FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 2: Labelling assessment

Application A1230 – Very Low Energy Diets (VLED)

Executive summary

FSANZ has considered the labelling requirements for Very Low Energy Diets (VLED) in response to the applicant's request to apply specific labelling requirements and specific exemptions for VLED from existing requirements in the Code. Submitter comments in response to the Call for Submissions have also been taken into account.

This application relates to foods that are formulated and sold to form part of a very low energy diet; that is, a diet comprised of foods specially formulated for the dietary management of overweight and obesity and which, together, provide the sole source of nutrition when consumed according to the manufacturer's directions for use (for the purposes of this supporting document, these foods are referred to as 'VLED').

VLED are considered by FSANZ to be specialised foods used for weight loss for specific medical purposes, within the broader group of foods for special medical purposes (FSMP). FSANZ has therefore sought to align where appropriate with the existing labelling requirements for FSMP. In doing this, the labelling requirements in Part 1.2 of the Code that apply to other foods more generally have also been taken into consideration.

Labelling requirements proposed to apply to VLED during development of a previous proposal - Proposal P242 – Foods for Special Medical purposes - were also taken into consideration. VLED were removed from the scope of the proposal however labelling work done at the time has been revisited to inform this assessment.

FSANZ has also sought to align with the Codex Alimentarius *Standard For Formula Foods For Use In Very Low Energy Diets For Weight Reduction* (Codex 203-1995) (Codex Alimentarius 1995) where appropriate. The requirements in the European Union (EU) for the labelling of total diet replacement for weight control (EU 2017/1798) (European Union 2017) were also taken into account.

FSANZ has also had regard to the *Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods of the Code*[1], in particular, the following principle:

Adequate information should be provided, including through labelling and advertising of special purpose foods, to:

[1] Available at Food Regulation - Food policies

- *assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and*
- *provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.*

The following lists summarise the labelling requirements for packages of VLED, exemptions from the generic labelling requirements within the Code and Standard 2.9.5, and existing requirements that will apply to VLED with variations.

All labelling requirements apply individually to each VLED. They do not apply across the very low energy diet as a whole unless stated e.g. the statement of ingredients is to be for the individual product, not the very low energy diet, however the label for a very low energy food must also state the recommended daily quantity of all very low energy foods to be consumed in order to constitute a very low energy diet which provides the sole source of nutrition.

1. Labelling requirements for VLED consistent with current FSMP requirements

The following requirements that currently apply to FSMP will apply to outer packages of VLED for retail sale:

- legibility requirements
- irradiated food labelling requirements
- name or a description of the food sufficient to indicate the true nature of the food
- lot identification
- date marking, including allowing flexibility to use 'Expiry Date' or similar wording instead of 'Use By'
- directions for use and storage (with additional requirement – see 3 below)
- ingredient labelling, including allowances to use EU or USA ingredient labelling
- lactose and gluten claim conditions
- prohibition of claims of a therapeutic nature
- allergen declarations required by Standard 1.2.3
- certain advisory and warning statements required by Standard 1.2.3, if relevant to the product, i.e. if the food contains aspartame or aspartame-acesulphame salt, a statement to the effect that the food contains phenylalanine
- a statement to the effect that the VLED must be used under medical supervision
- a statement indicating the medical purpose of the food, which may include any disease, disorder or medical condition for which the food has been formulated
- a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated
- a statement indicating whether or not the food is suitable for use as a sole source of nutrition
- if a VLED is represented as being suitable for use as a sole source of nutrition, a statement to the effect that the food is not for parenteral use
- a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food
- a statement indicating where the food is intended for a specific age group.

Subsection 2.9.5—10(1) specifies that if a food is modified to vary from compositional requirements, then a statement indicating the nutrient or nutrients which have been modified is required. Modification from prescribed compositional limits set for very low energy diets is not permitted, therefore this requirement will not apply.

Labelling requirements for inner packages of VLED are:

- name or a description of the food sufficient to indicate the true nature of the food
- lot identification
- allergen declarations
- date marking.

Labelling requirements for transportation outers for VLED are (unless clearly discernible through the transportation outer, or in the case of the supplier name and address, provided in documentation accompanying the VLED):

- name or a description of the food sufficient to indicate the true nature of the food
- lot identification
- name and address of supplier in Australia or New Zealand.

The exemption from labelling requirements for FSMP served by institutions such as hospitals in a container such as a plate, cup or tray will also apply to VLED.

2. Variations from current FSMP requirements for VLED

The nutrition information requirements in Standard 2.9.5 are proposed to apply, including providing flexibility in the presentation of this information, however FSANZ is proposing to specifically require:

- the nutrition information to be provided on a per serving basis (rather than per 'given amount'), with the average quantity of the serving size also stated
- declaration of the average energy content rather than minimum amount
- declaration of linoleic acid and α-linolenic acid (in addition to the requirement to declare any substances used as a nutritive substance).

Following consideration of a submitter request, FSANZ has amended the draft variation proposed in the Call for Submissions to also require declaration of any vitamin, mineral or electrolyte used as a nutritive substance in the VLED, consistent with the approach for FSMP.

3. Additional requirements for VLED

Standard 2.9.5—9 requires the label to state the directions for the use or storage of the food if the food is of a nature to require these directions. There will be an additional requirement for the recommended daily quantity of all very low energy foods to be consumed for use as sole source of nutrition to be declared on the labels of VLED, with the quantity to be established by the manufacturer.

Following consideration of submitter comments, FSANZ has decided to amend the approach proposed for health claims and certain mandatory advisory statements, as follows.

FSANZ has decided to prohibit health claims on the labels and in the advertising of VLED's. FSANZ considered this approach will address submitter concerns about unregulated health claims and the marketing and advertising of VLED and submitter suggestions to take a similar approach to the EU whereby health claims are prohibited.

FSANZ has also decided to mandate a statement on the label about the importance of maintaining an adequate daily fluid intake while consuming VLED. FSANZ considers this requirement mitigates risks associated with dehydration and notes that it is also consistent internationally with the Codex STAN 203-1995 and EU 2017/1798.

Additionally, an advisory statement to the effect that the product is not recommended for pregnant, nursing, or lactating women or use by infants, children, adolescents and elderly, except where medically indicated will be required on the labels of VLED. This amendment is a more prescriptive requirement than the general FSMP requirement for a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food,to assist regulatory clarity.

4. Existing labelling requirements in the Code not applying to VLED

The following labelling requirements in the Code do not apply to VLED (consistent with the existing approach for FSMP):

- percentage of characterising ingredients and components labelling (Standard 1.2.10)
- Standard 1.2.7 – Nutrition, Health and Related Claims
- application of labelling requirements, except as indicated (Standard 1.2.1)
- some mandatory warning and advisory statements (Standard 1.2.3)
- nutrition information requirements, other than as indicated in section 1 above.

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1 Application of labelling requirements to different package types

1.1 Current Code requirements

The Code currently includes mandatory requirements for most packaged foods for retail sale to bear a label with certain information. There are also more limited labelling requirements for unpackaged foods, food for sale in an inner package and food for sale in a transportation outer (not taken away by the consumer). These overarching requirements are specified in Standard 1.2.1 and, for FSMP, in section 2.9.5—8.

The inner package[2] of an FSMP (i.e. an individual sachet (or sachets) of a powdered food contained within a box (for retail sale) that is fully labelled) is required to be labelled with the name of the food, lot identification, declaration of certain foods for allergy reasons, and date marking information.

Transportation outers (used when transporting FSMP before retail sale) are required to be labelled with the name and address olf the supplier (if not provided in accompanying documentation), the name of the food and lot identification. This information is not required on the transportation outer itself if it is on the package of the FSMP that would be for sale to the consumer and is able to be seen through the transportation outer.

There are no labelling requirements for unpackaged foods except for irradiated food labelling requirements (unlikely to be applicable to VLED).

All labels must comply with legibility requirements in Division 6 of Standard 1.2.1 (which is also required by subsection 2.9.5—9(2)).

1.2 Previous considerations

The labelling of inner packages, transportation outers and unpackaged VLED was not discussed in the Preliminary Final Assessment Report (PFAR) for the previous proposal considering VLED, Proposal P242 – Foods for Special Medical Purposes) (FSANZ 2004).

The requirements outlined above were discussed in the P242 Final Assessment Report (FAR) as relevant to FSMP (FSANZ 2012).

1.3 Discussion and decision

The applicant requested that sections 2.9.5—8 and 2.9.5—9 (outlined in Section 1.1) apply to VLED.

FSANZ supports the approach of applying the more limited FSMP labelling requirements (compared to requirements for outer packages of foods for retail sale) for unpackaged foods, inner packages and transportation outers to VLED[3]. The more limited requirements are appropriate for the different packaging layers as follows:

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[2] ***inner package***, in relation to a food for special medical purposes, means an individual package of the food that:
(a) is contained and sold within another package that is labelled in accordance with section 2.9.5—9; and
(b) is not designed for individual sale, other than a sale by a responsible institution to a patient or resident of the responsible institution.

[3] Further discussion about the approach taken for FSMP is provided in SD3 of the FAR for P242: Proposal P242 - Foods for Special Medical Purposes (foodstandards.gov.au)

- transportation outers – labelling requirements are to aid identification during transportation and distribution of the product, other information intended for consumers is not relevant and therefore not required
- inner packages – labelling requirements are to aid identification of the product, allergens, and date mark to protect health and safety of consumers, with other more information required on the outer package (as outlined in sections below)
- unpackaged – consistent with FSMP, the exemption from labelling requirements for FSMPs served by institutions such as hospitals in a container such as a plate, cup or tray will apply because it is impractical to expect labelling of VLED sold in these situations.

The requirements in the Code for legibility of labels will also apply to VLED.

Following assessment and consideration of submitter comments, FSANZ has decided on the labelling requirements for packages of VLED for retail sale other than those listed above, as outlined below.

2 Requirements for product identification

2.1 Current Code requirements

The Code (Standard 1.2.1) includes labelling requirements to assist in the identification of foods. These are:

- the name of the food sufficient to indicate the true nature of the food, or a prescribed name if one is prescribed in the Code
- lot identification
- the name and business address (in Australia or New Zealand) of the supplier of the food.

The requirements in Standard 1.2.1 for the name of the food (sufficient to indicate the true nature of the food) and lot identification also apply to packaged FSMP. Unlike other Special Purpose Foods, there is no prescribed name for FSMP.

The requirement for the name and business address of the supplier of the food however, applies only to FSMP in a transportation outer (used when transporting products before retail sale) and must be either:

- in a label on the transportation outer, or
- in a label of the package containing the food for sale and clearly discernible through the transportation outer, or
- provided in accompanying documentation.

2.2 Codex and EU requirements

The Codex Alimentarius Standard for Formula Foods For use in Very Low Energy Diets for Weight Reduction (Codex STAN 203-1995) requires the name of the food, lot identification and the name and address of the supplier of the food to be on the label of the food. Additionally, it requires that the name of the food shall be ‘Formula Food for Use in Very Low Energy Diets’ (Codex Alimentarius 1995).

In the European Union (EU), the product name required for total diet replacement for weight control products is ‘total diet replacement for weight control’ (European Union 2017).

2.3 Previous considerations

In the P242 PFAR, the approach outlined above in the current Code requirements for FSMP was also proposed to apply to VLED (FSANZ 2004).

In 2011 targeted consultations, some jurisdiction submitters requested that the Australian or New Zealand supplier details be required on each package of FSMP to assist with traceability, particularly in the case of food recalls. Information sought from industry confirmed that imported FSMP do not always have the Australian or New Zealand supplier details on each FSMP package. They indicated that if this information were required on each individual package of FSMP, this would impose a significant cost burden due to re-labelling for the Australia and New Zealand market.

2.4 Discussion and decision

The applicant requested the current approach for FSMP (outlined in Section 2.1) is applied to VLED. FSANZ supports this approach. The lot identification and name of the food are required in the case of food recalls. Furthermore, the name of the food is important to assist consumers and health professionals identify the food.

FSANZ considers the current requirement for FSMP for the name of the food to reflect the true nature of the food rather than prescribing a name is appropriate given the requirement outlined in Section 10.2 below for the product to be labelled with a statement indicating the medical purpose of the product. This approach would mean consumers and health professionals can still identify the purpose of the product and imported products would not need to be re-labelled to meet prescribed name requirements.

In terms of the requirement for the business name and address, the current approach for FSMP will apply to VLED for the reasons identified in P242, i.e. information on each package, such as the name of the food, lot identification and date mark would provide adequate information in the case of a food recall (FSANZ 2012). Furthermore, the locations from which VLED are permitted to be sold will be restricted (refer to section 2.3.2.4 in the Approval report) which will assist any tracing of products which may be required.

Overall, this approach is consistent with reducing the cost burden associated with re-labelling of this category of foods, while maintaining adequate identification.

3 Date marking

3.1 Current Code requirements

The Code (Standard 1.2.5) requires most packaged foods to be labelled with either a best-before date to indicate the date the food will remain fully marketable and retain any qualities for which claims have been made (unless the best-before date would be two years or more), or a use-by date if the food should not be consumed after a certain date due to health or safety reasons.

Packaged FSMP are also required to comply with these labelling requirements, however ‘Expiry Date’ or similar wording may be used instead of ‘Use By’. If the words ‘Expiry Date’ or similar are used on an FSMP, conditions in Standard 1.2.5 for a use-by date still apply (i.e. the FSMP must not be sold past its expiry date).

3.2 Codex and EU requirements

Codex STAN 203-1995 requires date marking in accordance with the *General Standard For The Labelling Of Prepackaged Foods* which is broadly consistent with the Code requirements, however it also allows for an 'expiration date' (Codex Alimentarius 1985a).

In the EU, the date of minimum durability or the 'use by' date are required on the label (European Union 2017).

3.3 Discussion and decision

FSANZ supports the applicant's request that the provisions for date marking applying to FSMP also apply to VLED.

Date marking is important for consumers of VLED as it provides valuable information on the quality and/or safety of the food. Permission to use the words 'expiry date' or similar means that VLED imported into Australia or New Zealand using that term will not require re-labelling to comply with the date marking requirements in the Code.

4 Directions for use and storage

4.1 Current Code requirements

Standard 1.2.6 (which does not apply to FSMP) requires foods to be labelled with:

- storage conditions if specific storage conditions are required to ensure the food will keep until its expiry date
- storage conditions and directions for use if the food must be used or stored in accordance with certain directions for health or safety reasons.

Standard 2.9.5 requires labels of FSMP to state the directions for the use or storage of the food if the food is of a nature to require these directions ((paragraph 2.9.5—9(1)(g)). These requirements are in addition to specific advisory statements outlined in Section 9 below.

4.2 Codex and EU requirements

Codex STAN 203-1995 requires any special conditions for the storage of the food to be declared on the labels of formula foods for use in very low energy diets for weight reduction if the validity of the date depends thereon. Additionally, storage instructions of opened packages of the food shall be included on the label to ensure the opened food maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening (Codex Alimentarius 1995).

Codex STAN 203-1995 also requires that the Codex Alimentarius Standard for the Labelling of and Claims for Foods For Special Medical Purposes (Codex Stan 180-1991) is met. That Standard requires adequate directions for the preparation including the requirement to add other ingredients, for the use of the food, and for its storage and keeping after the container has been opened, on the label. It also requires labelling with 'feeding instructions', including the method of administration and serving size, if applicable (Codex Alimentarius 1991).

The EU regulation for total diet replacement for weight control requires instructions for appropriate preparation where necessary and a statement as to the importance of following

those instructions. It also requires a statement that the product provides adequate daily amounts of all essential nutrients when used in accordance with the instructions for use (European Union 2017).

Additionally, the requirements for labelling in Regulation (EU) No 1169/2011 (Article 9(1)) (European Union 2011) apply to total diet replacement for weight control products. This regulation requires instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions. This is further elaborated in Article 27 which states *The instructions for use of a food shall be indicated in such a way as to enable appropriate use to be made of the food*.

4.3 Previous considerations

The regulatory approach for directions for use and storage for FSMP was developed under P242 and the same approach was proposed to apply to VLED before they were removed from the scope of that proposal.

It was also proposed in the P242 Draft Assessment Report to require the label for VLED to include a statement of the recommended daily consumption (FSANZ 2002). This information was proposed to advise of appropriate use. Several submitters indicated that the labelling of a recommended daily quantity for VLED established by the manufacturer is inappropriate because the dosage and concentration is the responsibility of the supervising health professional and in addition, VLED can often be used in smaller quantities with food.

In the P242 PFAR the requirement was no longer proposed, noting it was highly prescriptive, especially given that overseas VLED regulations did not prescribe it and it was onerous on manufacturers when most VLED are used under medical supervision(FSANZ 2004).

4.4 Discussion and decision

The applicant requested that the requirements for labelling with the directions for use and storage of FSMP also apply to VLED.

FSANZ considers that aligning with the requirement for FSMP to state the directions for the use or storage of the food if the food is of a nature to require these directions is appropriate. FSANZ supports the requested approach as it is important for VLED to inform consumers about the intended storage and use of the product.

The applicant also requested an additional requirement for a statement on the labels of VLED of the recommended daily quantity of the product to be consumed, with the quantity to be established by the manufacturer. FSANZ also supports this approach and considers such instructions are important given very low energy diets are intended to provide the sole source of nutrition for an overall daily intake with limited energy intake when consumed in accordance with the total diet replacement plan. The compositional requirements for VLED are based on a daily intake when consumed according to directions for use across a very low energy diet, not on a per product basis, however nutrition information for a VLED must be in relation to an individual product. The information relating to recommended daily quantity of a product to be consumed can therefore be used in association with the nutrition information panel information to assist consumers and health professionals to determine how to achieve desired daily intakes of energy and nutrients. It will also assist enforcement agencies in checking composition of very low energy diets for enforcement purposes.

5 Statement of ingredients

5.1 Current Code requirements

Requirements for a statement of ingredients on the labels of foods are included in Standard 1.2.4. This standard includes specific requirements such as the order of the ingredients in the list and the naming of food additives.

For FSMP, a statement of ingredients is required (paragraph 2.9.5—9(1)(d)) however that statement can comply with either the requirements in Standard 1.2.4, the EU regulation (Articles 18-20 of 1169/2011) or the US regulation (21 CFR Part 101.4).

5.2 Codex and EU requirements

Codex STAN 203-1995 requires a list of ingredients that complies with the requirements in the General Standard For The Labelling Of Prepackaged Foods (similar to Code requirements) (Codex Alimentarius 1995).

The requirements for labelling with a list of ingredients in Regulation (EU) No 1169/2011 apply to total diet replacement for weight control products (European Union 2011, 2017).

5.3 Previous considerations

The regulatory approach for ingredient labelling for FSMP was developed under P242 and the same approach was proposed to apply to VLED before they were removed from the scope of that proposal.

5.4 Discussion and decision

The Applicant requested that the approach for ingredient labelling of FSMP also applies to VLED.

As stated in P242, FSANZ considers that the EU or USA ingredient labelling requirements (listed above) provide sufficient information for consumers and health professionals about the ingredients in VLED to assist with making an informed decision (FSANZ 2012). Requirements in the EU and USA are not radically different from the Code requirements for statements of ingredients. Allowing VLED to comply with EU or USA ingredient labelling requirements provides additional flexibility for imported products and may mean the ingredient list on any VLED complying with the EU or US requirements would not need revising in order to meet the requirements in Standard 1.2.4.

In summary, FSANZ considers that the current provision for FSMP to be labelled with a statement of ingredients that complies with either Standard 1.2.4 or the EU or US ingredient labelling requirements is appropriate and will apply to VLED.

6 Characterising ingredients

6.1 Current Code requirements

Requirements for declaring the proportion of characterising ingredients or components of a food are included in Standard 1.2.10, to assist consumers make informed choices when purchasing food.

6.2 Codex and EU requirements

Codex does not require quantitative labelling of ingredients for foods for special medical purposes (Codex Alimentarius 1991).

In the EU, the requirements for labelling the quantity of certain ingredients or categories of ingredients in Regulation (EU) No 1169/2011 (similar to the requirements in the Code) apply to total diet replacement for weight control products (European Union 2011, 2017).

6.3 Previous considerations

Percentage labelling requirements were not proposed to apply to VLED in the P242 PFAR (FSANZ 2004).

6.4 Discussion and decision

The applicant did not request that requirements for labelling of charactering ingredients or components apply to VLED.

The requirements in Standard 1.2.10 will not apply to VLED, consistent with the current approach for FSMP and for the reason provided in P242 (FSANZ 2012). That is, they are specifically designed for a medical purpose and consumers and health professionals are unlikely to use this information to assist with purchase decisions. This information could however, be voluntarily provided on the label of VLED.

7 Nutrition information

7.1 Current Code requirements

Standard 1.2.8 requires a nutrition information panel (NIP) on the labels of most packaged foods. The panel must include a declaration of energy, protein, fat, saturated fat, carbohydrate, sugar and sodium and any other claimed nutrients or substances, on both a per serving and per unit quantity (100 g or ml) basis. The serving size of the food and number of servings per package of the food must also be declared in the NIP. The format for the NIP is prescribed. If the label on the food indicates that food should be reconstituted with water before consumption, the information in the NIP must be declared as a proportion of the reconstituted food. A declaration of the percentage of recommended dietary intake is required in the NIP if nutrition content or health claims are made about vitamins or minerals. A declaration of the percentage daily intake values for energy and macronutrients is permitted if certain conditions are met.

The requirements in Standard 1.2.8 for NIPs do not apply to FSMP. Instead, Standard 2.9.5 (section 2.9.5—13) sets out requirements for certain nutrition information to be provided (minimum or average energy content and minimum or average quantity of protein, fat, carbohydrate, and any substance that has been used as a nutritive substance in the food (including vitamins, minerals and electrolytes)). The format for providing the nutrition information is not prescribed. The basis required for the declarations is per ‘given amount’ of food (i.e. per serving or per 100 g) and there is no requirement to declare the serving size of the food or number of servings per package. There are no provisions for declaring nutrients as a percentage of nutrient reference values (i.e. as a percentage of recommended daily intake values for vitamins and minerals).

7.2 Codex and EU requirements

Codex STAN 203-1995 requires the energy, protein, available carbohydrate, and certain vitamins and minerals in formula foods for use in very low energy diets for weight reduction to be declared on the label per 100 g or ml of the food as sold and, where appropriate, for a specified quantity of the food as suggested for consumption. The amounts of other nutrients may also be declared. Additionally, the quantity of nutrients may be expressed in terms of percentages of internationally acceptable recommended daily nutrient standards (Codex Alimentarius 1995).

In the EU, the requirements for nutrition information in Regulation (EU) No 1169/2011 generally apply to total diet replacement for weight control products. There are however, a number of more specific requirements for nutrient declaration for total diet replacement for weight control products ((European Union 2017), including:

- the amount of each mineral and vitamin present in the product (if required to be included in the product)
- the amount of choline present
- the amount of dietary fibre, if added
- the energy and nutrients must be expressed per total daily ration and per portion and/or per consumption unit of the food ready for use after preparation in accordance with instructions
- information may also refer to 100 g or ml of the food as sold
- the energy value and amount of nutrients cannot be expressed as a percentage of reference intakes.

7.3 Previous considerations

The regulatory approach for nutrition information for FSMP was developed under P242 and the same approach was proposed to apply to VLED before they were removed from the scope of that proposal (FSANZ 2004).

7.4 Discussion and decision

The Applicant requested that the approach for nutrition information for FSMP also applies to VLED. FSANZ considers that approach is appropriate for VLED with the following exceptions (as detailed below):

- the nutrition information is to be provided on a per serving basis (rather than per ‘given amount’), with the average quantity of the serving size also stated
- declaration of the average energy content rather than minimum content
- declaration of linoleic acid and α-linolenic acid (in addition to the requirement to declare any substances used as a nutritive substance).

7.4.1 Basis for declaration

The requirement for FSMP for the declaration to be expressed ‘per given amount of the food’ means there is no specific requirement for the basis of the amounts (i.e. per serving or per 100 g). FSANZ notes that nutrition information on the two major VLED brands in Australia and New Zealand is currently provided on a per serving basis (with some also on a per 100g or mL basis) in association with instructions for replacing all three meals with a VLED. FSANZ considers that provision of nutrition information on the basis of a serving is essential in order for consumers and health professionals to determine daily intakes of energy and nutrients and for enforcement agencies to check composition of a very low energy diet for

enforcement purposes (as outlined in Section 4 above). FSANZ therefore proposes that for VLED, the nutrition information must be provided on a per serving basis, with the average quantity of serving size also stated. The information could also voluntarily be provided on the basis of other given amounts of the food, for example per 100 g or 100 mL. Although this approach deviates from the approach for other FSMP, the proposed compositional requirements for very low energy diets are based on daily intake (typically made up of three VLED) rather than an energy basis (MJ) as is the case for other FSMP and therefore FSANZ considers that this approach is warranted.

7.4.2 Substances to be declared

In the Call for Submissions, FSANZ intended to propose a requirement to declare the average energy content, minimum amount or average quantity of protein, fat, carbohydrate and any substance used as a nutritive substance in the VLED. The draft variation however, did not accurately reflect this intention with respect to substances used a nutritive substance, whereby only those substances listed in the table to section S29—22 that were used as a nutritive substance were required to be declared. One submitter requested that there be a mandatory requirement to also declare the substances listed in S29—20. Noting other nutritive substances in addition to those listed in S29—22 can be added to VLED, FSANZ has therefore reconsidered this requirement and decided to also require declaration of the minimum amount or average quantity of any other vitamin, mineral or electrolyte that has been used as a nutritive substance in the VLED. This information also aids medical professionals clinical guidance and judgement regarding product selection and use.

Specific requirements are also proposed to require the minimum amount or average quantity of linoleic acid and α-linolenic acid to be declared. These fatty acids may be present in the VLED as part of an ingredient such as a vegetable oil and therefore not captured by the requirement mentioned above to declare any substance that has been used as a nutritive substance. There are compositional requirements proposed for these fatty acids and their declaration is important for the reasons noted above.

The minimum amount or average quantity per serving of any substance about which a nutrition content claim is made must also be declared on the label of the VLED. For example, if a claim about dietary fibre is made, such as ‘high in fibre’, the miniumum amount or average quantity per serving of dietary fibre must be declared on the label.

In terms of the energy declaration, VLED must be labelled with the average energy content per serving rather than the minimum content (as permitted for FSMP currently). This information, in combination with information about the daily quantity of VLED to be consumed (refer to Section 4.4 above) will aid enforcement of the requirements for the average energy content of VLED. Declaration of the minimum energy content could also result in consumers or health professionals underestimating the energy content which would be problematic for their use in weight loss.

In summary, the following will be required to be declared on the label of a VLED on a per serving basis:

- the average energy content
- the minimum amount or average quantity of the following:
  - protein, fat, carbohydrate
  - linoleic acid and α-linolenic acid
  - the substances listed in the table to section S29—22 that were used as a nutritive substance in the VLED
  - any other vitamin, mineral or electrolyte that has been used as a nutritive substance in the VLED

- any substance about which a nutrition content claim is made.

FSANZ proposes that the quantity of dietary fibre is not required to be declared but could be declared voluntarily. This is because there are no mandatory compositional requirements for dietary fibre and consumers of VLED are encouraged to consume additional fresh vegetables which would provide a fibre source.

Overall, this approach will ensure declaration of relevant information is provided to consumers and health professionals about the mandatory composition of VLED, which is important given the very low energy diet is intended to be the sole source of nutrition. It also allows for declarations to be consistent with those required in the EU. It generally reflects the current approach for FSMPs. The mandatory declaration will also assist with checking against the compositional requirements to assist with enforcement. Nutrition information for energy and an extensive range of nutrients in the product is currently provided on VLED labels.

7.4.3 Percentage intake declarations

The requirements and provisions in Standard 1.2.8 for the declaration of the percentage of recommended dietary intake if nutrition content or health claims are made about vitamins or minerals will not apply to VLED. Likewise, the requirements for when percentage daily intake values for energy and macronutrients voluntarily declared will not apply. Percentage recommended daily intake and percentage daily intake declarations could be made voluntarily, however there would be no requirements in the Code for these declarations, including no requirement for the nutrient reference values to be used as the basis for these claims. FSANZ expects however, that the prescribed values in the Code or in the Codex Guidelines on Nutrition Labelling (Codex Alimentarius 1993) would likely be used. Additionally, the composition of very low energy diets is prescribed for the purpose of being the sole source of nutrition, therefore it is expected that the nutrient content will be adequate and safeguard consumers. This approach is consistent with the current approach for FSMP.

7.4.4 Format for nutrition information

The actual format for presenting the nutiriton information will not be prescribed, consistent with the current approach for FSMP.

8 Nutrition content and health claims

8.1 Current Code requirements

Standard 1.2.7 sets out the conditions for nutrition content and health claims made on food labels and in advertising for food. Standard 1.2.7 does not apply to FSMP, meaning nutrition content and health claims can be made about FSMP, however the conditions in Standard 1.2.7 for those claims do not need to be met.

Conditions for claims about gluten and lactose content are however, specifically included in Standard 2.9.5 as well as prohibitions for claims that are therapeutic in nature, including claims that refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition. These provisions are consistent with those in Standard 1.2.7.

8.2 Codex and EU requirements

The Codex *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CXS 146-1985) prohibits claims as to the suitability of a food for

special dietary uses for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition unless in accordance with provisions for those foods (Codex Alimentarius 1985b). Additionally, the *Guidelines For Use Of Nutrition And Health Claims* (CAC/GL 23-1997) apply to all foods for which nutrition and health claims are made without prejudice to the Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes (Codex Alimentarius 1997). The Codex *Standard For Formula Foods For Use In Very Low Energy Diets For Weight Reduction* (Codex 203-1995) (Codex Alimentarius 1995) requires a labelling statement that the product may not be recommended for use of purposes other than the dietary management of obesity. In EU regulation (2017/1798), nutrition and health claims are not permitted on total diet replacement for weight control products with the exception of the nutrition claim 'added fibre'. Labelling, presentation and advertising of these products are not permitted to refer to the rate or amount of weight reduction which may result from its use. The EU regulation also specifically permits the following statements:

- 'very low calorie diet' for total diet replacement for weight control products provided that the energy content of the product is below 3360 kJ/day (800 kcal/day)
- 'low calorie diet' for total diet replacement for weight control products provided that the energy content of the products is between 3360 kJ/day (800 kcal/day) and 5040 kJ/day (1200 kcal/day) (European Union 2017).

8.3 Previous considerations

At the time P242 was being considered, Standard 1.2.7 was under development and had not been gazetted. In P242 the general approach for all FSMP was to not apply the requirements of Standard 1.2.7 (when drafted) with the exception of a prohibition on therapeutic claims and application of the conditions for making nutrition content claims about gluten and lactose.

The majority of Standard 1.2.7 requirements were not applied to FSMP to prevent confusion about whether references to a disease, disorder or medical condition on an FSMP label should be regulated under the health claims standard. Additionally it was considered that the impending nutrition content and health claims regulations were to regulate claims on foods for the general public, not specifically for claims made to health professionals or consumers of FSMP used under medical supervision. As the sale of FSMP was to be restricted, it was considered that claims on FSMP would less likely be targeted to the general public.

The prohibition of therapeutic claims was to maintain consistency with the prohibition on therapeutic claims for all other foods sold in Australia and New Zealand and to help to distinguish between food products and complementary medicines at the food/medicine interface.

Regarding gluten and lactose claims conditions, FSANZ considered that claim conditions were required (as opposed to no claim conditions) to protect the health and safety of consumers of FSMP. There are circumstances where consumers of FSMP require 'lactose free' or 'gluten free' products for medical reasons and health professionals need to be sure that the foods claiming to be 'free' are in fact 'free'. Applying the Code conditions for such claims to FSMP ensures consistency across all foods sold in Australia and New Zealand, thereby providing consistent labelling information to consumers.

Stakeholders were generally in favour of permitting reference to disease states on FSMP but opposed to claims of therapeutic or prophylactic action.

In the Call for Submissions for this application, FSANZ proposed that the conditions for nutrition content claims about gluten and lactose should be applied to VLED consistently with the requirements for FSMP. Therapeutic claims were also proposed to be prohibited. Similar to other FSMP it was proposed that Standard 1.2.7 would not apply to VLED thereby

allowing nutrition content and health claims to be made on labels and in advertising of VLED, with no requirement to meet specific conditions in the Code. In response, some submitters expressed concern about unregulated claims and suggested nutrition content and health claims should be prohibited apart from statements about their intended purpose and potentially about dietary fibre.

8.4 Discussion and decision

The applicant noted that the clause that exempts FSMP from complying with certain labelling requirements in the Code, including Standard 1.2.7, was applicable to VLED. They did not however, specifically address nutrition content or health claims, including the prohibition of therapeutic claims.

FSANZ has taken into consideration concerns from submitters about unregulated claims and decided to prohibit health claims (as currently defined in the Code) in the labelling and advertising of VLED. This approach will help address submitter concerns about unregulated health claims and the marketing and advertising of VLED, and submitter suggestions to take a similar approach to the EU whereby health claims are prohibited. A statement of the medical purpose of the product, which may include reference to dietary management of overweight or obesity, will still need to be declared on the label and such a statement is not regulated as a claim, however health claims, including those that may attract the non-target consumer, will not be permitted. FSANZ considers this approach aligns with the intent of VLED, i.e. a special purpose food formulated for the dietary management of overweight and obesity, to be used under medical supervision. As noted by submitters, it also aligns with the EU and therefore will not impact on VLED imported into Australia or New Zealand from the EU. A prohibition on health claims is comparable to the requirement in Codex 203-1995 that states the product may not be recommended for use for purposes other than the dietary management of obesity.

One submitter suggested rather than permitting broad, unregulated health claims, a specific pre-approved claim is permitted 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). FSANZ has not permitted a pre-approved claim as suggested, for the reasons outlined above, in particular that VLED must refer to the medical purpose of the food.

With respect to nutrition content claims, FSANZ has decided to continue with approach proposed in the Call for Submissions, to permit nutrition content claims in relation to a VLED. These nutrition content claims will enable VLED suppliers to highlight the presence and levels of energy and nutrients as appropriate to their product, enabling product differentiation, for example, ‘high protein’. The average amount or minimum quantity of any substance about which a nutrition content claim is made will also need to be declared, as outlined in Section 7.4.2 above.

The conditions for nutrition content claims about gluten and lactose will be applied to VLED consistently with the requirements for FSMP, to protect the safety of consumers as outlined in the section above. Consistent with the approach proposed in the Call for Submissions and with the approach for other FSMP, specific conditions for other permitted nutrition content claims will not apply. Legislation in both Australia[4] and New Zealand[5] that prohibits misleading or deceptive representations would apply to nutrition content claims made in relation to VLED (on both labels and in advertising).

[4] Australian Consumer Law (ACL) contained in the *Competition and Consumer Act 2010*, and state and territory Fair Trading Acts and Food Acts
[5] *Food Act 2014* and *Fair Trading Act 1986*

The prohibition of claims of a therapeutic nature is also important for VLED to protect consumers. As the statement indicating the medical purpose of the food, which could include reference to dietary management of overweight or obesity (see Section 10.2 below) will be a mandatory requirement, it would not be prohibited by the overarching prohibition on claims of a therapeutic nature.

9 Required warning and advisory statements

9.1 Current Code requirements

Standard 1.2.3 and Schedule 9 set out requirements for certain mandatory advisory statements and the mandatory declaration of certain foods (to advise consumers allergic to those foods of their presence, for example, milk, egg). Standard 1.2.3 also includes a requirement for a mandatory warning statement about royal jelly.

Only some of the advisory statements required under Standard 1.2.3 and Schedule 9 are required for FSMP (2.9.5—9(1)(d) and 2.9.5—10(2)). The following are required if the FSMP contains:

- bee pollen; a statement to the effect that the food contains bee pollen which can cause severe allergic reactions
- aspartame or aspartame-acesulphame salt; a statement to the effect that the food contains phenylalanine
- guarana or extracts of guarana; a statement to the effect that the food contains caffeine
- propolis; a statement to the effect that the food contains propolis which can cause severe allergic reactions
- certain polyols or polydextrose above specified limits; a statement to the effect that excess consumption of the food may have a laxative effect.

A warning statement about royal jelly is also required if an FSMP contains royal jelly (2.9.5—9(1)(d) and 2.9.5—10(3)).

The requirements in Standard 1.2.3 for declarations of certain foods, i.e. egg, milk, for allergy reasons also apply to FSMP. More prescriptive requirements for the wording, formatting and presentation of food allergen declarations were included in the Code in February 2021. These however, were not applied to FSMP, to ensure the supply of specialised FSMP can continue uninterrupted, and in recognition that they are used under medical supervision and cannot be directly accessed by consumers[6].

Standard 2.9.5 also currently requires FSMP to be labelled with a statement indicating any precautions and contraindications associated with consumption of the food, if there are any.

9.2 Codex and EU requirements

Both the Codex General Standard for the Labelling of Prepackaged Foods (Codex Alimentarius 1985) and the EU Regulation (European Union 2017) (which applies to total diet replacement for weight control products) require declarations of certain foods for allergy reasons, similar to the list in Standard 1.2.3.

[6] Subsection 1.2.3—6(4). These requirements were considered under P1044 – Plain English Allergen Labelling [link to webpage].

Codex STAN 203-1995 requires compliance with the Standard for labelling for foods for special medical purposes (Codex Alimentarius 1995). That standard requires a statement concerning adequate precautions, known side effects, contraindications and product-drug interactions as applicable (this information can be provided in an accompanying leaflet (in which case reference shall be made to this fact on the label of the package).

In EU regulation (2017/1798), there is a specific requirement for a statement regarding laxative effects if a product provides a daily intake of over 20 g of polyols. It also requires a statement that the advice of a healthcare professional must be sought regarding the possibility of supplementing with dietary fibre if dietary fibre is not added to the product (European Union 2017).

9.3 Previous considerations

The regulatory approach outlined above for advisory and warning statements and declarations was developed under P242 after VLED were removed from the scope of that project (FSANZ 2012).

9.4 Discussion and decision

The applicant requested that the approach for these labelling requirements for FSMP also applies to VLED. FSANZ supports this approach and considers that the application of these statements to VLED is important to provide adequate information to consumers and health professionals and to protect the health and safety of consumers. The specific statements will only be required if relevant to the product, for example, the warning statement for royal jelly would not be required if the product does not contain royal jelly.

As was the case for other FSMP, other advisory statements required by Standard 1.2.3 and Schedule 9 are not considered to be relevant (for example, the statement relating to cola beverages), or appropriate for VLED (for example, the statements indicating that the product is unpasteurised, for unpasteurised egg and milk products) and therefore will not apply.

Due to the risks associated with the consumption of allergenic substances by certain consumers, these will be required to be declared on VLED if present, for example, egg, milk, soybeans, added sulphites if 10 mg/kg or more, tree nuts, based on clause 4 of Standard 1.2.3. The additional wording, formatting and presentation requirements for their declaration will not apply to VLED, consistent with the approach for FSMP. The requirements in the EU and USA for declaring these substances on FSMP are similar to the requirements in Standard 2.9.5. Therefore, most VLED imported into Australia or New Zealand are unlikely to require re-labelling in order to meet these declaration requirements.

The requirement to indicate any precautions and contraindications associated with consumption of the food is considered appropriate and will apply, with the supplier of the VLED responsible for determining specific precautions and contraindications relevant to their product.

10 Other specific statements

10.1 The food must be used under medical supervision

10.1.1 Current Code requirements

The Code currently requires the label of FSMP to state that the food must be used under medical supervision.

10.1.2 Codex and other overseas requirements

Codex CXS 180-1991 requires Foods for Special Medical Purposes to be labelled with a prominent statement 'USE UNDER MEDICAL SUPERVISION' on the label in bold letters in an area separated from other written, printed or graphic information (Codex Alimentarius 1991).

In the EU, total diet replacement for weight control products are required to be labelled with a statement that the product should not be used for more than 8 weeks, or repeatedly for shorter periods than this, by healthy overweight or obese adults without the advice of a healthcare professional (European Union 2017).

10.1.3 Previous considerations

In the P242 PFAR a requirement to label FSMP (including VLED) to the effect that 'Foods for Special Medical Purposes are to be used only under medical supervision' was proposed (FSANZ 2004).

10.1.4 Discussion and decision

The applicant requested that the statement that the food must be used under medical supervision be required on the labels of VLED.

FSANZ agrees that this labelling requirement be applied to VLED. As noted under P242, it is a useful reminder to consumers of how VLED are intended to be used and will assist in preventing inappropriate use (FSANZ 2012). This statement aligns with the overall proposed regulation of VLED including restriction on sale. It is also consistent with the Policy Guideline on the intent of Part 2.9 – Special Purpose Foods[7], in particular, the principle referring to the provision of adequate information to provide for safe use by the intended population.

10.2 Statements in relation to the medical purpose of the food

10.2.1 Current Code requirements

The Code currently requires the following on the labels of FSMP (paragraphs 2.9.5—10(1)(c)-(d)):

- a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated
- a statement describing the properties or characteristics which make the food appropriate for that medical purpose.

10.2.2 Codex and EU requirements

Codex STAN 203-1995 requires formula foods for use in very low energy diets to be labelled with:

- the statement (direction) 'for the dietary management of obesity' to be declared on the label, in close proximity to the name of the food on the label of the package
- a labelling statement that the product may not be recommended for use for purposes other than the dietary management of obesity (Codex Alimentarius 1995).

[7] Available at Food Regulation - Food policies

Codex STAN 203-1995 also requires formula foods for use in very low energy diets to comply with the Standard for labelling for foods for special medical purposes (180-1991). That standard requires a warning statement if the food poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended (Codex Alimentarius 1991).

EU regulation for total diet replacement for weight control products (2017/1798) requires:

- a statement that the product is only intended for healthy overweight or obese adults who intend to achieve weight reduction
- a statement that the product provides adequate daily amounts of all essential nutrients when used in accordance with the instructions for use (European Union 2017).

The EU regulation also specifically permits the following statements:

- 'very low calorie diet' for total diet replacement for weight control products provided that the energy content of the product is below 3 360 kJ/day (800 kcal/day)
- 'low calorie diet' for total diet replacement for weight control products provided that the energy content of the products is between 3 360 kJ/day (800 kcal/day) and 5 040 kJ/day (1 200 kcal/day) (European Union 2017).

10.2.3 Previous considerations

In the P242 Draft Assessment Report the following warning statement (with prescribed wording) was proposed specifically for VLED: 'this product is for the dietary management of obesity'. It was considered that this was necessary for medical professionals and consumers to be able distinguish VLED from other FSMP, as there was a small risk that VLED could be mistaken for other FSMP if they do not have any information on the label that clearly distinguishes them from other products (FSANZ 2002).

No submitters opposed this requirement however one submitter considered it was not necessary.

In the P242 PFAR the proposed approach for this warning statement was retained for the reasons outlined above (FSANZ 2004).

10.2.4 Discussion

The applicant requested the following labelling statements be required for VLED, with the actual wording not prescribed:

- a statement to the effect that a VLED is a nutritionally complete formula presented for use in energy restricted diets for the dietary management of obesity
- a statement to the effect that the product is for the dietary management of obesity.

The applicant considered that although these requirements are more specific than the current requirements for FSMP, the additional detail is relevant and helpful to consumers, and addresses some concerns raised during P242, such as the inappropriate consumption of VLED by non-target consumers.

In the Call for submissions for this application, FSANZ proposed to apply to VLED the general requirements in Standard 2.9.5 to label with statement indicating the medical purpose of the food. That statement may optionally include a disease, disorder or medical condition for which the food has been formulated. The statement must also refer to the properties or characteristics that make the food appropriate for that purpose.

One submitter to the Call for Submissions for this application requested a statement to the effect that VLED are appropriate for the dietary management of obesity to be included on the label. FSANZ has further considered this issue but decided to maintain the approach proposed in the Call for submissions for the following reasons.

Applying the general requirements in Standard 2.9.5 to the label with a statement indicating the medical purpose would address the request from the applicant to require VLED to be labelled with a statement to the effect that they are for use in energy restricted diets. The label would also need to refer to the energy content of the food as the 'properties or characteristics' which make the food appropriate for that medical purpose. Reference specifically to the dietary management of overweight and/or obesity would be optional wording rather than specifically mandated by that requirement. The definition of an FSMP however, refers to a food that is either represented as being a food for special medical purposes or represented for the dietary management of a disease, disorder or medical condition. VLEDs would therefore need to be represented in either of these ways in order to be captured by Standard 2.9.5.

A reference to energy restricted diets on labels should be adequate to enable consumers and health professionals to identify appropriate products for use in energy restricted diets for specific medical purposes without mandating a reference to obesity as such.

As is the approach for FSMP and other foods in general, the location of these statements will not be prescribed as it is by Codex. The statement indicating the medical purpose of the food may be located near the product name or elsewhere on the label, or it may actually be the product name itself (if it also meet the requirement for the product name).

FSANZ will not require a labelling statement referring to 'nutritionally complete formula'. This is discussed further in Section 10.3 below.

FSANZ considers that this approach is consistent with the Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods of the Code, in particular, the following principle:

Adequate information should be provided, including through labelling and advertising of special purpose foods, to:

- *assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and*
- *provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.*

10.3 Statements in relation to sole source of nutrition

10.3.1 Current Code requirements

The Code currently requires the following on the labels of FSMP (paragraphs 2.9.5—10(1)(f) and (g)):

- a statement indicating whether or not the food is suitable for use as a sole source of nutrition
- if the FSMP is represented as suitable for use as a sole source of nutrition:
  - a statement to the effect that the food is not for parenteral use
  - if the food has been modified to vary from certain compositional requirements to fall short of the prescribed minimum or exceed the prescribed maximum, a

statement indicating the nutrient(s) which have been modified and a statement indicating whether the nutrient(s) has been increased, decreased or eliminated.

10.3.2 Codex and other overseas requirements

Codex CXS 180-1991, which also applies to formula foods for use in very low energy diets requires statements on the labels of Foods for Special Medical Purposes:

- indicating whether the product is or is not intended as the sole source of nutrition
- specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification
- that the product is not to be used for parenteral administration (Codex Alimentarius 1991).

EU regulation for total diet replacement for weight control products (2017/1798) requires a statement that the product provides adequate daily amounts of all essential nutrients when used in accordance with the instructions for use (European Union 2017).

10.3.3 Previous considerations

During P242 considerations, statements relating to sole source of nutrition were not proposed to apply to VLED (FSANZ 2004).

10.3.4 Discussion and decision

The applicant requested that the required statements for FSMP relating to the product as a sole source of nutrition not be required for VLED as they are not relevant (the applicant also requested that the compositional requirements for food represented as being suitable for use as sole source of nutrition not apply to VLED).

FSANZ however, has decided that the first two requirements listed in Section 10.3.1 above (referring to 'suitable for use as a sole source of nutrition' and that the food is not for parenteral use) will apply to VLED. FSANZ considers that wording referring to 'nutritionally complete', as requested by the applicant (see Section 10.2.4 above), could be used to meet the requirement to label with a statement indicating that the food is suitable for use as a sole source of nutrition.

Very low energy foods need to meet the compositional requirements prescribed in section 2.9.5—18 and be consumed in accordance with the manufacturer's directions for use. Very low energy food must meet the nutrition composition of 'very low energy diet' when consumed in sufficient quantity. The very low energy food must provide the sole source of nutrition when consumed according to the directions for use on the label. The label of a very low energy food must therefore be labelled to state that it is a sole source of nutrition when consumed according to the directions on the label for consuming with other very low energy foods.

The requirement for labelling of nutrients modified from a prescribed composition is not proposed to apply as there is no such modification proposed to be permitted.

10.4 Specific population groups

10.4.1 Current Code requirements

The Code currently requires the following on the labels of FSMP (paragraphs 2.9.5-10(1)(b) and (e) respectively):

- a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
- if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group.

10.4.2 Codex and other overseas requirements

Codex 203-1995 requires labelling on formula foods for use in very low energy diets that the product is not for pregnant, nursing, lactating women or use by infants, children, adolescents and elderly, except where medically indicated (Codex Alimentarius 1995).

Codex Stan 180-1991, which also applies to formula foods for use in very low energy diets, requires that if the product has been formulated for a specific age group, it should carry a prominent statement to this effect (Codex Alimentarius 1991).

Additionally, Codex Stan 180-1991 requires a statement concerning adequate precautions, known side effects, contraindications and product-drug interactions as applicable.

Codex 203-1995 allows for the three statements outlined above to be provided in an accompanying leaflet, in which case reference shall be made to this fact on the label of the package.

EU regulation for total diet replacement for weight control products (2017/1798) requires a statement that the product should not be used by pregnant or lactating women and by adolescents (European Union 2017).

10.4.3 Previous considerations

In P242 it was not proposed to apply the labelling statement referring to age groups to VLED. A specific advisory statement that the product may not be suitable for pregnant, nursing or lactating women or by infants, children, adolescents or the elderly, except where medically indicated, was instead proposed. It was considered that while that advisory statement appeared inconsistent with NHMRC clinical practice guidelines (as it recommended that VLED therapy in adolescents should be undertaken only by specialist obesity-management teams and that VLED therapy is never indicated for children), adding a qualifier ‘except when medically indicated’ would ensure it was not inconsistent with the guidelines and ensure consistency with Codex (FSANZ 2004).

10.4.4 Discussion and decision

The applicant requested that a statement on the label of VLED be required to the effect that the product may not be suitable for use by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except where medically indicated.

In the Call for Submissions for this application FSANZ decided not to require the specific statement requested by the applicant. Rather than a prescriptive approach, it was considered that the existing requirements for FSMPs to be labelled with a statement referring to precautions and contraindications (see Section 9 above) and specific age groups would

result in labelling to the effect requested by the applicant if deemed appropriate for the product. In response to submitter comments, FSANZ has reconsidered this issue and decided to specifically require an advisory statement to the effect that the product is not recommended for pregnant, nursing, or lactating women or use by infants, children, adolescents and elderly, other than under medical supervision. This amendment aims to assist regulatory clarity and interpretation of the drafting. It aligns with Codex and to some extent the EU requirement, and the request by the applicant. FSANZ notes that some VLED are currently labelled with such a statement.

FSANZ also notes that VLED are more consumer facing than other FSMP, and the proposed advisory statement will mitigate risks associated with consumers outside of the intended demographic using the product.

FSANZ also notes that the NHMRC clinical guideline referred to during P242 consideration has since been rescinded and not replaced. FSANZ is aware that health professionals do on occasion recommend the use of very low energy diets for medical reasons to adolescents. The requirement to refer to other than under medical supervision accommodates that.

10.5 Reference to the importance of maintaining an adequate daily fluid intake

10.5.1 Current Code requirements

There are no specific labelling requirements in the Code relating to the importance of maintaining adequate daily fluid intake. The Code more generally requires a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food (paragraph 2.9.5—10(1)(b)).

10.5.2 Previous considerations

The advisory statement ‘it is important to maintain an adequate daily fluid intake while using the product’ was proposed in the P242 Draft Assessment Report (FSANZ 2002). The reason for this requirement was so medical professionals had adequate information to be able to advise their patients of how to correctly use products. Only one submitter did not support this statement; because they believe VLED are used under medical supervision and this advice should be routinely provided to the patient. In the P242 PFAR it was recommended that the requirement for this statement be retained (FSANZ 2004).

10.5.3 Codex and other overseas requirements

Codex STAN 203-1995 requires a labelling statement referring to the importance of maintaining adequate daily fluid intake (Codex Alimentarius 1995).

EU regulation also requires a statement on the importance of maintaining an adequate daily fluid intake for total diet replacement for weight control products (European Union 2017).

10.5.4 Discussion and decision

The applicant requested that VLED are required to be labelled with an advisory statement referring to the importance of maintaining an adequate daily fluid intake.

In the Call for Submissions for this application FSANZ proposed to not mandate this specific requirement and allowed suppliers of VLED to include this information on the label if considered appropriate. Following submitter concerns FSANZ has reconsidered this issue and has decided to mandate a statement about the importance of maintaining an adequate

daily fluid intake on the label of VLED. As very low energy diets promote mild ketosis there is a risk of dehydration if consumers do not have adequate fluid intake. This requirement is also consistent internationally with the Codex STAN 203-1995 and EU 2017/1798.

FSANZ is also aware that the two main suppliers of VLED in Australia and New Zealand currently include this information on labels of VLED and in accompanying documents.

11 References

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