



17 December 2021

Tēnā koe,

Application A1230 – Very Low Energy Diets (VLED)



New Zealand Food Safety (NZFS) welcomes the opportunity to comment on Application A1230 – Very Low Energy Diets (VLED). NZFS is supportive of the general approach to regulate VLED products as a food for special medical purposes (FSMP) under Standard 2.9.5 of the *Australia New Zealand Food Standards Code* (the Code). This approach has the potential to provide more regulatory certainty and align requirements between Australia and New Zealand.

However, NZFS cannot support the proposed draft variation to the Code as currently proposed under Application A1230. Our overarching key concerns are:

- **Concern 1:** Products that are not ‘very low energy foods’ may be able to position themselves as FSMP, which may be advantageous for these products.
- **Concern 2:** Insufficient risk mitigation measures are proposed to adequately protect against the risk of unsupervised and inappropriate use of VLED products.
- **Concern 3:** Enforceability issues if products cannot be easily identified as VLED products.

The regulation of VLED products is complex (as acknowledged by their omission from Proposal P242 – Food for Special Medical Purposes). Any future regulations must be clear and unambiguous to protect the public health and safety of consumers, as well as to facilitate trade and ease of enforcement. NZFS is keen to ensure that VLED products are regulated in a way that is fit-for-purpose for current products on the market whilst also being future proof. We consider that the narrow assessment of this Application, in line with the Applicant’s request, may not enable robust regulation of VLED products.

We raise a number of concerns in the attached submission – many of them complex and interlinked – and these will require a whole system perspective to resolve. Where able, we have offered potential solutions for FSANZ to consider and would welcome further discussion with FSANZ to achieve a robust and practical outcome for the regulation of VLED products in the Code.



Attachment: NZFS Submission to Application A1230 – Very Low Energy Diets

The Application from Nestle Australia and Nestle New Zealand seeks to regulate VLED as FSMP under Standard 2.9.5 of the Code, in alignment with requirements in the CODEX *Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction* (Codex STAN 203-1995).

Proposal P242 considered regulating VLED products as FSMP. However, VLED products were eventually excluded from the FSMP category with FSANZ citing issues such as overlap for VLED products with other formulated foods for weight reduction both in presentation and use of products, and the risk of inappropriate use as a result of direct advertising to consumers. FSANZ was to raise a new proposal after P242 to specifically investigate the most appropriate way to regulate VLED relative to other formulated foods for weight reduction purposes, however to date this has not eventuated.

The current situation sees FSANZ assessing an application from Nestle Australia and Nestle New Zealand, rather than a self-raised proposal, to consider how best to regulate VLED products for Australia and New Zealand. NZFS is concerned that assessing this issue under an application may have narrowed the scope of FSANZ's assessment resulting in a different outcome had this work been considered under a proposal. In particular, not considering alignment with the relevant and recent EU regulation 2017/1978, as the Applicant only requested alignment with the Codex STAN 203-1995, which was developed in 1995. Furthermore, the proposed variations to the Code appear to cater for the Applicant's existing products and corresponding weight loss programme, and do not accommodate for future development/import opportunities of products in this area.

NZFS supports the general approach

In reviewing FSANZ's assessment of Application A1230, NZFS supports that:

- VLEDs have a valid medical purpose in the dietary management of overweight and obesity - to totally replace the daily diet for a short period of time to achieve safe and rapid weight loss, when medically indicated and under medical supervision.
- VLED products be classified as FSMP – as these products satisfy all components of the FSMP definition in section 2.9.5—2(1).
- Standard 2.9.6 be amended so that the Standard no longer applies to 'very low energy food' two years after commencement of the variation under Application A1230. Standard 2.9.6 will otherwise remain intact until such time that adequate provisions are provided in the Code to accommodate for all foods regulated by this Standard.
- Regulation of VLED products in the Code will provide regulatory certainty for industry and provide consistency in trans-Tasman regulation for these products.
- Restriction on the sale of FSMP should apply to VLED products – by whom and the premises at which they may be sold.
- VLED products must be used under medical supervision.

Areas of significant concern for NZFS

NZFS acknowledges that developing an effective regulation for VLED products in the Code is a complex issue. As indicated, we have a number of concerns with the approach as proposed in

the A1230 call for submission (CFS) and many of these issues are interlinked. We have addressed our specific issues under three overarching key concerns:

Concern 1:

Products that are not ‘very low energy foods’ may be able to position themselves as FSMP, which may be advantageous for these products

NZFS considers that the concern raised in P242 of potential overlap for VLED products with other formulated foods for weight management is still valid and has not been adequately addressed in the proposed approach. We consider the proposed approach creates a potential loophole for products that are not ‘very low energy foods’ to position themselves as FSMP for the dietary management of overweight and obesity. In addition, the proposed definitions may allow for a wider range of foods than just VLED products to be represented as a ‘very low energy diet’. This combined with more relaxed regulation for composition afforded to FSMPs (including addition of nutritive substances and novel foods without express permission and health claims) may result in a range of products marketed as VLED products that may be harmful to public health and safety.

Overlap in food product categories

Foods for the dietary management of overweight and obesity extend beyond VLED products. As well as VLED products, foods may include some general purpose foods (e.g. low fat or reduced calorie foods), formulated meal replacements, formulated supplementary foods, and foods formulated under Standard 2.9.6. FSANZ acknowledged this potential for overlap in product categories when it excluded VLED products from consideration in P242.

VLED products have a specific medical purpose and require a set nutrient composition to ensure nutritional adequacy for the consumer during the period of use to achieve this purpose. Therefore, robust definitions are needed to ensure only VLED products are captured as FSMP, in combination with restrictions on health claims and addition of nutritive substances and novel foods.

To create a clear and unambiguous product category for VLED products, we propose changes are made to the definitions for ‘very low energy diet’ and ‘very low energy food’ (see section below on definitions). In addition, we recommend that subsection 1.1.2—5(2) is not repealed (as proposed in the draft variation). Instead, we propose it is retained but specifically excludes ‘very low energy food’, i.e. for subsection 1.1.2—5(2) to state (or to the effect that):

Despite subsection (1), a food is not food for special medical purposes if it is:

- (a) formulated and represented as being for the dietary management of obesity and overweight, excluding very low energy food; or*
- (b) an infant formula product.*

Definitions for ‘very low energy diet’ and ‘very low energy food’

The draft variation proposes two definitions for the VLED product category – one for ‘very low energy diet’ and another for ‘very low energy food’, with the latter referring to the first. NZFS was unable to find an explanation in the CFS for the use of two definitions or a breakdown of the regulatory purpose of each component of the definitions. This level of detail would have been very useful to help determine the suitability of these definitions to regulate this product category.

The definitions must be robust to only capture VLED products. NZFS has seen in the past where definitions for specific food categories were not clear and open to interpretation, and this hampered enforcement action and allowed manufacturers to use loopholes to their advantage.

Specifically, NZFS's concerns with the proposed definitions are:

1. The definition of 'very low energy diet' refers to a range of FSMP

Reference to '...a range of food for special medical purposes specially formulated for the dietary management of overweight and obesity....' in the proposed definition for 'very low energy diet' does not preclude non-VLED foods represented as FSMP for weight management to be part of a 'very low energy diet'. We consider that replacing this reference with 'very low energy food' may have the desired effect to limit the foods that can comprise a 'very low energy diet' to 'very low energy foods' alone, i.e.:

very low energy diet means a range of very low energy foods and which provide the sole source of nutrition when consumed according to the directions for use on the label.

2. Compositional requirements relating to the 'diet' could permit 'very low energy foods' with little nutritional value

The interplay of the two definitions alongside the proposed compositional requirements relating to 'per daily intake' (rather than the individual food), could mean the 'diet' may comprise of a range of 'foods' with huge variation in the nutritional value of each food rather than each food containing a similar nutritional profile. For example, the 'diet' may include three 'foods' with one food providing the majority of all energy and nutrients required 'per daily intake', and the remaining products with low nutritional value but potentially added substances (i.e. nutritive substances or novel foods) purported to be beneficial for weight loss. This is of particular concern as these VLED products would be standalone products and for purchase individually. We are not confident that the proposed definitions would stop low nutritional value foods (e.g. 'fat blasters') and/or non-usual food formats (e.g. capsules and tablets) from being represented as 'very low energy foods' and therefore part of a 'very low energy diet'. We are not aware of other instances in the Code where composition requirements exist for the diet rather than a food.

We request that FSANZ considers whether the definition for 'very low energy food' should include reference to minimum energy/nutrient composition to help address this issue (e.g. that each 'very low energy food' must contain 25-50% of minimum amount per daily intake of required energy and nutrients). Alternatively, FSANZ could consider stipulating that each individual 'very low energy food' must be able to meet the nutrition composition of 'very low energy diet' when consumed in sufficient quantity.

3. Reference to 'sole source of nutrition' in the definition for 'very low energy diet' is considered misleading

The Code does not define the meaning of 'sole source of nutrition', though the term implies that the product is nutritionally complete to meet an individual's dietary requirements. However, the proposed compositional requirements for VLED products do not meet the nutrient reference values for Australia and New Zealand, which provide the amount of nutrients required on an average daily basis for adequate physiological function and prevention of deficiency/disease.

NZFS notes the proposed use of VLED products for short term use and considers use of the term 'total diet replacement' to be more suitable than 'sole source of nutrition' in this context.

We note the EU requirements require the name of these products to be ‘total diet replacement for weight control’. Use of ‘total diet replacement’ is also consistent with that used in the definition of ‘formulated meal replacement’, which is a category of foods that could be used for weight management purposes that needs to be clearly distinguished from VLED products.

We also question the need to include reference to ‘sole source of nutrition’ (or ‘total diet replacement’) in the definition, particularly when the composition for VLED products is prescribed.

Depending on the outcome of the above consideration, the relevance to VLED products of the statement in subsection 2.9.5—10(1)(f) indicating whether or not the food is suitable for use as a sole source of nutrition will also need to be reconsidered. We consider this statement should not apply to VLED products. Instead, a more applicable statement to meet the purpose of VLED products could be ‘can be used as a total diet replacement’.

4. Non-FSMP foods may be captured in definition for ‘very low energy diet’

Reference to ‘.....which provide the sole source of nutrition when consumed according to the directions for use on the label’ in the definition for ‘very low energy diet’ may create an additional loophole to that described in 2. We consider this may allow foods that are not FSMP, but are part of the associated VLED programme (e.g. low starch vegetables and oil), to be classified as part of the ‘very low energy diet’. Given the compositional requirements relate to the ‘diet’ this could mean that the nutrient content of non-FSMP foods may count towards these requirements. While non-FSMP foods may be recommended as part of the diet, these should be ‘extra’. The definitions need to be tightened to avoid these ‘extra’ non-FSMP foods from being captured in the definition and consequently the compositional requirements.

Addition of nutritive substances and novel foods

NZFS does not consider it is appropriate for ‘very low energy foods’ to contain added nutritive substances or novel foods without express permission in the Code. ‘Very low energy foods’ have a specific medical purpose and specific compositional requirements for energy and nutrients – and no other nutritive substance, bioactive or novel food is required to achieve this medical purpose. Therefore, NZFS recommends that 2.9.5—3(a) is amended to not apply to ‘very low energy food’ – and thus, express permission in the Code will be required if a ‘very low energy food’ is to contain nutritive substances or novel foods outside the compositional requirements. The one exception might be for other vitamins and minerals to ensure continuity of supply of products that contain vitamins and minerals not specified in the compositional requirements.

We also consider the above restriction to be important to avoid consumers being misled as to the benefits of a particular ‘very low energy food’ and potentially leading to inappropriate use – particularly if the addition of a nutritive substance or novel food (e.g. *garcinia cambogia*) was coupled with unsubstantiated health claims about its purported benefit for weight loss (as it is proposed that Standard 1.2.7 – Nutrition, Health and Related Claims will not apply to VLED products in line with other FSMP). We include more information on health claims in the section below.

Concern 2:

Insufficient risk mitigation measures are proposed to adequately protect against the risk of unsupervised and inappropriate use of VLED products

VLED products have a valid medical purpose in the dietary management of overweight and obesity - to totally replace the daily diet for a short period of time to achieve safe and rapid weight loss, when medically indicated and under medical supervision. They should only be used in specific medical situations, for example in preparation for surgery. [The New Zealand Ministry of Health](#) do not recommend very low energy diets for most people who need to lose weight.

Also, the definition of FSMP supports this specific medical use. Use of VLED products for the general management of overweight and obesity does not satisfy 2.9.5-2(1)(a)(ii), which states an FSMP is specifically formulated for individuals whose dietary management cannot be completely achieved without the use of the food. For most individuals a weight loss plan with reduced calorie intake and an increase in energy expenditure is sufficient to achieve weight loss – and the use of VLED products is not necessary.

Adequate measures to protect against the risk of unsupervised and inappropriate use of VLED products is paramount. Particularly as very low energy foods are likely to have broad appeal to consumers (unlike other FSMP products) for general weight loss purposes given the high rates of overweight and obesity in Australia and New Zealand – and the common objective of many to lose weight.

Restrictions on sale

NZFS supports the restriction on the sale for FSMP (2.9.5—5) to also apply to VLED products, thus restricting the persons by whom and the premises at which FSMP may be sold.

We consider this component is an important risk management strategy in the regulation of VLED products to help protect consumers from the unsupervised and inappropriate use of VLED products for general weight loss purposes.

Current VLED products on the market in New Zealand are easily accessible to consumers, particularly with the growth in online sales and discount pharmacies. They can currently be purchased through these avenues without medical supervision and are relatively inexpensive at ~NZD\$10 per day (if used as a total diet replacement compared to the cost of traditional meals). They also appear on shelf alongside other non-VLED products for weight management including dietary supplements, which could add further challenges to protecting consumers.

The access to these products and the need for them to be used under medical supervision needs to be tightened as part of the proposed regulation of VLED products. The restriction on sale components of Standard 2.9.5, alongside enforcement of this component, will go some way to mitigate the unsupervised and inappropriate use of VLED products.

Restriction on advertising

VLED products, unlike many other FSMP, may have broad appeal to consumers for use for general weight loss (rather than medically indicated weight loss). If VLED products are readily accessible (as is the current situation) and directly advertised to consumers this may result in inappropriate use by the general public.

The Optifast website advertises the benefit of weight loss directly to consumers and how their very low energy products can be used in popular diets such as intermittent fasting and ketosis.

Proposal P242 considered restricting advertising directly to consumers as a means of managing potential health and safety risks associated with the unsupervised and inappropriate use of FSMP, in particular VLED products. At that time these restrictions were not incorporated in Standard 2.9.5, a key factor cited was the omission of VLED products from the Standard.

NZFS considers that the risk of direct advertising of VLED products to consumers, identified in P242, is still valid. Therefore, we consider that restrictions on advertising of very low energy diets/foods direct to consumers (including in print and online) should be considered to mitigate this risk.

Health claims

While it is appropriate that Standard 1.2.7 does not apply for FSMP, this opens a way for unsubstantiated health claims on VLED products and for those products to imply a slimming effect. NZFS do not support VLED products being able to make broad, unregulated nutrition and health claims. A pragmatic approach to this and to restricting advertising to consumers could be to only permit a specific pre-approved claim for 'very low energy foods' related solely to its special medical purpose – i.e. to totally replace the daily diet for a short period of time to achieve safe and rapid weight loss, when medically indicated and under medical supervision.

Precedent for pre-approved claims exists in the Code, for example the inclusion of a pre-approved claim in relation to the tonicity of electrolyte drinks (2.6.2-12(3)).

To reduce the potential appeal to consumers, no other health related claims on 'very low energy foods' should be permitted. This aligns with the EU, which does not permit nutrition and health claims on total diet replacements for weight control products.

Advisory/warning statements

Very low energy diets are not appropriate for certain population groups – such as pregnant and breastfeeding women, children, older people – and have specific precautions and contraindications. It is important to ensure that the product label and accompanying information provides sufficient information about the appropriate use of these products by different population groups.

NZFS considers that section 2.9.5—10 should be strengthened for VLED products. Firstly, to require 'very low energy food' to carry a prescribed mandatory statement to the effect that: 'the product is not recommended for children, or pregnant or lactating women, or older adults'. And secondly, to require prescribed statements relating to precautions and contraindications relevant to VLED products – namely, the importance of maintaining an adequate daily fluid intake and the appropriate time period for use. This approach is considered appropriate for VLED products given they are a specific category of FSMP (when coupled with effective definitions) and it aligns with the approach internationally.

Concern 3:

Enforceability issues if products cannot be easily identified as VLED products

Enforceability of the proposed standard could be problematic if products cannot be easily identified as 'very low energy foods', due to the overlap in product categories, unclear definitions, and lack of specific labelling (e.g. no prescribed name).

Enforcement agencies must be able to easily identify 'very low energy foods' on the market to undertake compliance checks for these products in order to protect consumers. Having compositional requirements for the 'diet' presents enforcement challenges to assess compliance of individual very low energy foods to the 'per daily intake' requirements, especially when a range of food formats (e.g. bars, shakes, soups) are proposed to be permitted with potentially widely varying nutrient contents. This highlights the importance for clear and unambiguous definitions that prevent overlap of product categories for foods for the dietary management of overweight and obesity (we have expanded on this in concern 1).

We consider a prescribed name should be required for 'very low energy food'. This approach is consistent with that taken for other formulated foods, such as formulated meal replacements, formulated supplementary foods and formulated caffeinated beverages. The relevant Codex and EU standards also require a prescribed name for these products. A prescribed name would allow easy identification of products for consumers, enforcement purposes, and would also be useful information for health professionals.

Noting the interchangeable use of 'energy' and 'calorie' and the international trade of VLED products, we suggest that companies could choose to use either 'very low energy food' or 'very low calorie food' as the prescribed name.

Conclusion

As outlined in our submission, NZFS has a number of significant concerns with the proposed approach under Application A1230 for the regulation of VLED products in the Code. As a result, NZFS cannot support the draft variations to the Code provided in Attachment A of the CFS.

Where able, we have offered potential solutions to address these issues and would welcome further discussion with FSANZ to achieve a robust and practical outcome for the regulation of VLED products in the Code. Given the nature of these concerns we request that FSANZ undertakes a second round of targeted consultation to help achieve consensus on these issues.