Comments from the Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.

Due date of submission –17 December 2021

The Victorian Departments of Health and Jobs, Precincts and Regions (the departments) welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

Application *A1230 – Very Low Energy Diets (VLED)* seeks to vary Standard 2.9.5 – Foods for Special Medical Purposes to include Very Low Energy Diets (VLED) in alignment with the CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (Codex STAN 203-1995).

From the Food Standards Australia New Zealand (FSANZ) Assessment report it is understood that:

- A new division will be created under Standard 2.9.5 to regulate the composition and labelling of VLED products.
- Compositional requirements will be based on Codex STAN 203-1995.The definition of a 'Food for Special Medical Purpose' (FSMP) will be amended to remove the exclusion of foods formulated and represented as being for the dietary management of obesity or overweight from being a FSMP.
- Standard 1.1.2 will be amended to add the following definitions for very low energy diet and for very low energy food:
    - **very low energy diet** means a range of food for special medical purposes specially formulated for the dietary management of overweight and obesity and which provide the sole source of nutrition when consumed according to the directions for use on the label.
    - **very low energy food** means a food for special medical purposes produced for consumption as part of a very low energy diet.
- There will be a requirement to ensure VLED are consumed within the recommended daily quantity when used as the sole source of nutrition.
- This amendment will include a provision stating that Standard 2.9.6 (applicable in New Zealand only) will cease to apply to VLED two years after commencement of the draft variation.

The departments agree a solution is required to address the regulatory gap for VLED products to ensure these specialised medical products are appropriately regulated for consumer protection and to provide certainty and clarity for both businesses and regulators. The departments also agree that including VLED products in Standard 2.9.5 is appropriate to recognise their special medical nature, and to be subject to risk management strategies such as sale restrictions and labelling about using under medical supervision.

The departments have a number of concerns relating to the general approach, definitions, labelling and the enforceability of the proposed variations in A1230 and as such do not support progression of the application in its current form. Within the shortened four-week time frame, there has not been ample time to develop suitable suggested solutions but

the departments are willing to work with FSANZ to ensure the final variations are fit-for-purpose, future proof and enforceable. Our concerns are:

The stated aim to create a regulatory provision for VLED products that aligns with Codex.

VLED products were initially considered ten years ago under P242 – Foods for Special Medical Purposes but excluded in the final stages due to the complexity and health concerns that needed to be captured in the regulation of these products. In developing a new provision for the regulation of VLED, the starting point should be the protection of public health and safety and creating a provision that is fit-for-purpose based on the best available scientific evidence, in addition to aligning with international guidelines where possible. The current approach to align with Codex and consider the risks of doing so, does not allow adequate consideration of this new regulatory provision.

Definition of FSMP and implications for product capture.

If the FSMP definition in 2.9.5 is amended to remove the clause that states, 'a food is not food for special medical purposes if it is: (a) formulated and represented as being for the dietary management of obesity or overweight,' this could potentially create issues at the food medicine interface by opening up the Standard to the large range of weight loss/ fat burning supplements that might reposition themselves as a FSMP (due to the benefit of little to no compositional requirements and no requirement to substantiate any associated weight loss claims). The definition for FSMPs might be interpreted to capture some of these supplements. Rather than remove this clause altogether, an exemption could be created for VLED products as defined in the standard (provided the definition for VLED more clearly differentiates these products from meal replacements and other weightloss products).

Definition of Very Low Energy Diet and Very Low Energy Food and enforcement concerns

The proposed definitions are circular and the only defining feature of a very low energy food is that it is a FSMP that is part of a very low energy diet. For enforcement purposes, it is not clear how regulators would determine whether an individual product is a valid VLED product and not a formulated meal replacement or another product which presents itself as a FSMP and part of a VLED range (for example a 'fat burning' type supplement). The proposal to apply the compositional requirements to the total very low energy *diet* and not individual very low energy *foods* adds to the ambiguity. The definition of a VLED product needs to be tightened to clearly differentiate these products from other products for enforcement purposes.

VLED products to be labelled as suitable as a 'sole source of nutrition' or 'nutritionally complete'.

The proposed compositional requirements of VLED products are inconsistent with the definition that requires a very low energy diet to be suitable as a sole source of nutrition and the ability to reflect this in the labelling on VLED products. The proposed compositional requirements are nutritionally inadequate in a number of nutrients including protein (males), potassium, magnesium and zinc. Some, but not all of these nutrients, may be met with the addition of regular food. FSANZ indicates that the nutrient composition of VLED is supported by *optional* additional intakes included in the total diet replacement plans prescribed by the manufacturers and that these additional intakes ensure adequate intake of essential nutrients. This suggests that VLED (FSMP) foods themselves cannot be used as a sole source of nutrition. FSANZ has indicated that while Codex requires fewer vitamins than listed in EU regulations 2017/1798, or listed in the Australia New Zealand Nutrient Reference Values, it has assessed the nutritional risk of adopting the Codex

requirements as being low due to the short-term use of these products, the instructions for the associated diet plan which recommends adding a spoon of oil and 2 cups of vegetables to the diet, and the current products in the market, which add more vitamins than is required under Codex.

This raises concerns about truth in labelling, setting a standard for a 'minimum nutritionally complete requirement' which is inadequate and the risks for those that use these products for longer periods. It assumes companies will add additional micronutrients not captured in the standard whereas there is the potential for future products to not include these but be considered compliant with regulations despite being nutritionally inadequate. The departments are aware that some bariatric clinics indicate usage can involve multiple rounds of 12-week regimens, with some patients using these products for extended periods. FSANZ indicates companies' practice of providing a brochure outlining instructions for the VLE diet, which includes additional vegetables and oil is a sufficient risk management strategy, however this does not address that the proposed regulatory nutritional requirements, even with the added vegetables, do not represent a nutritionally adequate diet.

If the regulatory requirements are to remain nutritionally inadequate in terms of micronutrients, then labelling about the use of these products as total diet replacements should declare that they are not nutritionally complete or suitable to be used as a sole source of nutrition without added foods and micronutrients.

Nutrition and health claims

FSANZ notes that standard 1.2.7 nutrition and health claims will not apply, and so products will be able to make nutrition content and health claims that do not need to meet the conditions of 1.2.7 (such as including a minimum amount of a substance to make a claim or requiring a health claim to be evidence-based). The vast majority of FSMPs are very specialised products with a very narrow market, so the risk of unregulated claims could be considered low. Given greater than 60% of adults are above a healthy weight, there is the potential for these products to have a wider target audience and appeal. Even if they are not sold in supermarkets, many chemists these days are larger market-type stores with limited pharmacist oversight. The potential to capture other weight loss products as an FSMP under 2.9.5 is also concerning if claims about weight loss are not required to be based on evidence. Limiting the definition of FSMP to VLED products and better defining VLED products would go some way to address these concerns.

The departments do not support VLED products being able to make broad, unregulated nutrition and health claims. Similar to the EU regulations, nutrition and health claims should be prohibited, with the exception of statements about the intended purpose and potentially about fibre.

Advertising

During Proposal P242 it was noted that the risk of unsupervised and inappropriate use of FSMP, particularly for VLED, was a concern. The consultation papers at the time noted that Australian and New Zealand studies have found that, across different geographical regions and age groups, a significant proportion of those who attempt to lose weight will resort to extreme and often dangerous dietary behaviours (with females the most likely group to use dangerous techniques to achieve weight loss, particularly adolescent girls). FSANZ proposed a restriction on advertising (in addition to access restrictions) to reduce the opportunity to promote FSMP to the general public, thereby reducing the risk of

unsupervised use of FSMP. It noted this would also act as a disincentive to manufacturers who may wish to inappropriately market their products to the general public. When VLED products were removed from the scope of P242, the advertising restrictions (aimed mainly at these products) were also removed. Further consideration of advertising restrictions to the general public for these products is required. 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.