

# FOOD REGULATION POLICY OPTIONS CONSULTATION PAPER

## **for the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods**

Produced for the Food Regulation Standing Committee (FRSC)

By the Intent of Part 2.9 – Special Purpose Foods

FRSC Working Group

07 October 2008

## Introduction

This Food Regulation Policy Options Consultation Paper has been developed by the Food Regulation Standing Committee's (FRSC) Working Group on the Intent of Part 2.9 – Special Purpose Foods of the Australia New Zealand Food Standards Code (the Code), and endorsed by the Food Regulation Standing Committee. Stakeholder responses to the proposed options are now being sought (see template for responses at Attachment A).

The purpose of this Consultation Paper is to seek comment on the intent of Part 2.9 – Special Purpose Foods, and specifically, on the working definition of special purpose foods, and to consider options for the development of a policy guideline.

The policy guideline will be drafted to provide overarching guidance on the intent of Part 2.9. The policy guideline is intended to ensure that foods regulated under Part 2.9 of the Code meet the definition of a special purpose food and that they will not, as a matter of course, be promoted and consumed as a general food.

Where more detailed or specific policy guidance on a Standard is required, a separate policy guideline will be considered by another FRSC Working Group. For example, there is currently a separate FRSC Working Group on Standard 2.9.1 – Infant Formula Products which is working on the development of detailed specific policy guidance for infant formula products.

## Background

At its meeting on 2 May 2008, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) noted that a FRSC Working Group would develop a Policy Guideline for the intent of Part 2.9 – Special Purpose Foods of the Code (see Terms of Reference for the FRSC Working Group at Attachment B).

The intention is that this Policy Guideline will assist Food Standards Australia New Zealand (FSANZ) in reviewing the intent of Part 2.9 of the Code, as requested by Ministerial Council in March 2005, as well as in consideration of any future development and review of food standards in Part 2.9 of the Code. It is not the intention of the Policy Guideline to remove any Standards from the Code. The Policy Guideline will provide FSANZ with guidance to ensure that Standards relating to Special Purpose Foods are placed appropriately within the Code, and conversely Part 2.9 Standards do not unintentionally capture foods that are general purpose in nature.

## Process

Following this consultation process, all submissions will be considered to finalise the proposed policy approach to the intent of Part 2.9 of the Code (for further information on the Principles and Operating Protocols for Stakeholder consultation, see Attachment C).

The draft Policy Guideline, taking into account the stakeholder feedback received will be provided to the Ministerial Council to assist the Council in its determination of food regulation policy guidelines in relation to the intent of Part 2.9 - Special Purpose Foods in the Code. The final Policy Guideline will be provided to FSANZ for guidance in developing food standards, in accordance with its legislative requirements.

**Important notice to all submitters:** All submissions are subject to the *Freedom of Information Act 1982* in Australia and the *Official Information Act 1982* in New Zealand. If you consider that all or part of your submission should not be released, please make this

clear when making your submission and indicate the grounds for withholding the information. A general summary of submissions will be produced and published on the [Food Regulation Secretariat](#) website and the [New Zealand Food Safety Authority](#) website.

Copyright in an original submission resides with the copyright owner of that submission, but the act of making a submission will grant the Australian Government and the New Zealand Government a licence to use the submission for the purpose of making a summary of the submission for the website and for future policy or standard development work.

Electronic submissions to the e-mail addresses below are preferred.

Submissions should be provided using the response form provided, or in a similar format, by Monday 2 March 2009 to:

**Australia**

Submissions – Intent of Part 2.9 –  
Special Purpose Foods

C/- Food Regulation Secretariat  
PO Box 4  
WODEN ACT 2606

Or email the [Food Regulation Secretariat](#)

Or fax to: (02) 6289 5100

**New Zealand**

Submissions – Intent of Part 2.9 –  
Special Purpose Foods

C/- Ursula Egan  
Joint Food Standards Group  
New Zealand Food Safety Authority  
PO Box 2835  
WELLINGTON

Or email [Food Standards NZ](#)

Or fax to: (04) 894 2583

If you have any questions in relation to this document, please call Kylie Jonasson on (02) 6289 1770 in Australia or Ursula Egan on (04) 894 2451 in New Zealand.

## Purpose

The Ministerial Council requested that a policy guideline be developed to provide a clear policy context for the review and future development of Part 2.9 to ensure a systematic approach to any future review. This options consultation paper seeks stakeholder input on the proposed definition of special purpose foods and policy options to prepare a policy guideline on the intent of Part 2.9 – Special Purpose Foods.

It is not the intention of the Policy Guideline to remove any Standards from the Code. The Policy Guideline will provide FSANZ with guidance to ensure that Standards relating to Special Purpose Foods are placed appropriately within the Code, and conversely Part 2.9 Standards do not unintentionally capture foods that are general purpose in nature.

The issues requiring consideration include an examination of how other countries define and regulate special purpose foods, the proposed definition of special purpose foods and consideration of the impact of special purpose foods on public health, consumers, industry and government.

## The Food Regulation System – Australia and New Zealand

The Australia and New Zealand food regulation system is a cooperative arrangement between the Australian Government, New Zealand and the Australian States and Territories to develop and implement uniform food standards.

The food regulatory system is underpinned by a number of agreements and legislative instruments:

- The Australia New Zealand Joint Food Standards Agreement between Australia and New Zealand, otherwise known as The Treaty, provides for New Zealand's involvement in the food regulatory system.
- The Food Regulation Agreement is an inter-governmental agreement signed by the Australian Government, States and Territories and commits these signatories to a co-operative national system of food regulation.
- The agreement establishes the Ministerial Council which sets food regulatory policy and considers food standards for Australia and New Zealand.
- The Food Standards Australia New Zealand Act 1991 (FSANZ Act) came into effect on 1 July 2002, and establishes the legislative basis for the bi-national statutory authority, FSANZ. The objective of the FSANZ Act is to ensure a high standard of public health protection throughout Australia and New Zealand by maintaining a safe food supply. All food sold in Australia and New Zealand must be safe.
- FSANZ is the independent statutory authority that develops food standards.
- Once approved, food standards are incorporated into the Australia New Zealand Food Standards Code (the Code). Australian States and Territories adopt the Code under State and Territory legislation. New Zealand adopts the Code under the Food Act 1981.
- Enforcement of the Code occurs through State and Territory agencies and local councils. New Zealand enforces the Code through its national enforcement body, the New Zealand Food Safety Authority.
- The Fair Trading Acts in New Zealand and the States and Territories of Australia and the *Trade Practices Act 1974* (Commonwealth) apply to the supply of food in trade and commerce relating to any conduct that is considered false, misleading or deceptive.

## Regulation of Special Purpose Foods

### Australia and New Zealand

Currently Part 2.9 of the Code loosely regulates foods that are designed to assist nutritionally at-risk groups to meet their dietary requirements which cannot always be met by a normal diet.

The Food Standards currently contained in Part 2.9 of the Code are detailed in the table.<sup>1</sup>

Part 2.9 Food Standards	Description
2.9.1 – Infant Formula Products	Provides the compositional and labelling requirements for foods intended as a substitute for breast milk, including infant and follow-on formula, and products intended for infants with special nutritional requirements.  Note: Another FRSC Working Group has been set up to consider policy guidance for Standard 2.9.1 - Infant Formula Products. The FRSC Working Groups on both Part 2.9 – Special Purpose Foods and Standard 2.9.1 – Infant Formula Products are coordinating on related issues where necessary.
2.9.2 – Foods for Infants	Provides the compositional and labelling requirements of foods intended to be fed to infants (up to 12 months of age) in addition to breast milk and/or infant formula.
2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods	Provides the compositional and labelling requirements for formulated meal replacements <sup>2</sup> and formulated supplementary foods <sup>3</sup> , including those intended for children aged 1 – 3 years.
2.9.4 – Formulated Supplementary Sports Foods	Provides the compositional and labelling requirements of foods specially formulated to assist sports people in achieving specific nutritional or performance goals.

FSANZ has also proposed inclusion of a draft Standard for Foods for Special Medical Purposes (FSMP) in Part 2.9 (draft Standard 2.9.5). FSMP are principally formulated food products, used under medical supervision for the dietary management of individuals with certain conditions or disease states. In addition Part 2.9 includes reference to two standards<sup>4</sup> listed as reserved. FSANZ's work plan to date has not foreshadowed any work commencing on these reserved standards.

Given the special nature and intended purpose of the foods regulated by the Standards in Part 2.9 of the Code, they may be permitted to contain certain added nutritive substances,

<sup>1</sup> Food Standards Australia New Zealand: The Code

<sup>2</sup> **formulated meal replacement** means a single food or pre-packaged selection of foods that is sold as a replacement for one or more of the daily meals but not as a total diet replacement.

<sup>3</sup> **formulated supplementary food** means a food specifically designed as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements.

<sup>4</sup> Standard 2.9.6 – Foods Formulated for Special Diets and Standard 2.9.7 – Macronutrient Modified Foods

such as vitamins and minerals, that are not permitted to be added to other foods or are permitted at levels outside those allowed in the general food supply. Consequently, the compositional provisions for special purpose food may be complemented by specific labelling requirements to advise on the safe and appropriate use of the food.

*Q1 - What is your understanding of the current intent of Part 2.9 – Special Purpose Foods?*

### **International context**

#### *a) Codex Alimentarius*

Codex Alimentarius defines ‘foods for special dietary uses’ in the General Standards for the Labelling of and claims for pre-packaged foods for special dietary uses (CODEX STAN 146-1985) as those *which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such (including foods for infants and young children). The composition of these foodstuffs must differ significantly from the composition of general purpose foods with comparable nature, if such general purpose foods exist.*

Additional provisions relating to foods for special dietary uses are contained within various Codex standards or guidelines for specific foods for special dietary uses.

#### *b) European Community*

European Commission Directive 89/398/EEC includes a definition of ‘foodstuffs for particular nutritional uses’ (PARNUTS) as *being foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability. A particular nutritional use must fulfil the particular nutritional requirements of: certain categories of persons whose digestive processes or metabolism are disturbed; certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or infants or young children in good health.*

There are specific provisions for groups of foods for particular nutritional uses which are provided in specific Directives for these foods.

#### *c) United States of America (USA)*

Part 105 – Foods for Special Dietary Uses of the United States of America Code of Federal Regulations (21CFR105) includes the following definition for ‘special dietary uses’ as being uses for:

- i. supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;*
- ii. supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood; and*
- iii. supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property.*

Part 105 also includes specific labelling provisions for certain foods for special dietary uses.

d) Canada

Division 24 – Foods for Special Dietary Use of the Canadian Food and Drug Regulations defines ‘food for special dietary use’ as *food that has been specially processed or formulated to meet the particular requirements of a person: in whom a physical or physiological condition exists as a result of a disease, disorder or injury; or for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods.*

This Division also contains provisions specifically related to various foods for special dietary use.

e) Japan

In Japan food for special dietary uses (FOSDU) refers to foods that are permitted to display that the food is appropriate for special dietary uses. There are five categories of FOSDU; medical foods for the ill; formulas for pregnant or lactating women; infant formulas; foods for the elderly with difficulty in masticating or swallowing; and foods for Specified Health Uses (FOSHU). The provisions for FOSDU include specific labelling requirements.

f) Malaysia

The Malaysian Food Regulations 1985 define ‘special purpose food’ as meaning a food named or described as particularly suitable for consumption by persons requiring special nutritional needs and includes the food for which a standard is prescribed in regulations 389 to 393. Regulations 389 to 393 included the following: infant and follow on formula; canned foods for infants (12 months and less) and children (1 – 3 years); cereal based foods for infants and children; low energy food; formula dietary food; and special dietary food with low sodium content including salt substitute. There are specific requirements for labelling and composition within these regulations.

<p><i>Q2 - Please comment on the adequacy of the current Australian and New Zealand regulatory system to identify and appropriately regulate special purpose foods.</i></p>
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### **Key Impacts**

The key priority for the food regulatory system is to protect public health and safety. In the competitive environment of innovation and rapidly changing technological developments, it is important that the food regulatory system maintains appropriate measures, including transparency of operation to ensure ongoing public confidence in the food supply.

### **Public Health Impacts**

The extent to which policy guidelines address public health interests such as nutrition guidelines, health status of the population or demographic groups and individual health impacts need to be considered.

### **Consumer Impacts**

The increasing sophistication of the consumer and the increasing breadth of consumer interests need to be addressed. Both perceived and actual concerns should be reflected. Also of concern is the cost of the policy options on food. A number of special purpose food are readily available in the general food supply and this consumers have a potential wide choice of products, however some foods intended as special purpose foods may be incorrectly used as general foods by some consumers.

## Industry Impacts

In determining the intent of Part 2.9, the implications on industry need to be considered. These may include relabelling costs if information needs to be added and/or removed from current labels and potential associated awareness raising costs to inform consumers why certain foods are being labelled differently when there may have been no change to the product per se. Depending on the agreed definition of special purpose foods, industry may have to reformulate products to remain compliant with the Code. Industry may have to reconsider their innovation priorities if there are changes to the market access of products currently regulated under Part 2.9.

## Government Impacts

The Australian, New Zealand and State and Territory Governments may be impacted in differing ways by each of the policy options under consideration. In many cases the enforcement agencies, food safety agencies and departments of health, trade and agriculture/primary industries will be most significantly affected. Some of the impacts on government agencies include: harmonisation and consistency in food regulation, addressing public health issues, removal of unjustifiable trade barriers, international obligations, broad economic implications including industry growth and innovation, and implications for enforcement.

## Key Issues

In considering the key issues below, please take into account the key impacts (outlined in the previous section) to public health, consumers, industry and government.

### a) The definition of Special Purpose Foods

The working group has proposed the following definition for Special Purpose Foods:

*“a special purpose food is defined as a food that is specially processed or formulated to meet the particular dietary requirements of nutritionally vulnerable groups that cannot be met by a normal diet. In this context nutritionally vulnerable groups are defined as those:*

- *with a particular physical or physiological condition or diseases/disorders; and/or*
- *infants (under 12 months).*

*Q3 - Is the proposed definition of Special Purpose Foods adequate to capture those foods or groups of foods you consider to be special purpose foods? Why or why not? What refinement, if any, would you suggest?*

*Q4 - Should the policy guidance require the special purpose of the food to be stated and articulated clearly by the manufacturer including reasons why the particular dietary requirement cannot be met by the normal diet?*

### b) Specific trans-Tasman requirements and current provisions

Trans-Tasman trade in food is supported in two ways:

1. Harmonised food regulation under the Code; and
2. The trans-Tasman Mutual Recognition Arrangement (TTMRA) which excludes therapeutics and high risk foods. Article 7 of The Treaty explicitly references the application of TTMRA to food

*Q5 – Are you aware of any specific trans-Tasman requirements or current provisions that impact on the intent of Part 2.9 - Special Purpose Foods.*

*c) International regulatory approaches*

Internationally, regulatory systems do specifically recognise foods for special dietary purposes, although the range of foods which fall within ‘special purpose foods’ do vary between the differing regulatory bodies. Some encompass a broad scope whereas others are more focused on fewer foods. However in general there are common approaches taken in recognition of the special nature and intended purpose of these foods through the application of specific additional requirements such as labelling. Adopting similar regulatory approaches to special purpose foods in Australia and New Zealand with those taken internationally will aid consistency and harmonisation of food standards and thereby help to facilitate trade.

*Q6 - Please comment on the impact of international regulatory approaches on the regulation of Special Purpose Foods under the Code.*

*d) The labelling, access and advertising/marketing of Special Purpose Foods*

*Labelling*

Special purpose foods should be labelled to provide sufficient information to consumers to make an informed choice and ensure the safe and appropriate use of a product. Currently this may include a requirement to be labelled with a prescribed name for food identification purposes, and may include advisory or warning statements and specific requirements for declaring or making claims regarding the nutritional content of a special purpose food.

*Q7 – Are you aware of any particular issues with the current labelling of special purpose foods? How could these be addressed?*

*Access*

According to the current regulatory framework under Part 2.9 of the Code, special purpose foods are those that have been formulated to fulfil special dietary needs. Currently foods regulated by the Standards within Part 2.9 of the Code are not subject to any restrictions on access.

*Q8 - Can you identify any instances where access to special purpose foods should be considered? If so, how? Why?*

*Q9 - If you believe there should be access controls, what sort of controls should these be and at what point should these controls be applied?*

*Advertising/Marketing*

Under the current regulatory framework under Part 2.9 of the Code, special purpose foods are those that have been formulated to fulfil special dietary needs. In relation to advertising currently requirements for special purpose foods are similar to those for general purpose food in that requirements and conditions in relation to making labelling claims also relate to claims made in advertising.

*Q10 - Can you identify any particular issues with the advertising/marketing of special*

*purpose foods? Can you suggest any approaches to address these issues?*

e) Other policy guidance

There are a number of policy guidelines that are relevant to consideration of the intent of Part 2.9- Special Purpose Foods. These include policy guidance on fortification with vitamins and minerals, the addition of substances other than vitamins and minerals and nutrition health and related claims.

The *Fortification with Vitamins and Minerals Policy Guideline* was developed for the general population and therefore was not intended to apply to special purpose foods. Levels of fortification of vitamins and minerals in general foods are based on population level recommendations. Part 2.9 – Special Purpose Foods regulates foods that are intended for at-risk groups whose dietary requirements cannot always be satisfied by a normal diet.

The policy guidelines on the Addition of Substances other than Vitamins and Minerals was developed for the general population and therefore was not intended to apply to special purpose foods. Addition of substances other than vitamins and minerals is based on safety, identification of the purpose, and the ability of the substance to deliver the purpose without negative impacts at a population level. Part 2.9 – Special Purpose Foods regulates foods that are intended for at-risk groups whose dietary requirements cannot always be satisfied by a normal diet. Policy guidance therefore needs to consider the intent of the addition of substances other than vitamin and minerals in special purpose foods.

However, the Nutrition, Health and Related Claims Policy Guideline does apply to special purpose foods.

*Q11 - Please comment on any issues in relation to the intent of Part 2.9 - Special Purpose Foods and any relevant policy guidance.*

f) Maintaining clarity and consistent risk-based regulatory decisions at the food-medicine interface

Some Standards within Part 2.9 – Special Purpose Foods of the Code may interface with the regulation of medicines. Some medicines may contain similar ingredients, or have similar formulations or indicated uses to Special Purpose Foods.

An Implementation Sub-Committee working group (Food-Medicine Interface Working Group) has developed a process for considering the most appropriate regulatory status of products at the food- medicine interface. This process will provide, in the long-term, for a maximum degree of consistency in decision making between food and medicine/ therapeutic product regulators in Australia and New Zealand.

*Q12 - Please comment on any issues in relation to maintaining clarity and consistent risk-based regulatory decisions at the food-medicine interface.*

*Q13 Are there any foods currently regulated under Part 2.9 that you think should not be considered as Special Purpose Foods? If so, why?*

*Q14 - Can you identify any additional issues for public health, consumers, industry and government relating to Special Purpose Foods?*

### **Draft Policy Principles**

This section of the Policy Options Consultation Paper provides information about what

policy principles would be considered in the drafting of a Policy Guideline to clarify the intent of Part 2.9 of the Code.

### **Scope/Aim**

The Policy Guideline will provide guidance on the intent of Part 2.9 of the *Australia New Zealand Food Standards Code* (the Code) – Special Purpose Foods.

Specifically, this Policy Guideline will provide clarity around the intent of Part 2.9, including:

- a) the definition of special purpose foods.
- b) consistency in the application of the definition of special purpose foods to each of the standards within Part 2.9.
- c) other requirements, such as access, advertising/marketing and labelling.

This policy guideline does not apply to products that should be or are regulated as therapeutic goods.

### **GUIDING PRINCIPLES**

**High Order Policy Principles –are standard text as these principles are generic and apply to the development of all food regulation policy guidelines.**

The *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) establishes a number of objectives for FSANZ in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
  - a) the protection of public health and safety; and
  - b) the provision of adequate information relating to food to enable consumers to make informed choices; and
  - c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:
  - a) the need for standards to be based on risk analysis using the best available scientific evidence;
  - b) the promotion of consistency between domestic and international food standards; (c) the desirability of an efficient and internationally competitive food industry;
  - c) the promotion of fair trading in food;
  - d) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the authority.

These objectives apply to the development and review of standards contained within Part 2.9 - Special Purpose Foods of the *Australia New Zealand Food Standards Code*.

A number of other policies are also relevant to the development of food standards including COAG Principles (Australia only), New Zealand Code of Good Regulatory Practice (November 1997), the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System and World Trade Organisation (WTO) agreements.

### **Specific Policy Principles**

Principles that relate specifically to Special Purpose Foods. These must clearly set out the principles that the working group will use in the development of food regulation policy

guidelines. These will often include a more detailed statement of concerns raised by the High Order Policy Principles, for example, setting out the particular public health and safety concerns that relate to a particular issue.

The following specific policy principles directly relate to the Scope / Aim of the draft policy principles:

**a) The definition of special purpose foods.**

Policy Principle: That the Policy Guideline applies only to those foods that meet the following definition of a Special Purpose Food:

“a special purpose food is defined as a food that is specially processed or formulated to meet the particular dietary requirements of nutritionally vulnerable groups that cannot be met by a normal diet. In this context nutritionally vulnerable groups are defined as those:

- with a particular physical or physiological condition or diseases/disorders; and/or
- infants (under 12 months).”

The key elements of this proposed definition are:

- It refers to foods that are specially processed or formulated to meet the needs of nutritionally vulnerable population subgroups.
- It limits the population target groups for special purpose foods to people who are nutritionally vulnerable. Nutritional vulnerability arises from situations where people are unable to meet their normal dietary requirements.
- It specifies that special purpose foods are only relevant in situations where dietary requirements cannot be met through a normal diet.
- It encompasses foods for infants in particular recognising that for infants under six months, infant formula may be the sole source of nutrition among infants who are not breastfed.

**b) Consistency in the application of the definition of special purpose foods to each of the standards within Part 2.9.**

Policy Principle: The definition of special purpose foods will be applied consistently across the standards within Part 2.9.

**c) Other requirements, such as access, advertising/marketing and labelling.**

Policy Principle: Any access, advertising/marketing and labelling conditions placed on Special Purpose Foods should be evidence based within a risk management framework, and cognisant of the target groups these products are intended for. Special purpose foods should not, as a matter of course, be promoted and positioned as a general food. Consideration should be given to monitoring the access, advertising and labelling of SPF, in order to adequately regulate the policy guideline.

**Additional Policy Guidance**

The intent of this Policy Guideline is **NOT** to remove Standards from the Code but to ensure that Standards are placed appropriately within Part 2.9- Special Purpose Foods or elsewhere in the Code.

## **Policy Options**

Policy options for the development of a policy guideline on the intent of Part 2.9 - Special Purpose Foods of the Code are explored in this section. Stakeholders are asked to comment on their preferred policy option, which could also be a combination of specific elements from a number of the policy options. The policy options are listed below for quick reference.

In brief, the policy options are:

Option 1. – Maintain the status quo

### **Summary**

This option would maintain the current situation in relation to there being no specific policy guidance on the intent of Part 2.9 - Special Purpose Foods of the Code.

### **Advantages**

- There may be no change to the placement of current standards for special purpose foods – Part 2.9 of the Code.

### **Disadvantages**

- This option will not provide a food regulatory policy context to allow a review of the intent of Part 2.9 of the Code in addition to any future consideration of Part 2.9.
- There may be no change to the placement of current standards for special purpose foods – Part 2.9 of the Code.

Option 2. – Provide a food regulation policy context on the intent of Part 2.9

### **Summary**

This option would provide clarity around the definition of a special purpose food and what foods are intended to be captured under Part 2.9 of the Code. It is not the intention of policy guidance to remove any Standards from the Code, but to provide FSANZ with guidance to ensure that Standards relating to Special Purpose Foods are placed appropriately within the Code. Conversely, policy guidance will ensure that Standards in Part 2.9 do not

unintentionally capture foods that are general purpose in nature.

### **Advantages**

- Provides clarity around the definition of special purpose foods, in order to identify what should and shouldn't be captured by Part 2.9 of the Code.
- This option will provide FSANZ with policy guidance in order to complete the review of the intent of Part 2.9 of the Code that has been requested by the Ministerial Council.
- This option will ensure that Standards for Special Purpose Foods are placed appropriately within the Code.
- Greater clarity around the definition of special purpose foods may mean that some Standards currently captured under Part 2.9 of the Code may need to be placed more appropriately within another part of the Code.

### **Disadvantages**

- Greater clarity around the definition of special purpose foods may mean that some Standards currently captured under Part 2.9 of the Code may need to be placed more appropriately within another part of the Code.

Q15 - Which policy option do you prefer and what are your reasons for this preference?

Q16 - Please provide any examples, and data if available, of the risks, benefits and costs that might arise as a consequence of the policy options explored in this paper.

Q17 - Are there any other comments you would like to make about the issues discussed in this paper? Please describe your reasons for raising them and offer solutions where possible.

## Attachment A

### RESPONSE SHEET

#### POLICY OPTIONS FOR THE REGULATION OF SPECIAL PURPOSE FOODS

Name: Title: Organisation: Address:

Telephone: Fax: Email:

Summary of questions from the consultation paper to guide your response:

1. What is your understanding of the current intent of Part 2.9 – Special Purpose Foods? (p.6).
2. Please comment on the adequacy of the current Australian and New Zealand regulatory system to identify and appropriately regulate special purpose foods (p.7).
3. Is the proposed definition of Special Purpose Foods adequate to capture those foods or groups of foods you consider to be special purpose foods? Why or why not? What refinement, if any, would you suggest? (p.8)
4. Should the policy guidance require the special purpose of the food to be stated and articulated clearly by the manufacturer including reasons why the particular dietary requirement cannot be met by the normal diet? (p8)
5. Please comment on specific trans-Tasman requirements, current provisions and their implications on the intent of Part 2.9 – Special Purpose Foods (p.8).
6. Please comment on the impact of international regulatory approaches and the impact of the regulation of Special Purpose Foods under the Code (p.9).
7. Are you aware of any particular issues with the current labelling of special purpose foods? How could these be addressed? (p.9)
8. Can you identify what would be particular instances where access controls to special purpose foods should be considered? If so, how? (p.9)
9. If you believe there should be access controls, what sort of controls should these be and at what point would these controls be applied? (p.9)

10. Can you identify any particular issues with the advertising/marketing of special purpose foods? Can you suggest any approaches to address these issues? (p.9)
11. Please comment on any issues in relation to the intent of Part 2.9 - Special Purpose Foods and any relevant policy guidance. (p.10)
12. Please comment on any issues in relation to maintaining clarity and consistent risk-based regulatory decisions at the food-medicine interface. (p.10).
13. Are there any foods that you think should not be considered as Special Purpose Foods?  
If so, why? (p.10)
14. Can you identify any additional issues for public health, consumers, industry and government relating to Special Purpose Foods? (p.10)
15. Which policy option do you prefer and what are your reasons for this preference? (p.15)
16. Please provide any examples, and data if available, of the risks, benefits and costs that might arise as a consequence of the policy options explored in this paper (p.15).
17. Are there any other comments you would like to make about the issues discussed in this paper? Please describe your reasons for raising them and offer solutions where possible. (p.15)
18. Additional Comments: Comments should be provided by **Monday 2 March 2009** to:

#### **Australia**

Submissions – Intent of Part 2.9 –  
Special Purpose Foods

C/- Food Regulation Secretariat  
PO Box 4  
WODEN ACT 2606

Or email the [Food Regulation Secretariat](#)

Or fax to: (02) 6289 5100

#### **New Zealand**

Submissions – Intent of Part 2.9 –  
Special Purpose Foods

C/- Ursula Egan  
Joint Food Standards Group  
New Zealand Food Safety Authority  
PO Box 2835  
WELLINGTON

Or email [Food Standards NZ](#)

Or fax to: (04) 894 2583

Would you like to receive future information about food regulatory issues? If so, please indicate your main areas of interest and detail your e-mail address here:

## Attachment B

FRSC Working Group to develop a Policy Guideline on The intent of Part 2.9 of the Food Standards Code Terms of Reference (TOR)

Food Regulation Standing Committee (FRSC) agreed at the 7 March 2008 meeting that the 'present Addition to Food of Substances other than Vitamins and Minerals Working Group should continue, with revised terms of reference, to develop a policy guideline for the intent of Part 2.9 of the Food Standards Code - Special Purpose Foods'.

The working group will prepare draft policy guidelines to ensure that foods that meet the working definition of a special purpose food are regulated under Part 2.9 of the Code.

This working definition incorporates the key elements of the Codex definition for food for special dietary uses<sup>5</sup>.

A special purpose food is defined as one which is specially processed or formulated to meet the particular dietary requirements of nutritionally vulnerable groups that cannot be met by a normal diet. In this context nutritionally vulnerable groups include those with a particular physical or physiological condition or diseases / disorders; and/or infants (under 12 months).

Special purpose foods will not, as a matter of course, be promoted and consumed as a general food.

1. To prepare the policy guideline, the working group should consider relevant issues including:
  - a. the "intent" of Part 2.9 – Special Purpose Foods
  - b. the definition of Special Purpose Foods
  - c. specific trans-Tasman requirements and current provisions
  - d. international regulatory approaches
  - e. labelling, access, advertising and marketing relating to Special Purpose Foods
  - f. other policy guidance, such as fortification with vitamins and minerals, the addition of substances other than vitamins and minerals and health claims
  - g. maintaining clarity and consistent risk-based regulatory decisions at the food-medicine interface.
2. The working group will provide a final draft policy guideline for FRSC at the 6 March 2009 meeting.

<sup>5</sup> Codex defines foods for special dietary uses as those which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are

presented as such (This includes foods for infants and young children). The composition of these foodstuffs must differ significantly from the composition of ordinary foods with comparable nature, if such ordinary foods exist.

## Attachment C

### PRINCIPLES AND OPERATING PROTOCOLS FOR STAKEHOLDER CONSULTATION

(Adopted by the Australia and New Zealand Food Regulation Ministerial Council - April 2003)

An effective and adaptable consultation mechanism will inform the development of food regulation policy guidelines by Ministers. The new food regulatory arrangements relating to food regulation policy to apply in Australia (under the Food Regulation Agreement), and New Zealand (through the Agreement between the Government of Australia and the Government of New Zealand concerning

a joint Food Standards System) provides for effective stakeholder consultation. Such a consultation arrangement is separate from and additional to the statutory consultation requirements that Food Standards Australia New Zealand (FSANZ) must fulfil as part of its processes during the development of food standards.

Stakeholder consultation on food regulation policy guidelines aims to:

1. provide for the views of stakeholders to be considered by the Australia and New Zealand Food Regulation Ministerial Council when setting food regulation policy guidelines;
2. inform the policy guideline development process;
3. provide increased accountability and transparency in decision making on food regulation policy guidelines; and
4. enhance stakeholder confidence in the food regulatory system and build relationships with those developing policy.

Food regulation stakeholders include consumers, public health professionals and the food industry sectors which each represent a collection of groups and individuals with some common but many diverging interests. The diversity of stakeholders across Australia and New Zealand must also be accommodated.

#### Principles

The consultation mechanism will ensure:

- transparency;
- accountability;
- flexibility;
- increased stakeholder awareness of policy issues;
- broad stakeholder input and involvement;
- efficiency and effectiveness;
- promotion of stakeholder confidence; and
- an understanding of stakeholder perspectives.

## Operating protocol

1. The following minimum level of consultation will be undertaken on all food regulation policy guidelines:

- Information will be provided to stakeholders in such a way that they clearly understand who is consulting and why, the way in which decisions will be made (and by whom) and the type of consultation to be undertaken in particular cases.
- The food regulation policy guidelines workplan will be available on the Food Regulation

Secretariat website, with links from the jurisdictions' websites.

- All policy guideline development will be subject to open consultation, with consultation being notified on the websites of all jurisdictions.
- Notice of the consultation will be sent to all those identified as potentially interested parties.
- Jurisdictions will consult with stakeholders and the public generally in their jurisdiction as they see fit.
- Where there is a need for further detail to be sought from specific sectors or stakeholders there will be further targeted consultation as appropriate.
- Comments and/or summaries of comments will be provided to the Food Regulation Standing

Committee and the Ministerial Council.

- Outcomes of the consultations will be made publicly available.
- An annual consultative stakeholder forum will be held to gather issues to be presented to Ministers.

2. It is at the discretion of the Australia and New Zealand Food Regulation Ministerial Council and the Food Regulation Standing Committee to conduct additional consultation using the following options:

- working through already established jurisdictional advisory, expert or technical committees or groups;
- targeted consultation with specific stakeholder groups or in specific geographic areas;
- workshops;
- meetings;
- public forums;
- discussions at seminars and conferences;

- purpose-specific, time-limited advisory committees;
- hard copy mailouts or web-based mechanisms calling for submissions;
- interactive web-based consultation (e.g. surveys, response sheets, ‘frequently asked questions’);

and

- surveys.

3. Factors to be considered in determining the most appropriate consultation mechanism in each circumstance will include:

- the amount and type of consultation already undertaken;
- the level of broad stakeholder interest;
- the degree of complexity of the issue;
- the range of stakeholder groups affected;
- the level and type of expertise required (expertise may be required on other matters such as economic issues); and
- the time and resources available.

4. The Food Regulation Standing Committee will review this process in 12 months to evaluate the effectiveness of this approach to consultation. There will also be an ongoing monitoring and review process to identify and address the strengths and weaknesses of the mechanism.