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

Supporting document 3

Labelling Assessment – Proposal P242 (Final Assessment)

Food for Special Medical Purposes

Executive summary

This document contains details of Food Standards Australia New Zealand (FSANZ) review of the labelling requirements for food for special medical purposes (FSMP) since the Preliminary Final Assessment in 2004. In reviewing the labelling requirements, FSANZ has considered submitter comments to the Preliminary Final Assessment Report, the December 2010 Consultation Paper and targeted consultations in 2010 and 2011.

In the Preliminary Final Assessment Report and in subsequent consultations in 2010 and 2011, FSANZ proposed that the generic labelling requirements in Part 1.2 – Labelling and Other Information Requirements of the Code, would not all apply to FSMP. Instead, certain generic labelling requirements (e.g. ingredient labelling and date marking) would be selectively applied to FSMP. Some additional labelling requirements specific to FSMP (e.g. a statement to the effect that the food must be used under medical supervision) were also proposed. In addition, at consultations in 2011, FSANZ proposed not to apply other generic standards which contain certain labelling requirements, such as Standard 1.1A.2 - Transitional Standard on Health Claims and Standard 1.3.2 - Vitamins and Minerals.

At Final Assessment, FSANZ has continued to apply certain generic labelling requirements currently contained in Part 1.2 to FSMP. These are included to protect the health and safety of users of FSMP and to provide health professionals and consumers with adequate information to make informed choices. The additional labelling statements specific to FSMP which will also apply (e.g. statements about medical supervision, sole source of nutrition, intended age group), provide further useful information to health professionals and consumers and help to protect against inappropriate use.

As nearly all of FSMP in Australia and New Zealand is imported, the labelling requirements which FSANZ has applied are, where possible, consistent with international requirements and/or with current industry practices. FSANZ has particularly sought to harmonise with European Union (EU) requirements as the majority of FSMP are imported from Europe. United States of America (USA) requirements were also considered as the USA is another source of imported FSMP, along with Codex Alimentarius requirements, where applicable.

As these are specialised foods which are essential for the dietary management of certain individuals, FSANZ has sought to find a balance between effectively informing FSMP consumers and minimising potential barriers to trade (e.g. re-labelling costs) that could potentially reduce the supply of some FSMP to Australia and New Zealand. The approach to only apply certain provisions from Part 1.2 was considered necessary to provide the appropriate balance.

The application of labelling requirements to FSMP, including specific mandatory statements, is in accordance with the *Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods of the Code* (see Section 1.4 of the Final Assessment Report), 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.*

For instance, the requirement to label FSMP with directions for use and storage provides information for the safe use of FSMP. Also, specific mandatory statements (e.g. statements on medical supervision, medical purpose, and intended age group) assist consumers and health professionals understanding of the specific nature, intended population group, and intended special purpose of the food.

The following lists summarise the labelling requirements for FSMP, including the generic labelling requirements within the Code which will not apply to FSMP, and those which will apply to FSMP in Standard 2.9.5. Labelling requirements for inner packages of FSMP and transportation outers are also listed.

1. Labelling exemptions for FSMP

- FSMP not in a package is exempt from the labelling requirements (clause 8(5) of Standard 2.9.5)
- Application of Labelling Requirements (Standard 1.2.1)
- Some mandatory warning and advisory statements, other than those outlined above (Standard 1.2.3)
- Nutrition Information Requirements, other than lactose and gluten claims (Standard 1.2.8), instead more flexible nutrition labelling requirements are provided as indicated in the list (2) below
- Percentage of characterising ingredients and components labelling (Standard 1.2.10)
- Country of origin labelling (Standard 1.2.11)
- Standard 1.1A.2 - Transitional Standard on Health Claims and Standard 1.2.7 – Nutrition, Health and Related Claims, when that Standard is gazetted
- Labelling requirements and claim conditions in Standard 1.3.2 – Vitamins and Minerals.

2. Labelling requirements for FSMP

- name or a description of the food sufficient to indicate the true nature of the food
- lot identification
- allergen declarations
- ingredient labelling, with allowances to use EU or USA ingredient labelling
- date marking, allowing flexibility in the wording
- directions for use and storage
- nutrition information, providing flexibility in the presentation of this information
- lactose and gluten claim conditions
- legibility requirements
- a statement to the effect that the FSMP must be used under medical supervision
- a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food
- 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 where the food is intended for a specific age group
- a statement indicating whether or not the food is suitable for use as a sole source of nutrition
- if a FSMP 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
- if a FSMP is represented as being suitable for use as a sole source of nutrition, and has been modified to vary from the prescribed compositional requirements, a statement indicating:
  - the nutrient/s which have been modified, and
  - whether each modified nutrient has been increased, decreased or eliminated from the food (this may be provided in documentation instead of on the label)
- advisory statements required if an 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
- warning statement required if an FSMP contains:
  - royal jelly as an ingredient as defined in Standard 1.2.4, the warning statement: 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers'
- genetically modified food and irradiated food labelling requirements (i.e. no exemption from Standards 1.5.2 and 1.5.3 is provided in Standard 2.9.5).

3. Labelling requirements for inner packages[1] of FSMP

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

4. Labelling requirements for transportation outers

- The transportation outers of FSMP must be labelled with the following information:
  - 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
- However, a label on a transportation outer is not required if this information is clearly discernible through the transportation outer, or in the case of the supplier name and address, is provided in documentation accompanying the FSMP.

[1] The term 'inner package' has been defined to mean an individual package of the food that is contained and sold within another package that is fully labelled in accordance with the general labelling requirements for FSMP (Subdivision 2 of Division 4 of Standard 2.9.5), and is not designed for individual sale.

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Introduction

Food Standards Australia New Zealand (FSANZ) conducted prior assessments of the labelling requirements for food for special medical purposes (FSMP) in the Draft Assessment Report (2002) and Preliminary Final Assessment Report (2004). These prior assessments considered previous submitter comments to the Initial Assessment Report and Draft Assessment Report. The labelling assessments are available on the FSANZ website in the Draft Assessment Report (at Attachment 3) and Preliminary Final Assessment Report (at Attachment 4).

The following sections discuss FSANZ's review of the labelling requirements for FSMP since the Preliminary Final Assessment in 2004. The approaches proposed in the Preliminary Final Assessment Report and the December 2010 Consultation Paper for the labelling of FSMP is provided, along with any significant changes proposed at targeted consultations in 2010/2011. The relevant submitter comments to these consultation stages are discussed, along with FSANZ's decision on each labelling component, and the rationale for this decision.

A number of international and other national regulations were referred to during the consideration of the labelling provisions for FSMP. These are listed below. The European Union and Codex have specific requirements for FSMP. However, there is no specific regulation for FSMP in the United States of America.

European Union (EU):

- Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.
- Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.
- Commission Directive 2007/68/EC of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients.
- Commission Directive 2008/5/EC of 30 January 2008 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 2000/13/EC of the European Parliament and of the Council.

United States of America (USA):

- Code of Federal Regulations, Title 21 – Food and Drugs, Part 101 – Food Labeling (21CFR101).
- Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA).

Codex Alimentarius (Codex):

- Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991).
- Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (Codex Stan 146-1985).

Review of labelling requirements

1 Application of labelling and Part 1.2

1.1 Previous approach and submitter feedback

At Preliminary Final Assessment (2004), FSANZ proposed that the generic labelling requirements in Standard 1.2.1 – Application of Labelling and Other Information Requirements, and consequently Part 1.2 - Labelling and Other Information Requirements of the *Australia New Zealand Food Standards Code* (the Code), would not apply to FSMP. Instead, some of the generic labelling requirements from Part 1.2 would apply to FSMP where appropriate. This approach to selectively apply the generic labelling requirements to FSMP and not apply all of Part 1.2 was maintained in the December 2010 Consultation Paper. Some changes to the generic labelling requirements that would apply to FSMP were proposed during the 2010 and 2011 consultations (e.g. addition of allergen declaration requirements and warning and advisory statements).

Submitters to the Preliminary Final Assessment Report who specifically commented on this approach, indicated their support. No other relevant comments on this approach were received. Submitter comments regarding the application of specific generic labelling requirements (e.g. allergen declarations) are discussed in the relevant sections of this Report.

1.2 Decision and rationale

FSANZ has maintained its decision not to apply all the generic labelling provisions in Part 1.2 of the Code to FSMP. For example, the percentage labelling and country of origin labelling requirements in Standards 1.2.10 and 1.2.11 have not been applied. However, this approach does not preclude manufacturers from voluntarily complying with the provisions in Part 1.2 that have not been applied to FSMP, such as country of origin labelling.

Certain generic labelling provisions in Part 1.2 which FSANZ has considered should still apply to FSMP (for example, allergen declarations), are included within Standard 2.9.5.

Nearly all of FSMP in Australia and New Zealand are imported from the European Union (EU) and the United States of America (USA). Industry have indicated in consultations that the volume of FSMP imported from the EU and USA into the Australia and New Zealand market, is small compared to the global market. Therefore, the majority of imported FSMP are currently labelled according to either EU or USA legislation. If all generic labelling requirements in Part 1.2 were applied, some imported FSMP could potentially be withdrawn from domestic markets due to an increased cost burden associated with re-labelling.

As these are specialised foods which are essential for the dietary management of certain individuals, FSANZ has sought to find a balance between effectively informing FSMP consumers and minimising potential barriers to trade (e.g. re-labelling costs) that could potentially reduce the supply of some FSMP to Australia and New Zealand. The approach to only apply certain provisions from Part 1.2 was considered necessary to provide the appropriate balance.

The application of each of the generic labelling provisions is discussed further in the following sections.

2 Food identification

2.1 Previous approach and submitter feedback

2.1.1 Lot identification

FSANZ proposed in the Preliminary Final Assessment Report and December 2010 Consultation Paper that lot identification (as defined in Standard 1.1.1) would be required on the label of FSMP. No specific submitter comments have been received on this approach.

2.1.2 Name of the food

At Preliminary Final Assessment and December 2010 Consultation, FSANZ proposed that the generic labelling requirements for the name of the food (as set out in Standard 1.2.2 – Food Identification Requirements) would apply to FSMP. Clause 1 of Standard 1.2.2 requires the label on a package of food to include the name of the food or a description sufficient to indicate the true nature of the food. There was no prescribed name proposed for FSMP.

There were no specific submitter comments to the Preliminary Final Assessment Report or to the 2010 Consultation Paper on this labelling requirement. In 2011 targeted consultations, some jurisdiction submitters requested a prescribed name to assist in clearly identifying FSMP and provide certainty for enforcement purposes. Some industry submitters opposed a prescribed name indicating that it would have significant cost implications which could impact the supply of FSMP to Australia and New Zealand.

2.1.3 Name and business address of supplier

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSANZ proposed to include the requirement from Standard 1.2.2 to label FSMP with the name and business address of the Australian or New Zealand supplier (as defined in Standard 1.1.1) in the draft Standard.

FSANZ noted, however, that imported FSMP do not always include the name and address of an Australian or New Zealand supplier on each individual package. Therefore, the details of the Australian or New Zealand supplier were permitted to be included on the transportation outer (as currently defined in Standard 1.2.1) or in accompanying documentation rather than on the label of each individual FSMP package.

There were no relevant submitter comments to the Preliminary Final Assessment Report or to the December 2010 Consultation Paper on this issue.

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.

2.2 Decision and rationale

2.2.1 Lot identification and name of the food

Standard 2.9.5 requires a name or a description of the food sufficient to indicate the true nature of the food and lot identification on the label of FSMP. This information is essential in

the event that a food recall occurs and the affected food must be removed from the food supply. Furthermore, the name of the food is important to assist consumers and health professionals identify the food.

The EU requires FSMP to be labelled with the words 'food(s) for special medical purposes'. The USA has similar requirements to those in the Code for the name of the food and does not prescribe a name. Most FSMP also carry lot identification. Therefore, it is expected that FSMP imported into Australia or New Zealand will not require re-labelling in order to comply with these requirements.

To maintain the current supply of imported FSMP into Australia and New Zealand, FSANZ has determined not to require a prescribed name. However, the absence of a prescribed name requirement will not preclude imported FSMP from being named in accordance with EU requirements. Further information on FSANZ's decision and rationale on this matter is provided in Section 6.3 of the Final Assessment Report.

2.2.2 Name and business address of supplier

FSANZ has maintained its position to require the Australian or New Zealand supplier details to be provided on the transportation outer (note that the definition for 'transportation outer' will be moved to Standard 1.1.1 to apply to Standard 2.9.5) or in accompanying documentation instead of on each FSMP package.

FSANZ considered that information on each FSMP package, such as the name of the food, lot identification and date mark will provide adequate information in the case of a food recall. Furthermore, FSANZ has restricted the locations from which FSMP are permitted to be sold (see Section 6.5 of the Final Assessment 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 Mandatory warning and advisory statements and allergen declarations

3.1 Previous approach and submitter feedback

3.1.1 Mandatory warning and advisory statements

At Preliminary Final Assessment, FSANZ recommended that the warning and advisory statements currently required in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations (i.e. clauses 2,3 and 5) would not apply to FSMP. No relevant submitter comments were received on this matter and this position was maintained in the December 2010 Consultation Paper.

In response to submitter comments to the December 2010 Consultation Paper about Fermentable Oligosaccharides, Lactose, Fructose and Polyols (FOLFAPs) (see Section 6.7.5 of the Final Assessment Report), FSANZ proposed in targeted consultations in 2011, to apply the advisory statement about a laxative effect to FSMP which contain certain levels of polyols or polydextrose (clause 5 of Standard 1.2.3).

FSANZ also reviewed the application of other advisory and warning statements in Standard 1.2.3 to FSMP and in 2011, proposed to apply the statements about aspartame, bee pollen, propolis, guarana and royal jelly. Submitters who commented on this proposed approach indicated their support.

3.1.2 Allergen declarations

At Preliminary Final Assessment, FSANZ proposed not to apply allergen declaration requirements to FSMP. However, submitters to the Preliminary Final Assessment and at targeted consultations in 2010 did not support this exemption. FSANZ therefore changed its position in the December 2010 Consultation Paper, so that the allergen declaration requirements in clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations would apply to FSMP.

Submitters to the 2010 Consultation Paper were supportive of the approach to apply allergen labelling requirements. However, one industry submitter raised concern that the EU provides for certain exemptions from allergen labelling (e.g. for highly refined ingredients) which are not provided for under this proposed approach. Further information sought from industry indicated that only a small proportion (i.e. around 2%) of products imported from the EU would be affected.

3.2 Decision and rationale

3.2.1 Mandatory warning and advisory statements

FSANZ has applied the following advisory and warning statements to FSMP based on the requirements in clauses 2,3 and 5 of Standard 1.2.3 (i.e. in addition to the allergen declaration requirements indicated in Section 3.2.2 below):

Advisory statements required if an 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.

Warning statement required if an FSMP contains:

- royal jelly, the warning statement: ‘This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers’.

The application of these statements was considered important to provide adequate information to consumers and health professionals and to protect the health and safety of consumers of FSMP. For example, the statement about phenylalanine was considered important given that it will be relevant to a number of consumers of FSMP (i.e. those with phenylketonuria). This statement and the statement related to polyols are similar to statements required in the EU. Although there are no similar requirements in the EU for the other statements listed, industry submitters have indicated that the substances involved (e.g. bee pollen, royal jelly) are not currently added to FSMP. However, to protect public health and safety and ensure consistency across all foods sold in Australia and New Zealand, FSANZ considered that consumers must be provided with this information should the substances be present in the future

The statement related to polyols provides additional information to the current ingredient labelling about FOLFAPs for health professionals and consumers. Further details on the matter of FOLFAPs are provided in Section 6.7.5 of Final Assessment Report.

Other advisory statements from Standard 1.2.3 were not considered to be relevant (e.g. the statement relating to kola beverages), or appropriate for FSMP (e.g. the statements indicating that the product is unpasteurised, for unpasteurised egg and milk products). The advisory statement about quinine was also not relevant, as this substance has not been permitted to be added to FSMP. Furthermore, the advisory statements about complete milk foods/replacements for children and about added phytosterols and phytostanols have not been applied, as FSMP are generally recommended for use by a health professional, and the supervising health professional will determine the suitability of a product for children and other individuals.

3.2.2 Allergen declarations

Due to the risks associated with the consumption of allergenic substances by certain consumers, these will be required to be declared on FSMP if present, e.g. cereals containing gluten, crustacea, egg, milk, peanuts, soybeans, added sulphites if 10 mg/kg or more, tree nuts, sesame seeds (based on clause 4 of Standard 1.2.3).

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 FSMP imported into Australia or New Zealand are unlikely to require re-labelling in order to meet these declaration requirements.

FSANZ acknowledges however that the EU provides exemptions from declaring certain highly refined substances (e.g. fully refined soybean oil, glucose syrups and maltodextrins) which are not currently provided for in Standard 2.9.5. As such, a small proportion of imported FSMP will likely be impacted which, under the transition period, will have two years to comply with the Code requirements. However, to ensure consistency across all foods sold in Australia and New Zealand, the approach to apply the current Code requirements for allergen declarations (i.e. clause 4 of Standard 1.2.3) has been maintained.

Furthermore, FSANZ is currently scoping a separate project on possible labelling exemptions of refined ingredients derived from allergenic foods, to ensure that the emerging scientific evidence is reflected in food regulations and/or industry guidance. If the Code is amended to include such allergen labelling exemptions in the future, these exemptions may also be relevant to FSMP.

4 Ingredient labelling

4.1 Previous approach and submitter feedback

At Preliminary Final Assessment and December 2010 Consultation, FSANZ proposed to apply the ingredient labelling provisions in Standard 1.2.4 – Labelling of Ingredients to FSMP, but with the option to use equivalent EU or USA labelling requirements in place of Standard 1.2.4 (but not a combination of these requirements).

No relevant submitter comments have been received on this approach.

4.2 Decision and rationale

The labels on FSMP will be required to comply with the requirements for ingredient labelling under Standard 1.2.4, or with the equivalent EU or USA ingredient labelling requirements (listed below) instead of Standard 1.2.4 (but not a combination of these requirements):

- Article 6, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

- Title 21, Code of Federal Regulations (CFR), Part 101.4 - Food Labeling.

Ingredient listing is required so consumers are aware of substances (including food additives) used in the preparation, manufacture or handling of food. FSANZ considered that the EU or USA ingredient labelling requirements (listed above) provide sufficient information for consumers and health professionals about the ingredients in FSMP to assist with making an informed decision. Allowing FSMP to comply with EU or USA ingredient labelling requirements provides additional flexibility for imported products and will minimise the cost burden associated with re-labelling.

5 Date marking

5.1 Previous approach and submitter feedback

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSANZ applied the date marking provisions in Standard 1.2.5 – Date Marking of Food to FSMP. Under this Standard a 'best before' date would be required to indicate the date the FSMP 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. Alternatively, if the FSMP should not be consumed after a certain date due to health or safety reasons, a 'use by' date must be provided. Standard 1.2.5 would also require an FSMP label to include any specific storage conditions required to ensure that the FSMP would keep until the date specified in the date mark.

FSANZ also proposed to allow the use of the words 'expiry date' or similar, instead of the words '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 would apply.

Submitters who specifically commented on this approach indicated their support.

5.2 Decision and rationale

In general, the date marking provisions in Standard 1.2.5 will apply to FSMP. The words 'expiry date' or similar can be used instead of the words 'use by' on FSMP that require a use-by date. If the words 'expiry date' or similar are used on an FSMP, conditions in Standard 1.2.5 for a 'use by' date will still apply (e.g. the FSMP must not be sold past its expiry date).

Date marking is considered important for consumers of FSMP as it provides valuable information on the quality of the FSMP, or the period of time it will remain safe to eat. Permission to use the words 'expiry date' or similar means that FSMP imported into Australia or New Zealand using that term will not require re-labelling to comply with the date marking requirements in Standard 2.9.5.

6 Directions for use and storage

6.1 Previous approach and submitter feedback

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSANZ applied the requirements in Standard 1.2.6 – Directions for Use and Storage to FSMP.

No specific submitter comments have been received on this approach.

6.2 Decision and rationale

Directions for use and storage will be required on the label of FSMP if the food is of such a nature to require directions for health or safety reasons. This will provide consumers with sufficient information to ensure that FSMP are stored and used safely.

Feedback from stakeholders has indicated that most imported FSMP currently provide directions for use and storage and comply with the applicable requirements in the Code. FSANZ considered it was necessary to mandate the labelling of this information so that health professionals and consumers can ensure FSMP are used and stored safely.

7 Nutrition information requirements

7.1 Previous approach and submitter feedback

At Preliminary Final Assessment and December 2010 consultation, FSANZ proposed not to apply all of Standard 1.2.8 - Nutrition Information Requirements to FSMP (lactose and gluten claim conditions were applied as discussed under Section 10 below). Instead of applying the requirements in Standard 1.2.8 for nutrition information panels, more flexible nutrition information requirements were specifically provided in draft Standard 2.9.5.

In response to the December 2010 Consultation Paper, one submitter requested that the number of serves per package be declared on FSMP. This was sought to allow consumers to compare products available in both liquid and powdered forms, and determine which is the most economical. Other submitters also requested that FSMP represented as being suitable for the sole source of nutrition are labelled with the volume required to meet population nutrient requirements for a specified reference group, e.g. 18+ males 2000 kcal/day.

No other relevant comments were received.

7.2 Decision and rationale

The EU and USA requirements for nutrition labelling are not consistent with the requirements in Standard 1.2.8. Therefore, to minimise re-labelling costs that could potentially reduce the supply of certain FSMP products, and limit consumer choice, the requirements for nutrition information panels in Standard 1.2.8 will not apply to FSMP. Instead, more flexible nutrition labelling requirements are provided in Standard 2.9.5. These requirements ensure that valuable nutrition information is provided to consumers and health professionals and helps to determine the correct use of the FSMP.

The following nutrition information must be declared on FSMP under Standard 2.9.5:

- The minimum or average energy content of the FSMP
- The average quantity or minimum quantity in the FSMP of -
  - protein, fat, and carbohydrate
  - any vitamin, mineral or electrolyte, when these have been added
  - any other substance, where that substance is permitted to be added to FSMP (i.e. the other substances listed in column 1 of Schedule 1 of Standard 2.9.5) and has been added.

The requirements in Standard 2.9.5 allow more flexibility in the presentation of the information compared to the requirements under Standard 1.2.8 because:

- The definitions in Standard 1.2.8 will not apply, so that there is no conflict with definitions used in EU labelling regulations.

- The format for the display of the nutrition information on the label, and the measurements for expressing the nutritional information have not been prescribed, e.g. it is not mandatory to express energy in KJ, or to express protein in grams.
- The quantity of the FSMP upon which the declaration must be based has not been prescribed, e.g. it is not mandatory to provide the nutrition information per serving and per 100 g or 100 ml of the FSMP.

Regarding the request for the number of serves per package, FSANZ noted that consumers would also need additional information about each product in order to be able to make accurate economic comparisons, e.g. the nutrient and energy content per serve. We also considered that health professionals should be able to assist consumers in determining which product to purchase from an economical perspective. Therefore, a requirement for the number of serves per package to be on the label has not been prescribed, however such information may be provided voluntarily.

Regarding the request for the volume required to meet population nutrient requirements, FSANZ determined that in practice, such information will not be applicable to many FSMP consumers. The amount of an FSMP that needs to be consumed is highly dependent on the health of the consumer, and volumes are routinely adjusted following medical/dietetic recommendations. Information of this nature has therefore not been prescribed in Standard 2.9.5. The nutrition information which has been prescribed will assist health professionals to determine specific volume requirements for their individual patients needs.

8 Legibility

8.1 Previous approach and submitter feedback

Legibility requirements were inadvertently omitted at Preliminary Final Assessment. In the December 2010 Consultation Paper, FSANZ proposed to apply Standard 1.2.9 – Legibility Requirements to FSMP. Submitters who specifically commented on this approach were supportive.

8.2 Decision and rationale

The labels on FSMP must comply with the legibility requirements under Standard 1.2.9. These requirements are intended to ensure that the labels on FSMP are legible, prominent and in the English language, which were considered to be important aspects for the labels of FSMP. There is no indication that the requirements for presentation of labelling under Standard 1.2.9 will be inconsistent with the current labelling of imported FSMP.

9 Percentage labelling and country of origin labelling

9.1 Previous approach and submitter feedback

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSANZ recommended that the percentage labelling requirements in Standard 1.2.10, and country of origin labelling in Standard 1.2.11 would not apply to FSMP. No specific submitter comments were received on these recommendations to these consultations.

At targeted consultations in 2010, a comment was received that an exemption was not needed for percentage ingredient labelling information as there is software that automatically generates this information. A comment was also received that it was an unnecessary safety risk to omit country of origin labelling for imported FSMP.

9.2 Decision and rationale

The percentage ingredient labelling requirements in Standard 1.2.10 will not apply to FSMP. As FSMP are specifically designed for a medical purpose, FSANZ considered that consumers and health professionals are unlikely to use percentage ingredient information to assist with purchase decisions. However, this does not preclude manufacturers from voluntarily including percentage ingredient information on the label of FSMP.

Country of origin labelling requirements in Standard 1.2.11, will also not apply to FSMP. This does not preclude manufacturers from voluntarily providing information about the country of origin of an FSMP. The EU only requires this labelling if its omission could mislead or deceive the consumer. The potential increased costs of requiring country of origin labelling may cause importers to withdraw their products, and could therefore jeopardise the supply of FSMP to consumers in Australia.

Regarding the concern raised about the safety of imported food, the relevant standards in the Code are applied under the *Imported Food Control Act 1992* and are implemented through the Australian Government's Imported Food Inspection Scheme (IFIS). IFIS aims to ensure that imported foods are fit and safe for human consumption and meet other requirements (e.g. labelling, chemical residues and contaminants) through a program of inspection for compliance with the Code.

10 Nutrition and health claims

10.1 Previous approach and submitter feedback

10.1.1 Lactose and gluten claims

At Preliminary Final Assessment and December 2010 consultation, FSANZ proposed to apply the current conditions for gluten and lactose claims in Standard 1.2.8 to FSMP. This included the 'low' and 'free' claim conditions and the requirement to declare the amount of lactose and galactose or gluten present when a claim is made. However, other nutrition claim conditions in Standard 1.2.8 (claims about polyunsaturated, monounsaturated and omega fatty acids, low joule, salt and potassium) would not apply.

Whilst some submitters supported applying the conditions in Standard 1.2.8 for gluten and lactose claims, others requested that the conditions for gluten claims for FSMP be equivalent to the conditions in the EU. The EU currently allows a tolerance of up to 20 ppm of gluten for foods carrying gluten free claims, whereas in the Code, gluten must not be detectable. Alternatively, some requested that FSMP should not be required to meet the gluten free claim conditions in the Code (i.e. do not specify any conditions for making this claim in Standard 2.9.5). Submitters noted that applying the Code conditions would impact on imported FSMP which are currently labelled with gluten or lactose free claims which do not meet the Code requirements.

10.1.2 Vitamin and mineral claims and health claims

FSMP were not exempted from Standard 1.3.2 – Vitamins and Minerals in the Preliminary Final Assessment and December 2010 versions of the draft Standard. Therefore, the conditions for claims about vitamins and minerals and the associated labelling requirements in this Standard (e.g. declaration of the percentage of the recommended dietary intake (RDI) for the claimed vitamins and minerals in an FSMP) would have applied. This matter was not specifically considered or discussed in the Preliminary Final Assessment Report or December 2010 Consultation Paper and no relevant submitter comments were received.

At targeted consultations in 2011, FSANZ considered the application of Standard 1.3.2 – Vitamins and Minerals, and proposed to change the draft Standard so that this Standard would not apply to FSMP. Submitters who commented on this approach indicated their support.

Regarding health claims, the draft Standard in the Preliminary Final Assessment Report and December 2010 Consultation Paper included the requirement to meet the conditions contained in Standard 1.1A.2 – Transitional Standard for Health Claims, except for the prohibition on the reference to a disease or physiological condition (subclause 3(d)). This subclause was excluded to allow FSMP to be labelled with the disease state(s) that they have been designed for.

In the 2010 Consultation Paper FSANZ also recommended that once gazetted, the new Standard to regulate nutrition and health claims (Standard 1.2.7 – Nutrition, Health and Related Claims) would apply to FSMP.

However, in 2011 targeted consultations, FSANZ reconsidered the application of the health claims Standards and proposed to change our previous position so that these Standards (i.e. Standard 1.1A.2 and Standard 1.2.7 when gazetted) would not apply to FSMP. It was noted that there were similarities between the labelling statements required on FSMP under draft Standard 2.9.5 and the types of claims proposed for regulation under Standard 1.2.7, which could cause confusion. Some submitters supported this approach. Other submitters indicated their support providing that the sale of FSMP is restricted (as proposed in Section 6.5 of the Final Assessment Report), or the definition is amended to include the need for medical supervision and a prescribed name (see Sections 6.2 and 6.3 of the Final Assessment Report). Other submitters indicated that health claims must be supported by appropriate scientific evidence and queried what substantiation requirements would apply to claims made on FSMP.

Furthermore, we indicated that by not applying the health claims Standards to FSMP, the prohibition on therapeutic claims currently provided in Standard 1.1A.2 and proposed under draft Standard 1.2.7 would also not apply to FSMP. There were mixed views from submitters on whether or not to prohibit therapeutic claims on FSMP. Some submitters indicated that such claims should be permitted, whilst others indicated that therapeutic claims on FSMP should be prohibited.

FSANZ also proposed to require the quantity of any substance in an FSMP for which a nutrition claim (as currently defined in Standard 1.2.8) is made to be declared on the label. No submitter comments were received on this approach.

10.2 Decision and rationale

10.2.1 Lactose and gluten claims

Conditions for gluten and lactose claims are provided in Standard 2.9.5 (based on the claim conditions in Standard 1.2.8) and will be required to be met for FSMP carrying these claims. FSANZ considered that claim conditions are required (i.e. 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. FSMP will not be required to meet any other claim conditions in Standard 1.2.8.

Regarding the requests to apply EU conditions for gluten free claims, FSANZ acknowledges that the approach to apply the Code conditions will likely impact on the labelling of some imported FSMP. However, previous advice from the Australian Competition and Consumer Commission (ACCC) is that 'free' claims mean 'no presence of'. Specifying a threshold level of gluten in the Code to be permitted in 'gluten free' foods would be contrary to fair trading law which requires that information is not false, misleading or deceptive. FSANZ does not therefore have the discretion to permit 'gluten free' claims when a detectable quantity of gluten is present. A transition period of 2 years is provided to allow manufacturers to comply with the Code requirements.

10.2.2 Vitamin and mineral claims and health claims

FSANZ has determined not to apply Standard 1.3.2 to FSMP. This means that FSMP will not be required to meet the conditions in Standard 1.3.2 about vitamin and mineral claims, including declarations of the percentage of the RDI of a claimed vitamin or mineral in an FSMP. Such declarations will not be relevant to many consumers of FSMP, as some of their nutritional requirements are likely to be different to the nutritional needs of the general population, upon which the RDIs are based.

Also, the Transitional Standard for Health Claims (Standard 1.1A.2) and Standard 1.2.7 (when that standard is gazetted) will not apply to FSMP. This means that FSMP will not be required to comply with the conditions in these Standards for making nutrition and health claims. This exemption is provided to reduce the likelihood for confusion as to whether a reference to a disease, disorder or medical condition on a FSMP label is a health claim that should be regulated under the applicable health claims Standard.

FSANZ notes that there are requirements in the EU for nutrition and health claims[2] which differ to some of the requirements in the Code. For example, the recommended daily allowances (RDAs) used in the EU for vitamin and mineral claims differ to the reference values provided in the Code. Therefore, not applying the nutrition and health claims Standards (i.e. 1.3.2, 1.1A.2 and 1.2.7) to FSMP was considered necessary to minimise the cost burden associated with re-labelling for imported FSMP (which may not meet the Code conditions).

In addition, conditions in the Code for nutrition and health claims have been developed for general purpose foods 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 we are restricting the sale of FSMP (see Section 6.5 of the Final Assessment Report) to facilitate access to medical supervision, claims on FSMP are less likely to be targeted to the general public.

Regarding the concerns raised about substantiation of claims, any claims made on FSMP will be subject to fair trading laws which require that representations about foods must not be false, misleading or deceptive. Therefore, should a manufacturer choose to make a claim on an FSMP, the manufacturer must be able to support that the claim is truthful.

FSMP labels will be required to declare the quantity of any substance in an FSMP for which a nutrition claim is made (see paragraph 9(e)(iv) of Standard 2.9.5). This declaration will provide information to health professionals and consumers on the amount of the claimed substance present in the FSMP. The EU has similar requirements for such a declaration.

[2] Council Directive on nutrition labelling of foodstuffs (90/496/EEC), and Regulation (EC) no 1924/2006 on nutrition and health claims made on food.

FSANZ has determined not to permit therapeutic claims on FSMP. As such, an FSMP must not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or medical condition, and must not compare FSMP with therapeutic goods (see clause 4 of Standard 2.9.5). This approach maintains consistency with the prohibition on therapeutic claims for all other foods sold in Australia and New Zealand, and will help to distinguish between food products and complementary medicines at the food/medicine interface.

11 Genetically modified and irradiated food labelling

11.1 Previous approach

In the Preliminary Final Assessment Report, FSANZ proposed that FSMP would be required to comply with all of the requirements contained within Part 1.5 of the Code. This included the specific labelling requirements contained within Standard 1.5.2 – Foods Produced using Gene Technology and Standard 1.5.3 – Irradiation of Food. As Standards 1.5.2 and 1.5.3 were to apply to FSMP, there was no exemption provided under the proposed drafting. This was also the case with the drafting proposed in the December 2010 Consultation Paper, where no exemption from Standards 1.5.2 and 1.5.3 was provided.

No specific submitter comments were received on this approach.

11.2 Decision and rationale

FSANZ has determined that the labelling requirements for approved foods produced using gene technology (in accordance with Standard 1.5.2) and approved irradiated foods (in accordance with Standard 1.5.3) will apply to ingredients and components in FSMP products. Genetically modified (GM) foods and irradiated foods are labelled to help consumers make an informed choice about the food they buy.

The EU requires GM food labelling and also requires foodstuffs which have been treated with ionising radiation to be labelled with ‘irradiated’ or ‘treated with ionising radiation’. The USA has labelling requirements for irradiated food and voluntary GM labelling requirements. No issues have been raised by submitters and FSMP that are labelled in accordance with EU requirements for GM and irradiated foods, would meet the requirements of the Code. Therefore, FSANZ considered that there is no justification to exempt FSMP from these labelling requirements.

12 Inner packages

12.1 Previous approach and submitter feedback

The matter of labelling inner packages was inadvertently omitted at Preliminary Final Assessment. In the December 2010 Consultation Paper, FSANZ proposed an exemption from all labelling requirements for inner packages of FSMP. It was intended that this exemption would only apply to inner packages that are not for individual sale. The inner packages would be contained and sold within another package which is fully labelled (e.g. individual sachets packaged inside a box as a retail sale).

Many submitters expressed concern with the proposed exemption and suggested that some labelling information should be required on inner packages. Of particular concern was the potential lack of allergen information, although other information was also requested (e.g., use under medical supervision statement, the medical purpose of the food, nutrition information). Submitters were concerned about inner packages of FSMP in institutions (e.g. a hospital) being provided to the hospital wards and the patient without labelling.

FSANZ therefore proposed at targeted consultations in 2011 to apply the name of the food, allergen labelling and legibility labelling requirements to inner packages of FSMP. Most submitters supported this approach but requested that lot identification and date marking labelling requirements also be applied. Industry submitters noted that they already provide this information on FSMP in inner packages however, one raised the issue of EU allergen labelling exemptions. One submitter requested that the statement about medical supervision also apply. Another submitter noted that the EU does not mandate inner package labelling and questioned if the labelling should be mandatory.

12.2 Decision and rationale

FSANZ has determined that an inner package[3] of FSMP must be labelled with the name of the food (sufficient to indicate the true nature), lot identification, date mark and certain allergens if present (based on clause 4 of Standard 1.2.3). The labelling on inner packages will also need to be legible in accordance with Standard 1.2.9.

FSANZ considered the name of the food was essential to ensure that the FSMP can be easily and correctly identified by consumers and health professionals after it has been removed from the fully labelled package. The lot identification and date mark will also assist with correctly identifying the food, particularly in the case of food recalls. Date marking, especially the use-by (or expiry) date and the requirements to declare allergens is important to protect the health and safety of FSMP consumers. These mandatory labelling requirements will not preclude the provision of other voluntary information as is currently being provided on FSMP in inner packages imported into Australia and New Zealand.

In the EU there are no specific requirements for the labelling of inner packages, however FSMP suppliers have advised that they already provide the information required in Standard 2.9.5 on the label of inner packages. Therefore, it is expected that most imported FSMP will not require re-labelling to comply with these requirements. However, FSANZ acknowledges that a small proportion of FSMP will be impacted due to the allergen labelling exemptions provided in the EU (as already considered under Section 3 above).

A clause has been included in Standard 2.9.5 (Subdivision 3) to clarify that the labelling requirements for inner packages of FSMP still apply when a responsible institution[4] subsequently supplies the package to a patient or resident of that institution, even if the package at that stage is not an 'inner package' by definition. This is important for practical reasons, so that an inner package may be sold either from a retail outlet, such as a pharmacy (contained within another fully labelled package), or provided as an individual package (without the fully labelled packaging) by a responsible institution, such as a hospital, to a patient or resident. In both these scenarios, the labelling requirements will be the same. The name, lot identification, date mark and allergen information, will be available to staff serving FSMP and to patients or residents at the point of use in a responsible institution.

FSANZ considered that in a responsible institution, the staff serving the FSMP will be able to access further information from the fully labelled package (within which the inner package was contained and sold to the responsible institution) should it be needed. Similarly,a consumer of an FSMP (i.e. not in a responsible institution) will normally have the fully labelled package available and will therefore not be consuming FSMP from the inner

[3] An 'inner package' is defined in Standard 2.9.5 as an individual package of the food that is contained and sold within another package which is fully labelled in accordance with the general labelling requirements for FSMP (Subdivision 2 of Division 4); and that is not designed for individual sale, other than a sale by a 'responsible institution' to a patient or resident of the institution.

[4] The term 'responsible institution' used in the definition of inner package has been introduced to collectively describe a hospital, hospice, r aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

packages, without the additional labelling available. Therefore, FSANZ determined that it was not necessary to prescribe any further labelling requirements on FSMP in inner packages.

13 Transportation outers

13.1 Previous approach and submitter feedback

'Transportation outer' is currently defined in Standard 1.2.1 as being for the purpose of transportation and distribution and is removed before the food is used or offered for sale, or is not taken away by the purchaser of the food. The labelling requirements for transportation outers containing FSMP was not specifically discussed in the Preliminary Final Assessment Report or in the December 2010 Consultation Paper, or specifically indicated in the draft Standard 2.9.5, and no relevant submitter comments were received.

In targeted consultations in 2011, FSANZ proposed that transportation outers containing FSMP would be required to be labelled with the name of the food, lot identification, and the name and address of the Australian or New Zealand supplier (unless this information was clearly visible through the transportation outer on the labels on the FSMP packages within). Furthermore, the name and address of the Australian or New Zealand supplier could be provided in documentation accompanying the food instead of on the label of the transportation outer. Most submitters who commented on this approach indicated there support. Some jurisdiction submitters raised concern about the name and address of the supplier on the transportation outer of FSMP instead of on each individual package (this issue has been discussed under Section 2 above).

13.2 Decision and rationale

Given that transportation outers containing FSMP are for the purpose of transportation and distribution, it is not appropriate that they are required to be labelled with information intended for consumers. An exemption from most of the labelling requirements for FSMP has therefore been provided for transportation outers. However for identification purposes, transportation outers will be required to be labelled with the name of the food (sufficient to indicate the true nature), the lot identification and the name and address of the Australian or New Zealand supplier (if this information is not clearly visible through the transportation outer on the labels of the FSMP packages within). This is consistent with the current requirements in Standard 1.2.1 for the labelling of transportation outers for food not for retail sale. Further information can voluntarily be provided on the transportation outer if desired.

In addition, the name and address of the Australian or New Zealand supplier of the FSMP will not need to be provided on the transportation outer, if this information is provided in documentation accompanying the FSMP.

The definition of 'transportation outer' will be relocated from Standard 1.2.1 to Standard 1.1.1, so that it will apply to Standard 2.9.5.

14 FSMP not in a package

14.1 Previous approach and submitter feedback

The drafting at Preliminary Final Assessment and December 2010 did not specifically indicate the requirements for FSMP not in a package (see the definition for 'package' in clause 2 of Standard 1.1.1), such as those served to a patient in a cup. This matter was not specifically considered or discussed in the Preliminary Final Assessment Report or the December 2010 Consultation Paper and no relevant submitter comments were received.

In targeted consultations in 2011, FSANZ considered this matter and proposed that FSMP which are not in a package should not be required to be labelled. No issues were raised to this proposed approach.

14.2 Decision and rationale

FSANZ considered that if a patient or resident is served an FSMP that has been prepared in a vessel such as a glass or cup by staff in a responsible institution (e.g. where a nurse mixes a sachet of product with water in a glass) it is impractical to expect that that the glass or cup be labelled. Therefore, FSMP which are not in a package will not be required to be labelled (see subclause 8(5) of Standard 2.9.5). A clause is also provided in Standard 2.9.5 to clarify that a 'package' does not include an FSMP provided on a plate, cup or tray or other food container to a patient or resident in a responsible institution (subclause 2(2) of Standard 2.9.5).

15 Medical supervision

15.1 Previous approach

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSANZ proposed to require a statement to the effect that the FSMP must be used under medical supervision, as medical supervision is a defining feature of these products.

New Zealand submitters to the 2010 Consultation Paper suggested that the required statement be amended to incorporate supervision by a dietitian, i.e. that they must be used 'on the advice of a medical practitioner *or dietitian'*. This was suggested because dietitians are permitted to prescribe subsidised special purpose foods and related products in New Zealand. No other relevant comments have been received.

15.2 Decision and rationale

FSMP will be required to display a statement on the label to the effect that the food must be used under medical supervision. This labelling statement will provide a useful reminder to consumers that they should seek appropriate advice when using FSMP, which FSANZ considered to be important given the specialised nature of FSMP and their special role in the dietary management of medical conditions. This is consistent with the policy guideline principle (see Section 1.4 of the Final Assessment Report) that adequate information should be provided to assist consumer understanding of the special nature of the food and intended special purpose of the food.

In order to maintain consistency with EU and Codex requirements and current industry practice, FSANZ has not amended the statement to incorporate reference to supervision by dietitians. However, FSANZ has not prescribed the exact wording for this statement, and manufacturers can choose to voluntarily include a reference to dietetic supervision, as long as the requirement to indicate to the effect that the FSMP must be used under medical supervision is met.

16 Age group

16.1 Previous approach

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSANZ proposed that FSMP would be required to be labelled with a statement advising that the food

has been formulated for a specific age group, if applicable. No relevant submitter comments were received on this approach.

16.2 Decision and rationale

If a FSMP has been formulated for a specific age group, the label must include a statement to the effect that the food is intended for persons within the specified age group.

This statement provides useful information to health professionals and consumers to ensure the correct use of FSMP. It is consistent with the policy guideline principle (see Section 1.4 of the Final Assessment Report) that adequate information should be provided to assist consumer understanding of the population group the special purpose food is intended for. This approach aligns with EU and Codex requirements.

17 Medical purpose and properties that make FSMP suitable for that purpose

17.1 Previous approach

At Preliminary Final Assessment, FSANZ proposed to require a statement indicating the condition, disease or disorder for which an FSMP has been specifically formulated. In the December 2010 Consultation Paper and 2011 targeted consultations, FSANZ revised this requirement so that the statement indicated the medical purpose of the FSMP, including any conditions, diseases, or disorders for which the FSMP has been specifically formulated. A statement describing the properties or characteristics which make the product appropriate for the condition, disease or disorder as indicated was also proposed in 2010.

Some submitters to the 2010 Consultation Paper who specifically commented on this approach were supportive. One jurisdiction submitter recommended that an independent authoritative body assess the evidence to support a statement about the properties or characteristics which make the product appropriate before such statements are made. This is particularly problematic if FSMP are to be advertised to the general population.

17.2 Decision and rationale

FSMP must include a statement on the label indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated. This means that the medical purpose of the FSMP must be stated, however it is not mandatory to mention specific diseases, disorders or medical conditions. This avoids the need to list a number of diseases, disorders or medical conditions on an FSMP that has been formulated to address a broad range of medical conditions rather than a specific one (e.g. FSMP formulated for high energy/protein requirements).

FSMP must also include a statement describing the properties or characteristics which make the food appropriate for the medical purpose (including any diseases, disorders or medical conditions) indicated.

These statements will provide information to assist consumers and health professionals understanding of the specific nature of the food and its intended special purpose, and is in line with the policy guideline principles (see Section 1.4 of the Final Assessment Report).

This approach maintains consistency with current industry practice and is similar to EU and Codex requirements for foods for special medical purposes. The EU and Codex both require a statement '*For the dietary management of .....' where the blank shall be filled in with the*

diseases, disorders or medical conditions for which the product is intended. A description of the properties or characteristics that make the product useful is also required.

Regarding the recommendation about an independent assessment of the statement on the properties and characteristics, FSANZ notes that labelling on FSMP will be subject to fair trading laws. These laws require that representations about foods must not be misleading or deceptive. Therefore, a manufacturer must be able to substantiate that the statements on their labels are truthful. Furthermore, as we are restricting the sale of FSMP (see Section 8.5 of the Final Assessment Report) to facilitate access to medical supervision, FSMP will generally be recommended for use by a health professional and are less likely to be targeted directly to the general public. Therefore, FSANZ considered that prescribing a requirement for an independent assessment was not necessary.

18 Sole source of nutrition

18.1 Previous approach

At Preliminary Final Assessment and December 2010 consultation, FSMP were not required to indicate on the labels whether or not the food is suitable for use as a sole source of nutrition.

One industry submitter to the 2010 Consultation Paper supported this approach. A number of submitters did not support this approach and wanted the statement to apply to FSMP. These submitters indicated that the statement ensured proper usage of FSMP by health professionals and patients, and needed to be available for those situations where health professional advice on the FSMP may not be obtained.

In response to submitter requests, FSANZ proposed at 2011 targeted consultations to require FSMP labels to include a statement indicating whether or not the food is suitable for use as a sole source of nutrition. No issues were raised to this approach.

18.2 Decision and rationale

FSMP must include a statement on the label indicating whether or not the food is suitable for use as a sole source of nutrition. This will provide clear and adequate information to consumers and health professionals on whether an FSMP is suitable as the sole source of nutrition and assist to protect against inappropriate use.

This approach is consistent with EU and Codex requirements and is seen to align with current industry practice. In order to allow for consistency with statements made under these international regulations, the actual wording of the statement has not been prescribed. Therefore it is not expected to place any additional cost burden on imported FSMP.

19 Precautions and contraindications

19.1 Previous approach

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSMP were not required to include a statement on the label advising of any necessary precautions, and contraindications. No specific submitter comments received on this approach.

However, at targeted consultations in 2010, it was suggested that advice of this nature should be provided on the label of FSMP, where appropriate. In response, FSANZ proposed at targeted consultations in 2011 to require FSMP labels to include a statement indicating any precautions and contraindications, where applicable. One submitter sought clarification

of what this would include outside of the mandatory warning and advisory statements which were proposed to apply to FSMP (see Section 3 above).

19.2 Decision and rationale

FSMP must include a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food. The specific wording and content of this statement has not been prescribed. Therefore, it is up to the manufacturer to determine any applicable precautions and contraindications that health professionals and consumers should be aware of. For example, a statement indicating that a product is not for use in galactosaemia as currently seen on some FSMP labels. This requirement is in addition to the warning and advisory statements which have been prescribed for certain specified substances.

This approach is consistent with the policy guideline that information should be provided to provide for safe use by the intended population and to help prevent inappropriate use. It is consistent with EU and Codex requirements and is seen to align with current industry practice. Therefore, it is not expected to place any additional cost burden on imported FSMP.

20 Not for parenteral use

20.1 Previous approach

In the Preliminary Final Assessment Report and December 2010 Consultation Paper, FSANZ applied the mandatory advisory statement ‘not for parenteral use’ to FSMP represented as nutritionally complete. One industry submitter to the 2010 Consultation Paper requested that the statement be included on the labels of all FSMP, whether the FSMP is nutritionally complete or not. No other comments were received.

20.2 Decision and rationale

FSMP that are represented as being suitable for use as the sole source of nutrition (previously referred to as nutritionally complete, refer to Section 6.7.2.1 of the Final Assessment Report) require a statement on the label to the effect that the food is not for parenteral use. This statement provides advice to health professionals to protect against inappropriate use.

FSANZ is of the opinion that the only FSMP that are likely to be confused with parenteral products are those represented as being for use as the sole source of nutrition. Therefore, FSANZ has determined to only require this statement on FSMP represented for use as the sole source of nutrition. The requirement to have this statement is consistent with Codex and EU requirements and appears to align with current industry practice. Therefore, it is not expected to place any additional cost burden on imported FSMP.

21 Variation from prescribed micronutrients requirements

In the 2010 Consultation Paper FSANZ introduced an additional labelling statement which applied to FSMP represented as being suitable for use as the sole source of nutrition (previously referred to as ‘nutritionally complete’) which vary from any of the prescribed compositional limits for micronutrients. This statement was not proposed at Preliminary Final Assessment.

Further information on this labelling statement, including submitter feedback and the decision and rationale for this approach is provided in Section 6.7.4 of the Final Assessment Report.