

## **Application 1230**

### **Very Low Energy Diets**

#### **1<sup>st</sup> Call for Submissions**

### **Summary**

NSW appreciates the opportunity to comment on Application 1230 – Very Low Energy Diets (VLEDs). NSW further appreciates that VLEDs are a long-standing issue of concern with the Australia New Zealand Food Standards Code (the Code) that first emerged over the course of Proposal 242 – Foods for Special Medical Purposes. NSW supports inclusion of VLEDs in Standard 2.9.5 of the Code, as this appropriately reflects the specialist role these foods play as part of the management of persons who are overweight and obese.

NSW supports the majority of FSANZ suggestions for the future management of VLED in the Code but requests further information on several matters. These are described below.

### ***Definition of VLED in the Code and separation from formulated meal replacements***

Very Low Energy Diets (VLED) are a combination of specifically formulated foods and other specifically selected foods for the acute dietary management of overweight and obese persons who are seeking to lose weight very quickly under strict supervision of a medical professional.

The purpose of the VLED is to deliberately trigger mild ketosis in the body so the formulation, use and medical supervision of persons consuming these foods are essential. This ensures adequate monitoring of patient health whilst this specific metabolic process is intentionally triggered.

Given the very specific role of VLED and products specifically formulated for the express intent of triggering mild ketosis to achieve rapid weight loss, NSW suggests a very specific definition for VLED is required. This is to ensure that medical professionals can very easily distinguish products for VLED from formulated meal replacements regulated under Standard 2.9.3 of the Australia New Zealand Food Standards Code.

**Very low energy diet program** means a range of *very low energy food* which are foods for special medical purposes specially formulated for the dietary management of overweight and obesity (*BMI >30*) and which provide the *total* source of nutrition when consumed according to the directions for use on the label *which may include a requirement for additional foods and fluids and be used under medical supervision*.

***Very low energy food*** – must, when consumed with other low energy food according to the manufacturer’s directions for use, result in a diet that meets the compositional requirements for very low energy diet program.

***“Very low energy diet” (VLED)*** may be used interchangeably with “Very low calorie diet (VLCD)” given some products on the market use VLCD on label.

NSW suggests there may be merit in considering the adoption of a prescribed name for Very Low Energy Food (VLEF) as a sub-category of Foods for Special Medical Purposes (FSMP), given their very specific purpose and appropriate use and supervision.

FSANZ correctly identifies the specialist nature of VLEF as part of VLED and the possibility that dividing lines between these products and products regulated as formulated meal replacements (FMR) could arise. Adoption of a prescribed name for VLEF may remove this ambiguity as any product claiming to be VLEF would need to meet all facets of Standard 2.9.5 that apply to VLEF. This would include specifically formulated use and purpose (dietary management of overweight and obese) and comply with the compositional parameters and labelling statements.

Any concerns with products identified with VLEF in the marketplace could readily be remedied by comparison with all elements of Standard 2.9.5 applying to these foods. Foods failing to comply with all matters pertaining to VLEF would then be found non-compliant with advice provided to the manufacturer to re-formulate the food or re-label as a formulated meal replacement.

NSW considers the benefits of introducing a prescribed name for VLEF are substantial and requests that due consideration to the transition time for Application 1230 is provided to achieve this outcome.

NSW notes that all special purposes foods regulated by Standard 2.9.3 of the Code have prescribed names hence application of a prescribed name for VLEF is consistent with the regulatory management of other foods regulated by Part 2.9 of the Code.

### ***2-year transition period for the adoption of VLED measures***

NSW supports adoption of a 2-year transition period in the Code for VLED and VLEF as this provides sufficient time for manufacturers to determine if a product will continue to comply with FSMP requirement as a VLED or be better regulated as an FMR.

NSW would be supportive of a longer transition time should the idea of a prescribed name of VLEF be adopted by FSANZ.

### ***Composition of VLED (supporting document 1)***

NSW supports the majority of FSANZ suggestions concerning the composition of VLED, however comments are offered on the following matters:

***Carbohydrate minimum*** – NSW would appreciate further discussion on why adoption of the higher Codex value is better than use of the lower EU value. The objective of VLED is to promote rapid weight loss by inducing mild ketosis in the body. With this

objective in mind it would seem more preferable to use the lower Carbohydrate minimum rather than the higher value. NSW would appreciate further discussion on this matter.

*Status of additional ingredients not covered in Codex* – NSW requests clarity on the functional purpose played of substances in VLED that are not listed in Codex as these include a range of Vitamins, Minerals, Electrolytes and biologically active substances (e.g. *Vitamins* – Biotin: Vitamin B7, Pantothenic Acid: Vitamin B5, Vitamin K, *Minerals* : Manganese, Chromium, Molybdenum, Selenium, Chloride, Fluoride, *Nutritive Substance*: Choline). In the majority of other Part 2.9 standards in the Code these substances are identified as nutritive substances or as permitted forms of vitamins and minerals. NSW requests clarity from FSANZ on the identity of these substances if added to VLED on a voluntary basis, i.e. are they considered ingredients, nutritive substances, permitted vitamins and minerals?. NSW requests this clarity so there is no ambiguity of the regulatory status of substances included in VLEF.

### ***Labelling of VLED (supporting document 2)***

NSW supports the majority of FSANZ proposals for the labelling of VLED but offers comment on the following issues.

*Nutrition and health claims* – NSW suggests that FSANZ re-consider the merits of permitting un-regulated health claims on VLED as these foods are meant to be used under the supervision of a medical professional. VLED are already permitted to make claims about the special medical condition they are formulated to manage and why the VLED is appropriate for this purpose. Given this existing permission and the requirement for supervision by a medical professional, NSW considers that nutrition and health claims would offer little value. VLED products are specialist products, selection of a specific product for treatment is a matter for the supervising medical professional.

*Statement that product is suitable for the dietary management of obesity* – NSW considers that a statement to the effect that VLED products are appropriate for the dietary management of obesity should be included on the label. The purpose of VLED products is to induce mild ketosis on persons taking them and through this process promote rapid weight loss over a defined period. NSW requests that FSANZ re-consider its position to not make this statement mandatory on VLED products.

*Specific sub-populations* – NSW requests that FSANZ re-consider its decision to not provide warning statements concerning the in-appropriate use of VLED by vulnerable sub-populations. VLEF as part of VLED, are meant to be used under the supervision of a medical professional, therefore a warning statement to the effect that pregnant and lactating women and minors should not use these products is important. NSW notes that existing provisions within Standard 2.9.5 provide for advice on contraindications, however given the specific metabolic purpose of VLEF, NSW considers there is a risk of specific sub-populations mis-using VLEF. Two examples are adolescents who may seek to use these products to lose weight yet at risk of eating disorders, and women soon after giving birth. Persons in these population groups may be attracted to these products as they can offer rapid weight loss (when used under the supervision of a medical professional). Consumption of VLEF by these persons without medical supervision could present a safety hazard to these

people, and in the case of a new mother, an infant should the mother be breastfeeding.

NSW suggests this is a real risk as FSMP are not akin to the sale of S3 therapeutic goods where a conversation with the chemist is required prior to purchase. The chemist will only accept the purchase if the consumer has a legitimate medical need for the good. VLEF are precisely that type of food, they should only be sold to consumers following the direction of a medical professional, for use under the supervision of a medical professional. A simple warning statement to the effects that these products should not be used by these sub-populations, unless specifically directed by a medical professional could assist in mitigating this risk.

*Fluid intake* – NSW suggests that FSANZ re-consider its position on not placing a statement on the label of VLED encouraging fluid intake. As VLED products promote mild ketosis, appropriate hydration of the person taking VLED is important.

*Instructions for use of VLEF as part of VLED* – NSW note the additional labelling requirement for VLEF to indicate the recommended daily quantity of the product to be consumed (under Section 2.9.5—9). However, some products on the market also require the addition of fluid, low-carbohydrate vegetables, and oil to be consumed as part of the total VLED program. NSW suggests that the additional labelling requirement includes a statement to the effect that the product forms part of a total diet program and, directions for use should include the addition of any additional food, nutrients or fluid where required to meet the VLED compositional requirements.

An accompanying information pamphlet is standard practice with VLED in AU/NZ providing these instructions and therefore this should not pose additional burden to the manufacturers but rather future proof the Food Standards Code.

There is also a concern that some VLEDs only constitute a total source of nutrition with these added foods, fluids, or nutrients. Therefore, the addition of this requirement in the Food Standards Code is required to ensure the “total source of nutrition” statement is accurate and not misleading.

## **ENDS**

**The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.**