



When FSMP products were considered under Proposal P242 approximately ten years ago, there were concerns raised that VLED could be used in an inappropriate manner by individuals engaging in potentially dangerous and extreme dietary behaviours that may be a result of using the products unsupervised. At the time, there was a proposed advertising restriction, that could serve as an addition to access restriction which would reduce the ability to promote FSMP to the general public, and lessen the risk of the products being able to be used in an unsupervised manner. Further, this could serve as a barrier to companies to prevent the marketing of their products unethically to the public.

The importance of this is multifaceted as there may be impacts on product availability and how the products can be accessed. Even if these products are not sold off the shelf directly to consumers, many chemists nowadays are larger market-type stores with limited pharmacist oversight and additionally, products may be able to be purchased from these chemists online. Advertising restrictions are something that needs further consideration to ensure these specialised products are aimed at medical professionals only. If these are specialised products aimed at clinical use only and not advertised to the public, introduction of advertising restrictions to the public is unlikely to have a significant impact on manufacturers of these products.

The proposed definitions are not particularly clear in that the only defining feature of a very low energy food is that it is part of a very low energy diet, and a FSMP. This could prove difficult where enforcement is concerned, as regulators may need to differentiate between a valid VLED product and a product within the VLED range that presents itself as a FSMP (e.g. a supplement that promotes fat burning abilities) or a product that is a formulated meal replacement. The relevant Codex and EU standards require a prescribed name for these products which may assist with enforcement, as well as allowing for easy identification when being purchased by consumers. Consistent with the approach taken with other formulated foods, a prescribed name should be required for 'very low energy food'.

It appears that the proposed compositional requirements will group a range of VLED products, rather than an individual one and these products within the range will be able to be labelled as 'nutritionally complete'. This is even though they are not required to be nutritionally complete, which is based on FSANZ's nutritional assessment that the risk is low for adopting the Codex compositional requirements, due to the products being only used for the short term. Currently, the products are to be accompanied by adding a spoonful of oil and two cups of vegetables daily to the diet. Presently, in the current market products are adding more vitamins than are required under Codex. The concern is that should the standard allow for a minimum nutrition requirement that is not adequate, future products may cease to include these additional micronutrients not captured in the standard.

Further, companies presently provide written instructions in the form of a brochure regarding the inclusion of oil and vegetables which further serves to illustrate that these products are not suitable to be used as a sole source of nutrition without these added foods and micronutrients. Therefore, if the regulatory requirements around micronutrients are to remain, the labelling should be adjusted to reflect the fact that these products are not suitable to be used as a sole source of nutrition. As Standard 1.2.7 – Nutrition, Health and Related Claims will not apply to these FSMP products, there is a risk of unregulated health and nutrition claims being able to

be made without having to be evidence based or meeting minimum amounts of micronutrients. It is suggested that a similar approach to the EU regulations be adopted which prohibits these nutrition and health claims on VLED products.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Health Protection Branch, Department of Health on ( [REDACTED] )  
[REDACTED]

Food Safety Standards and Regulation  
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