely of protein…. deaths attributed to the low biological value of the protein…"; without producing the evidence of what is "prolonged" and "low biological value".

The report is from 1970 and there is no other study cited where detrimental health effects are found within the VLED 12-week maximum period of 3 meals per se of VLEFs as currently available in ANZ.

Extreme use, abuse and unsupervised behaviour with VLEFs is not within the provenance of FSANZ and ANZFSC.

(h) It is contended that mandatory fortification of protein to meet PDCAAS of a minimum of 1, without justification, is a health and medical prophylactic procedure which should not be a part of ANZFSC.

(i) Many amino acids may be derived from animal sources and hence the mandatory fortification of plant and non-animal-based proteins may render VLEFs as unsuitable for several population groups, such vegans, vegetarians and groups with religious dietary requirements such as Halal and Kosher.

(j) Most importantly "the Applicant has not requested to align with Codex Standard 203-1995 protein quality prescription and suggests that specifying protein quality is unnecessary for VLED" – refer Supporting Document 1 Nutrition assessment of 19 November 2021- Section 3.2.2 Protein Quality.

39 See paragraph 1.2 of the Call for Submissions and section 4 of Supporting Document 1, Micronutrient Assessment.

FSANZ has not provided any rationale as why this request is not proposed as part of the new Standard and this submission supports the position of the Applicant.

33.5 [4.1] Re the addition of Nutritive Substances, i.e. Vitamins and Minerals ("**V&M**"), it is noted that:

(a) The V&M do not include Biotin, Pantothenic Acid, Chromium, Manganese, Molybdenum, Selenium which are currently present in market VLED products in ANZ and have been for many years without comment or issue. FSANZ does not provide any explanation for these omissions.

(b) Even though FSANZ proposes to align with the Codex Standard for nutrition values, FSANZ has not adopted the Codex Standard express permission for essential nutrients, such as those listed in the immediately preceding paragraph, to be added to VLED products.

(c) Codex Standard CXS 203-1995 permits "other essential nutrients not specified … may also be included" under the heading Vitamins and Minerals. This is understood to mean that other V&M may be added to VLEDs. A1230 does not provide this option.

(d) Supporting Document 1 - "Nutrition assessment" of 19 November 2021, Section 4 – Micronutrient Assessment discusses all the proposed V&M (as well as unlisted Manganese) and it is assumed that ANZ data regarding *RDI* means Recommended Daily Intake and *UL* means Upper Limit of Intake, albeit these terms are not defined in the FSANZ documents.

It is assumed that the RDI and UL data are derived from "Nutrient Reference Values for Australia and New Zealand", NHMRC 2006 ("**NRV**").

(e) In the Supporting Document 1 - "Nutrition assessment" of 19 November 2021, Section 4, FSANZ includes Section 6 – References, but does not relate which data in the Document is derived from which particular reference.

33.6 [2.7] Regarding 2.9.5-18(3) page 23 of the Food and Agriculture Organisation of the United Nations ("**FAO**")/World Health Organisation ("**WHO**") Expert Consultation of Protein Quality- Paper No.51 does not contain the method for calculating the PDCAAS. Page 23 contains a comparative table and summary of PDCAAS, whereas it is suggested that the following wording is more accurate:

'The protein digestibility-corrected amino acid score shall be determined by methods given in section 5.4.1, 7.2.1, and 8.00 in "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation".

This quote is taken from the USA-FDA Code of Federal Regulations Title 21-101, part 101.9, 7(ii).

34. If FSANZ is inclined to codify VLED products within its Standards then we consider it may be more appropriately dealt with in a new and separate Standard or as a division within Standard 2.9.3.

35. Standard 2.9.3 relates to Formulated Meal Replacements and Formulated Supplementary Foods of which VLEDs are one. The definition of FSMP in Standard 2.9.5 would need to be amended for VLED to be captured within that standard, whereas VLEDs appropriately fall within *"formulated meal replacement: means a single food or pre-packaged selection*

of foods that is sold as a replacement for one or more of the daily meals but not as a total diet replacement". A sub division dealing with VLED nutritional requirements would be necessary.

36. We understand FSANZ considers VLEDs may be used as a meal replacement, for 3 meals per day. However, all experts have maintained that VLEDs should be accompanied by low starch vegetables and water consumption. They cannot therefore be considered a 'total meal replacement' or 'sole nutrition'.

37. For all the reasons identified above, if FSANZ intends to regulate VLEDs in ANZ then it should undertake its foreshadowed project to consult and then formulate an independent standard. At a minimum, a second round of submissions should be afforded to the public, enabling Opti-Pharm to comment on the other parties' submissions and to make any further submissions it considers appropriate, given the short period of time afforded to comment on A1230.