Policy Options for Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods

Summary of Submissions – Scoping Phase

The public consultation period on the Policy Options Consultation Paper – Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods commenced on 17 January 2009 and closed on 2 March 2009.

The Policy Option Consultation Paper (the Paper) forms part of the scoping phase of the food regulation policy development process. The paper is intended to prompt comment from stakeholders to assist in clarifying the scope and intent of a proposed policy guideline. In addition, the scoping phase aims to identify the range of issues that may require further consideration in the development of the final policy guideline.

Overview of submissions received:

Refer to **Attachment 1** for full list of submitters.

NB Opinions expressed in this summary are those of the submitters and do not necessarily reflect those of the Food Regulation Secretariat Committee Working Group. While every effort has been made to capture the key issues that arose from the consultation, this summary does not attempt to capture all views expressed by all submitters.

Summary of Submissions Received

There were 34 submissions received – 10 from jurisdictions, 6 from consumer and public health organisation, and 18 from industry. A submission was also received from the US Food and Drug Authority.

Refer to ***Attachment 2*** for a summary of comments on the questions posed in the consultation paper.

Analysis of the submissions received in response to the *Policy Options Paper for the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods* demonstrates that there is a diverse range of views and concerns in relation to this issue.

Most submitters responded to the specific questions posed in the paper and some have provided additional comments.

In terms of achieving the objectives of the scoping phase of policy development, the consultation process has provided a clear indication of the divergent views on this issue.

Synopsis of submissions

In response to the Policy Options Paper for the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods, the majority of submissions supported option two. However, while the majority of submissions supported option two, they noted that this support came with reservations about the definition. It was generally considered that the definition of special purpose foods needs to be more succinct and in line with international definitions. Overall there was a diverse range of views.

Of the 34 submissions received, 22 submissions supported option two. Only four submissions supported option one. The remaining submissions generally did not indicate a preferred option.

All public health organisations and jurisdictions preferred option two, as did 13 industry and business submissions. The reason for this preference is that option two gives FSANZ clear

guidance and promotes a more equitable marketplace. Jurisdictions and public health organisations also commented on the adequacy of the Australian and New Zealand regulatory system in regard to special purpose foods. In addition, submitters indicated a need for the definition to be clarified and broadened to capture those foods or groups of foods considered to be special purpose foods. Overall, a majority noted that the current standards in Part 2.9 are designed to meet special needs over and above those provided by general foods.

Four industry submissions supported option one as they believe that the standards are appropriate within Part 2.9 and that development of a generic definition should be the responsibility of FSANZ.

The majority of jurisdictions noted that a special purpose food that has been mixed with other food is of concern, and suggested that these mixed foods are outside the scope of Part 2.9. Four submissions, including industry and public health organisations, note that the labelling provisions for Special Purpose Foods are severely constrained by the prohibitions under Standard 1.1A.2 - Transitional Standard for Health Claims. Other industry submissions discuss labelling issues relating to Standard 2.9.1- Infant Formula Products. In particular, the difficulty for the consumer in obtaining adequate product information on infant formulae from labels, as according to the current Standard 2.9.1, this type of information is not permitted on the label. Several submitters give the example of toddler milks and potential issues that may arise relating to the standard for toddler milks as a result of the proposed definition of special purpose foods.

The majority of submitters indicated that the policy guideline should require that labelling of special purpose foods should state the intended purpose of the food to enable consumers to make an informed choice, and potentially reduce misuse of the food product. A number of submitters noted that labelling of special purpose foods should be considered as part of the Council of Australian Governments food labelling law and policy review.

In response to the issue of costs and risks, jurisdiction and public health organisations raised concerns that special purpose foods are marketed and available to the general public. Specifically, that such marketing may lead consumers to make poor nutritional decisions. A majority of the submitters raised concerns in regards to the relabelling of products. In particular concerns raised included costs of reformulation of products and the economic implementation with regards to imports and exports. No submission discussed the benefits.

Most submitters noted that the advertising/marketing of special purpose foods should be addressed in this Policy Guideline. Some submitters discussed the marketing of products. Access to medical foods and foods distributed through pharmacies was also discussed by several submitters.

In maintaining clarity and consistent risk-based regulatory decisions at the food-medicine interface, submitters agreed that there is a need for more transparency and definition of those products that are to be regulated as foods and those that are more appropriately regulated by the Therapeutic Goods Administration (TGA). Further, jurisdictions noted that there should be a review process where the TGA has deemed a product to be a food.

The majority of submitters did not directly discuss foods that are currently regulated under Part 2.9 that should not be considered special purpose foods. However, there was concern about special purpose foods that are marketed to the general population as a general purpose food. The majority of industry submitters note that many foods that start out as special purpose foods end up being promoted to the general population. It was suggested that foods that should not be identified as special purpose foods include sports foods, Milo style products and toddler milks.

The jurisdictions raised issues regarding lack of clarity, consumers being misled, and issues with monitoring special purpose foods. The industry submissions discussed flexibility to meet market needs, and fortification of the food supply. The majority of submissions (both industry and jurisdictions) had public health concerns relating to fortification and special purpose foods.

The majority of submitters noted that there is a need for Australia to address the access controls issue. However, there appears to be much debate about whether or not the controls are appropriate or if there needs to be changes. Many agree that while there should be access controls, they are already in place and no further changes should occur.

Most submitters raised concerns around the focus on the 'intent' of Part 2.9 which they feel will limit the scope to address the issues such as the access, marketing and advertising, addition of vitamins and minerals and other relevant policy guidance. There appears to be a general consensus among the manufactures of infant formulas that the self-regulation system that is currently in place appears to be working.

As identified above, almost all submissions noted that the intent should align with international regulation to facilitate trade, for example, Codex. The jurisdictions note that there is already a definition for special purpose foods in place under Codex and that this definition, along with labelling laws should be taken into consideration. The jurisdictions and ten industry submitters also mentioned that the definition for nutritionally vulnerable groups is different to those already in place with Codex. The submissions from Public Health organisations note that the broad definition given does appear to be consistent with Codex.

The preferred option by the submissions is Option 2.

List of Submitters

Addition to Food of Substances Other than Vitamins and Minerals

Scoping Phase

Consumers & Public Health total 4

- Dieticians Association of Australia.
- New Zealand Dieticians Association
- Public Health Association of Australia
- New Zealand Nurses Organisation

Food Industry total 20

- Australian Food & Grocery Council.
- Unilever.
- Dairy Australia.
- Sanitarium.
- WYETH Australia Pty Ltd
- Vita Tech Pty Ltd
- Nutricia Australia
- Nestle
- Parmalat Australia Ltd
- Adecron Food Tech Consulting
- National Foods
- Murray Goulburn Co-operative Co Ltd
- Infant Formula Manufacturers Association of Australia and NZ Infant Formula Marketers' Association
- Heinz
- National Association of Retail Grocers of Australia Pty Ltd
- Fonterra
- Dairy Goat Co-operative
- Chamber of Commerce and Industry Western Australia
- Bayer Healthcare – Consumer Care
- Complementary Healthcare Council of Australia

Jurisdiction total 10

- Queensland Department of Health.
- Australian Population Health Development Principal Committee, Queensland Health Department
- Australian Population Health Development Principal Committee, Tasmania Health Department
- Department of Health and Human Services, Tasmania.
- New Zealand Food Safety Authority
- Therapeutic Goods Administration
- Western Australia Department of Health
- Victoria Department of Health
- New South Wales Health/New South Wales Food Authority
- Centre for food safety and applied nutrition and US Food and Drug Administration

TOTAL = 34

Responses to questions posed in the Consultation Paper

1. What is your understanding of the current intent of Part 2.9 – Special Purpose Foods?

Analysis:

Several jurisdictions noted that the intent of Part 2.9 is not clear. Overall most submissions noted that the current standards in Part 2.9 are designed to meet special needs over and above those provided by general foods. Furthermore, these include a wide variety of products targeted at groups with specific dietary needs which may not be met through normal dietary intake. Examples of Milo, sports drinks, and infant formula labelling are mentioned within several submissions.

Comments:

- The overarching intent of Part 2.9 is not clear.
- There is a need to provide policy direction for the content of Part 2.9 to allow for the development of new standards and to review existing standards.
- To provide standards on foods that are designed to meet special needs over and above those provided by general foods. Generally understood to regulate foods that are designed to assist specific groups in meeting their dietary requirements which cannot be met by a normal diet.
- To meet a nutrient intake or special need necessary for a certain population group.
- At present not restricted to persons having a particular physical or physiological condition or specific disease or disorder.
- To protect public health and safety by regulating food composition and provision of consumer information through labelling for foods not for general purpose use.
- These foods may have different compositional and labelling requirements to general foods.
- There seems little value to ascribe intent to the current Part 2.9 but rather there is an opportunity to establish policy guidelines for special purpose foods.
- This process seems to overlap the roles of FRSC and FSANZ. FRSC should develop policy guidelines for special purpose foods which FSANZ should then use to examine the content of Part 2.9.
- The current list of standards under Part 2.9 does not appear to have a uniform intent.
- Part 2.9 was developed to include a wide variety of food categories addressing many different nutrition goals and needs and population groups and was not developed to address specific vulnerable population groups exclusively.
- There is no such thing as a normal diet. Some individuals may be nutritionally vulnerable because they cannot meet their nutritional needs from readily available mainstream products. Industry produced foods in response that supplement other foods in the diet or become the sole food in the diet. Foods that are provided as the sole source of nutrition may require a higher level of regulatory control.
- To permit the foods regulated in Part 2.9 to contain certain added nutritive substances that are not permitted to be added to other foods or are permitted at levels outside those allowed in the general food supply for specific requirements of sub-populations.
- There is a mismatch of how the intent of Part 2.9 is represented in the market place.

Some products are widely marketed to the general population such as sports drinks.

- Part 2.9 provides a regulatory framework for foods targeted to populations who are vulnerable as well as for groups who are in need of special nutritional requirements.
- The definition of special purpose foods should not exclude special purpose foods that are generally available to consumers as long as there is justification for the product to be marketed as a special purpose food.
- Part 2.9 originally was developed to capture long term existing foods groups that did not fit elsewhere in the Code e.g. Milo, sports drinks, infant formula and foods, diet meal replacements.

2. Please comment on the adequacy of the current Australian and New Zealand regulatory system to identify and appropriately regulate special purpose foods.

Analysis:

Jurisdictions and several public health organisations note that the regulatory system requires further development in regards to special purpose foods.

However, there are also several submissions that note that the regulation system is appropriate because there are no health and safety concerns and therefore there is no evidence of failure of the current food regulatory system.

Of particular concern was that the lack of harmonisation of the current special food regulations with international standards which submitters believe is limiting ability to supply products that meet export market expectations and international regulations. Other issues raised included failure of the current food regulatory system to appropriately regulate special purpose foods.

Because Part 2.9 has developed without clear policy guidance as to its scope and intent, the food- medicine interface has inadvertently been blurred. The purpose of the standards in the section have not always been worded sufficiently carefully to be sure that they do not adventitiously draw into their scope, products that should be regulated as therapeutic goods. Enforcement in these situations is compromised. Sports supplements regulated under Standard 2.9.4 are the prime example. Part 2.9 should not be used for standards for food products intended for the general population, such as sports drinks and foods.

Comments:

- More prescriptive standards are required for special purpose foods than for general foods.
- A standard for young children aged 1-3 years is an area that is not adequately regulated.
- The term Foods for Special Dietary use would seem more appropriate than Formulated Supplementary Food.
- The regulatory system requires further development and policy guidance to appropriately regulate special purpose foods.
- There is a lack of clarity for the food industry as to the distinction between general and special purpose foods.
- The regulatory system cannot adequately regulate special purpose foods without a clear definition of special purpose foods.
- The policy guideline needs to provide a mechanism for FSANZ to explore the definition of special purpose foods in order to review the content of Part 2.9 and ensure that it does not unintentionally capture foods that are general purpose in nature.

- Standard 2.9.4 Formulated Supplementary Sports Foods needs to be reviewed: the sports supplement industry is finding it increasingly difficult to comply with current outdated requirements and has difficulty in competing with innovative products on overseas markets.
- The current standards under Part 2.9 are successfully regulating Special Purpose Foods with no problems relating to public health and safety. Any change to the Standard should not increase the regulatory burden on the administrators or food manufacturers.
- As long as these standards are reviewed regularly and updated to reflect the latest science or align globally then the varying consumer needs or goals can be adequately met.
- The current regulatory environment for food for specific medical purposes is unclear.
- It is currently extremely difficult to develop a food for a particular nutritional purpose to fit within the current constrained regulatory framework and to clearly communicate the consumer benefits of the product to the target consumer.
- Given that Part 2.9 of the Code does not rely on the general provision, but simply provides the four standards there is little opportunity to consider whether Part 2.9 is adequate generally but only whether the specific Standards contained in Part 2.9 are adequate to regulate the specific foods covered under those Standards.
- The Code and the Dietary Supplement Regulations 1985 in New Zealand adequately regulate special purpose foods.
- The regulatory system is inadequate to identify and appropriately regulate special purpose foods. Foods marketed as general purpose foods are covered under a special category e.g. Milo.
- Part 2.9 offers an escape clause for fortifying standard foods outside of the general scope of the Code, e.g. fortified fruit juices.
- There are areas of non-harmonisation between the special purpose food regulations and corresponding international standards that limit export ability.
- The current application of Part 2.9 is wider than the intent implied in the proposed definition.
- Standard 2.9.4 does not adequately regulate sports foods or allow industry to formulate foods to assist sports people to achieve specific nutritional or performance goals. Some sports foods are regulated in Australia under the Therapeutic Goods Act and in New Zealand under the Dietary Supplement Regulation. This demonstrates that Standard 2.9.4 does not adequately regulate the range of sports foods that are currently on the market and therefore does not fulfil the role for which it was originally intended.
- There are concerns about the ability of the infant formula standard to appropriately regulate infant formula products the policy development process for infant formula products will address this issue.
- The regulatory system does not fully regulate special purpose foods, due to the undermining of the system in Australia by the Trans-Tasman Mutual Recognition Arrangement (TTMRA) which effectively allows for a range of these special purpose foods to be introduced to and marketed to the general public.
- The representations about these products need to be strictly controlled as currently they are effectively allowed to be promoted as general purpose foods.

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?

Analysis:

There was an overwhelming response from the majority of submitters that the definition is not adequate to capture those foods or groups of foods considered to be special purpose foods. However, some submitters believe that the key elements underpinning the definition are enough as the definition provides a succinct and relatively clear outline of what is actually being proposed. Finally, some submitters acknowledge that the proposed definition may sit better within the Food Standards Code rather than in the policy guidelines. The reasons and suggested refinement are below.

Comments:

- The proposed definition does not capture all foods considered to be Special Purpose Foods. The definition is restrictive in that it only addresses the dietary needs of persons with an established physiological condition or disease. It is suggested that the proposed definition also include those who cannot or do not meet their dietary requirements due to lifestyle or life stage needs.
- The proposed definition is at odds with the provisions identified within Part 2.9 of the Code, particularly sports foods. The proposed definition does not address the healthy population that due to the workload of sporting competition and/or exercise volume, cannot meet their nutritional needs through consuming a normal diet.
- The proposed definition is not supported and it is suggested that an overarching definition for special purpose foods that simply reflects that these foods are specifically formulated to meet the particular dietary requirements of a consumer that cannot be met from a normal diet. The definition should be removed from the draft policy guideline and that specific policy principles instead focus on identifying key elements for consideration. As a subset within this a second definition would provide for foods that are intended for nutritionally vulnerable populations and where the foods are likely to be the principle source of nutrition or are deemed to be medical foods.
- The intent should first be established before deciding on a definition. Some submitters, as a starting point, agree with the key elements underpinning the proposed definition. It was developed to generate discussion and debate. It would be more appropriate for the definition to be reviewed and defined by FSANZ as part of the standards development process. However the final definition should be developed by FSANZ as part of the drafting of Part 2.9.
- It is assumed that young children (1 – 3 years) were intended to sit within the definition as a nutritionally vulnerable group. However there may be debate about this as healthy toddlers are able to obtain their nutrients from a balanced diet. Regulation in other countries refers to infants and young children although whether this relates to all young children or just those nutritionally at risk is unclear. The definition is not appropriate because Toddler Milks would no longer fall under this section of the Code; however these products are specifically formulated to meet special dietary requirements, needs or goals of the target group. If some products do not fit within the definition of special purpose foods the paper suggests that industry may need to reformulate products to remain compliant with the Code. There needs to be an appropriate regulatory framework existing in the Code for toddler milks which are important export dairy products.
- The use of ‘nutritionally vulnerable groups’ in the definition is challenged. The wording

used in the USA for Foods for Special Dietary Uses is 'supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property'. There may be some advantage to spelling certain conditions out more clearly as is done in the USA e.g. including dietary needs by reason of age, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight or overweight.

- The specific policy principles provided are not consistent with the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) Principles and Protocols for the Development of Food Regulation Policy Guidelines. In particular the inclusion of a complete definition goes beyond the Ministerial Council role of developing policy guidelines and into FSANZ's responsibility for developing food standards.
- Specific policy principles should define what FSANZ's review of policy intent should aim to achieve e.g. a clear distinction between special purpose foods and foods regulated by other sections of the Code and the populations to which special purpose food should apply, for example nutritionally vulnerable groups, groups with specific needs etc.
- The definition should differentiate special purpose foods from general foods. The EU states "are clearly distinguishable".
- The definition and intent of part 2.9 should provide a solid regulatory platform for special purpose foods that supports an internationally competitive food industry.
- The term 'foods intended for particular dietary uses' would more accurately describe foods regulated under Part 2.9 than ' special purpose foods'. This would allow for particular uses to be specifically described and considered within the separate regulatory categories.

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?

Analysis:

Seven submitters did not agree that the manufacturer should be required to state the special purpose of the food.

The majority of submitters (22) believe that the policy guideline should require that the label of special purpose foods should state the intended purpose of the food to enable consumers to make an informed choice and potentially reduce misuse of the food product.

Other submitters noted that this question should be addressed through Standards review or development rather than through Policy consultation.

Comments:

- High order principles of the policy should require the provisions of adequate information relating to food to enable consumers to make informed choices.
- It would be appropriate for the special purpose to be articulated to assist consumer understanding of the specific nature and intended recipients of the foods.
- Inclusion of this information on labels would provide no additional health benefit to the consumer as information provided to ensure safe use is already provided.
- There is a need for the manufacturer to state why the food is a special purpose food. This would provide more information to consumers about the food and potentially reduce misuse of the food product.
- A clear purpose on the label should be included to ensure consumers are well informed.

- It is not the purpose of the label to provide advice of a medical nature; however consumer advice on special purpose foods is required. This requirement should be flexible and outcome based.
- It is essential to ensure that there is adequate information to enable consumers to make informed food choices and for regulators to adequately enforce. The target group and the specific need that the food is designed to meet.
- Describing the reasons why a particular dietary requirement cannot be met by a normal diet would not provide any additional benefit to the consumer and could potentially be confusing. This would also be a burden on manufacturers.
- This would be more appropriately managed as part of the standards setting process rather than policy guidelines.
- Health claims are not currently permitted. It would be difficult to accurately describe a products special purpose under this restriction.
- The opportunity for manufacturers to clearly and succinctly provide a statement of benefits provided to the consumer is supported.
- Yes, for reasons of consistency at the food medicine interface. Complementary medicines are required to carry an indication or their purpose. This helps ensure their appropriate use.
- Information should be provided on the pack to ensure proper use of the product.
- The specific dietary use should be stated on the label and in any associated advertising.

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

Analysis:

Three of the jurisdictions believe that the removal of the TTMRA would facilitate trade.

Most submitters discuss the TTMRA and noted that New Zealand has regulations that differed from Australia. Further to this discussion, six industry submissions mentioned that due to the TTMRA Australian manufacturers may be disadvantaged.

Three industry submitters noted that the final agreement may differ between Australia and New Zealand as a result of Part 1.1 A.6. Full discussion is below.

Comments:

- The TTMRA attempts to remove regulatory barriers to the movement of Goods and service providers between Australia and New Zealand, to facilitate trade, however, the TTMRA may also disadvantage Australian manufacturers.
- Under the TTMRA a good that may legally be sold in Australia may be sold in New Zealand, and a good that may legally be sold in New Zealand may be sold in Australia, regardless of difference in standards or other sale-related regulatory requirements between Australia and New Zealand. Therefore New Zealand produced food type dietary supplements can be manufactured in New Zealand and bought into Australia.
- The current New Zealand Dietary Supplement Regulations are proposed to be replaced with a New Zealand Supplemented Food Standard which will regulate food-type dietary supplements.
- It is proposed that this standard should adopt many of the provisions in the Code in order to harmonise it more closely with the Code.

- Dietary Supplements regulated under the New Zealand Dietary Supplement Regulations and any food regulated under the proposed New Zealand Supplemented Food Standard is not required to comply with the requirements of Standard 2.9.4 of the Code. Standard 2.9.4 Formulated Supplementary Sports Foods covers a limited number of products designed for high performance athletes. Yet, sports foods are one of the largest areas of food-type dietary supplements. Resolution of this is likely to require a review of Standard 2.9.4.
- Other products used by high performance athletes are covered by alternative legislation in both Australia and New Zealand.
- Some manufacturers in Australia feel that they are disadvantaged by the different regulatory approaches in the countries.
- It is recognised that this policy review will not address this issue immediately however it should be noted that this is currently having an impact on industry; it would strongly be encouraged the Food Regulation Standing Committee to resolve this issue as soon as possible.
- Some relaxation of the provisions for sports supplements within an Australian context would alleviate some of this concern being felt currently under TTMRA.
- From a safety aspect, there are concerns that the current provisions in place for sports supplements, which is resulting in a lack of innovation, will further lead to an increase in online purchasing of products that are not permitted to be sold in Australia. This also significantly impacts businesses based in Australia who are complying with the appropriate regulations.
- A definition exists for Special Purpose Foods in Standard 1.1A.6 – Transitional Standard for Special Purpose Food (New Zealand only). In this standard, Special Purpose Foods is already defined as: Special purpose food means a food specially processed or formulated to satisfy particular dietary requirements that exist because of: a particular physical or physiological condition; or a specific disease or disorder; or both such a condition and a disease or disorder; and are presented as such. Matters related to composition and labelling are also referred to in this Standard. There is potential for inconsistencies to be created between Standard 1.1.A.6 definition of Special Purpose Foods and the proposed definition in the consultation paper. A preferred definition is: ‘a special purpose food is defined as a food that is specially processed or formulated to meet specific dietary requirements or needs that may not be met through dietary intake’.
- An alternative approach to section 2.9 would be to have an overarching definition for Special Purpose Foods which would encompass foods specifically formulated to meet particular dietary requirements or specific nutrition goals or needs of a consumer. Consumers may have specific nutrition goals or Sports goals but not be at risk of being nutritionally vulnerable.
- There could be a subset of section 2.9 which addresses food intended for vulnerable populations.
- The FSANZ requirement for changing the Food Standards Code to permit different Special Purpose Foods is inflexible, expensive and not delivered in a timely manner. This issue requires prompt action to help address this inequality between New Zealand and Australian Food Industry.
- Yes the difference between TGA and New Zealand Dietary Supplement Regulations (NZDSR) regulatory systems, which offers a different route to market in NZ for local and imported products on the food/medicine interface. This means that part 2.9 applies more in Australia than in NZ, where it is easier to fit under the DS regulations or its proposed

replacement.

- Exemptions to the TTMRA may be granted substantially for the purpose of protecting health and safety of persons or preventing, minimising or regulating environmental pollution.
- Annex D of the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standard System (the Treaty) permits variation between two countries if it is based on the same reasons as quoted above.
- There is no prohibition on the mixing of foods covered by the Federal Safety Commissioner and this needs to be addressed to ensure that general and special purpose foods are not combined in any way.
- In New Zealand, businesses have the option of producing, importing and retailing such foods under the Dietary Supplements Regulations 1985. If such foods are considered foods by AQIS they can be sold in Australia under the provisions of the TTMRA.

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

Analysis:

Almost all of the submissions note that the intent should align with international regulation to facilitate trade, in particular, Codex and the European Union were mentioned. The majority of jurisdictions note that Codex and several countries have definitions for special purpose foods, often called 'foods for special dietary uses', as discussed in the consultation document. Common to these is recognition of the special nature of these foods through specific compositional and labelling requirements. These definitions, along with labelling laws should be taken into consideration.

The jurisdictions and ten industry submitters also mentioned that the definition for nutritionally vulnerable groups is different to those already in place within Codex. The industry submissions also discussed the market disadvantage to Australia that may occur. Finally the submissions from public health organisations note that the broad definition given does appear to be consistent with Codex.

Specific Comments:

- The Policy needs to allow FSANZ to develop standards that are in harmony with international standards especially Codex.
- The policy document should give consideration to utilising similar terminology as adopted internationally for some types of special purpose foods. E.g. foods for special dietary uses.
- Other international regulatory systems also recognise the need for foods that meet special dietary requirements. It is advocated that the development of a common regulatory approach for these foods to provide benefits of harmonised food standards, such as providing efficiencies across industry, and to increase trade opportunities.
- There is concern to ensure that the benefits by adopting a common approach must not be outweighed by increased regulatory burden, or costs on industry. It is strongly recommended that a cost benefit analysis be undertaken to determine the outcome on the Australian food industry before committing to international regulatory harmonisation.
- It is noted the European Union, Canada and Australia/New Zealand have their own prescriptive compositional approaches to Special Purpose Foods which can delay international transfer of new technology; this has a flow-on effect to what is accessible to

consumers.

- The USA however, consists of very little compositional guidance which is a concern in relation to safety and quality of products and would not be supported.
- It is suggested that the best approach, in relation to formulated supplementary sports foods, is to permit general foods to be used in formulations and have a positive list of additional ingredients which could be used to differentiate a Special Purpose Food from a general food product.
- There is a significant need for a mechanism by which the standard in the Code can be updated in a timely manner to assist industry innovation and competitiveness.
- The NZ Food-type dietary supplements proposal currently under consideration offers considerable scope for foods for special purposes to advantage the NZ community – both consumers and manufacturers.
- The inclusion of the limitation to 'nutritionally vulnerable populations', and its definition is subtly different to almost all the international examples given, and particularly extends beyond what is in the Codex Alimentarius definition.
- The proposed definition of Special Purpose Foods in section 2.9 of the Code also does not consider the definitions under both Codex Alimentarius and the European Commission. These definitions include 'young children' under the Special Purpose Foods definition but this is not explicit in the proposed consultation document definition, which defined the context of nutritional vulnerable groups as either those with a particular physical or physiological condition or disease/disorders; and/or infants (under 12 months).
- Given the vast majority of local Food for Special Medical purposes (FSMP) products are imported it is imperative that Standards development in this area is closely aligned to international legislation in the major exporting markets. It would be appropriate that the Standard development for FSMP including food for very low energy diets is progressed and included as a Standard under Section 2.9 of the Code.
- Given at a local level manufacturing is minimal and unlikely to be sustainable within such a small market, regulatory harmonisation is extremely pertinent. That is any significant local regulatory variation from larger global markets may have an economic effect acting as a barrier to trade and impact public health particularly those vulnerable populations with the healthcare sector and wider community that rely on products for sole nutrition.
- With the subsequent review of Proposal P242 – Food for Special Medical Purposes, it is necessary for the compositional requirements for FSMP products be taken into consideration and be appropriately aligned with the National Health and Medical Research Council's (NHMRC) nutrient reference values for Australia and New Zealand.
- If the proposed consultation document definition is progressed then it is not clear within the document how these foods currently falling under Section 2.9 of the Code will be encompassed within the current regulatory framework.
- If the eventual outcomes results in removal of many foods currently manufactured under Standards like 2.9.2, 2.9.3, and 2.9.4 there would be a considerable impact with regard to the composition requirements of these foods and significant barriers to trade created through pursuing an inappropriate non harmonised definition.
- If the proposed Special Purpose Food definition is pursued then the impact would be significant and at the detriment of a locally competitive and innovative food industry.
- The application of Special Purpose Foods internationally has largely been to restrict the

application of special purpose foods to deal with foods for a specific dietary need and a nutritionally vulnerable population. In this context formulated supplementary foods and sports drinks do not meet this definition on the grounds that they are meant to be consumed as part of a normal diet and the consumer is not nutritionally vulnerable. This creates inequity in the legislation and fails to adequately deal with the broader problem of ensuring that foods not intended for general consumption are safe and suitable for the intended consumer.

- Although international standards apply special medical purposes to some infant formulas, this is different to the proposed Standard 2.9.5 Foods for special Medical Purposes which specifically excludes infant formula products.
- There needs to be general labelling and composition requirements for infant formula products that would be regulated under Division 3 – Infant formula products for special dietary use. Labelling requirements can be specified to restrict inappropriate positioning of infant formula products for special dietary /medical uses so that a separate category for special medical uses is not necessary
- The objectives of food standards are firstly the protection of public health and safety. Good nutrition is fundamental to public health and as such foods that are required for a special purpose by specific population subgroups should be adequately implemented by the Code. Australia takes pride in the wide range of nutritious foods available and needs to protect optimum dietary habits; at times this will mean not harmonising with international regulatory approaches that are less stringent than those in Australia.

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

Analysis:

Four submissions including industry and public health organisations note that the labelling provisions for Special Purpose Foods are severely constrained by the prohibitions under Standard 1.1A.2 Transitional Standard for Health Claims. Other industry submissions discuss labelling issues relating to Standard 2.9.1- Infant Formula Products and in particular the difficulty for the consumer to get adequate product information on infant formulae from their labels, because according to the current Standard 2.9.1, this type of information is not permitted on the label.

Eight industry submissions suggest that this question should be addressed through Standards review or development rather than through Policy consultation.

The jurisdictions noted that the labelling of a special purpose food that has been mixed with other food is of concern. These mixed foods are outside the scope of Part 2.9. Several submitters give the example of toddler formula (toddler milks) and the labelling techniques used in the supermarkets and pharmacies for these products. Other issues are listed below.

Specific Comments:

- No specific issues that need to be addressed at the policy level.
- Any new or amended standard should be consistent with general labelling standards in that either a prescribed name or a description indicating the true nature of the food will be required.
- The purpose which puts it in the category of a special purpose food would be expected to be applied to the label [as per current practice].
- The only current issue with respect to labelling of special purpose foods is the prescribed name ‘Formulated Supplementary Food’ and other similar prescribed names, which are

not well understood by consumers. Consumers would tend to define the name of such products from other information, inclusive of any graphical representations, contained on the label.

- 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.
- The use of a Special Purpose Food as an ingredient for a mixed food will be of concern.
- Labelling would be more appropriately addressed via the standards setting process as opposed to policy setting guidelines, however current provisions do not high light any particular issues.
- Standard 2.9.3 permits the addition of iodine to formulated supplementary foods. There are only limited permissions for iodine in general purpose foods.
- Mixing a special purpose food with another food may produce a food outside the scope of Part 2.9. Such foods are then no longer subject to the labelling requirements of part 2.9 foods and may present a health risk to unwary consumers.
- Limit mixing of special purpose foods or labelling of resulting food with special purpose food requirements could be considered in the review of the standard.
- There are foods currently being classed as sports foods which would really be best placed under a separate section of the Code; for example, mineral waters which are currently being sold and promoted as sports drinks. One way to address this issue may be to broaden the permissions for Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods so a wider range of formulations can be utilised by the industry and provide people, who are not necessarily participating in excessive exercise, an additional source of nutrition; this would remove such questionable products from the formulated supplementary sports foods standard.
- Labelling requirements for Special Purpose Foods are already in place which indicates their "special purpose" nature in broad terms, for example, the requirement to label with "Formulated meal replacement" and the warning statement "this product must not be used as a total diet replacement".
- Vitamin supplements regulated by the TGA contain the labelling statements that include: Vitamin supplements should not replace a balanced diet'. Toddler milk is essentially a vitamin supplement in sweetened milk and does not replace appropriate feeding practices which impact on the dietary habits developed for life.
- The labelling requirements of special purpose foods are clear and workable.
- The number and length of advisory statements required on packaging and also visible to the consumer can be challenging. The wording is typically not explicit, rather 'intent of', providing some flexibility.
- A policy guide, such as the one to be developed by this Working Group, should address overarching policy principles: for example: ensuring that all labelling addresses the needs of the consumers rather than considering each individual need.
- Currently there is difficulty for the consumer to get adequate product information on infant formulae from their labels, because according to the current Standard 2.9.1, this type of information is not permitted on the label.
- It is supported that labelling on special purpose foods to allow the use of scientifically substantiated nutrition and health claims. This will bridge the information gap that currently exists in standard 2.9.1 and enable consumers to make an informed choice.
- The multiple warning & advisory statements required on sports foods can make it difficult to fit it all legible onto a label, especially for smaller products such as

protein/sports food bars. Make sure that specific wording is not long and academic but short and succinct.

- The warning statements should be clearly linked to those of the added nutrients and components that warrant that warning. As all of the additives are optional across products that fitted under the Sports food regulations that were not significantly different from formulated supplementary foods but required a lot more warnings on them.
- There needs to be clarity around the labelling of infant foods which reflects current understanding of issues related to allergies and the introduction of solids. For instance, recent changes to the Ministry of Health advice to pregnant and lactating women.
- In rare cases, excessive consumption of a food regulated under a standard in Part 2.9 may pose a health risk to the consumer. To manage risks in such cases, it may be appropriate for the food label to specify an appropriate daily consumption and include an advisory statement to the effect that exceeding that daily consumption may cause harm.

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

Analysis:

On the whole, many submissions noted that there should be access controls to special purpose foods. Several submitters noted that access controls could further increase the inappropriate and detrimental use of general purpose foods. Five submissions noted that these foods are already required to be labelled with warning statements and their prescribed name indicating that there was no need for further access control. There was also discussion surrounding access to hospital-only food, infant formula, and diet food.

Specific Comments:

Instances where access to special purpose foods should be considered

- Yes. As these food represent foods providing a special purpose, for a specific target audience, it is not appropriate that the general population has unlimited and uncontrolled access to these foods. Some products, for example special dietary products, those low in kilojoules, or those providing specific nutrients for identified population sub-groups will not be suitable for general consumption.
- Access controls do need to be considered in order to limit the opportunities for special purpose foods to be presented as general purpose foods and to reduce the possibility of misuse particularly where there could be a risk to health. However there may need to be different approaches for different products. Control of access may be quite difficult to administer.
- There are existing issues with “hospital-only” foods, specialised foods for patients (including those administered by lavage) which do not comply with the Code, which may in the future be standardised under part 2.9.5. Jurisdictions are presently compromised by ignoring their use in hospitals but preventing their retail sale through pharmacies.
- If restrictions on access to Special Purpose Foods are to be considered, for example for foods that should only be consumed under medical supervision, there should be consideration of whether these products are actually appropriately regulated as foods or whether they are more appropriately regulated under the Therapeutic Goods Administration.
- In reference to Special Purpose Medical foods consideration of this issue may be required to ensure a situation where patients on low incomes can have adequate access to these products via the pharmaceutical benefits scheme.

- Requiring access controls to Special Purpose Foods should be considered for products such as those formulated for athletes or weight loss products, where consumption by non-target audiences may lead to negative health outcomes.
- Careful consideration would need to be given as to whether the product should be regulated as a food, or whether it met the definition of a therapeutic good. Infant formulas for infants with certain inborn errors of metabolism could be a case in point, as could highly specialised enteral feeds.
- Access controls for therapeutic goods are of course delivered through the Standards for the Uniform Scheduling of Drugs and Poisons (SUSDP). In the absence of a similar system of controls for foods, development of a mechanism requiring dispensing by a pharmacist of any SPF which presented a risk if used inappropriately would merit consideration.
- It should be noted that where this is controlled; i.e., alcohol; the restriction is not dealt with through food standard setting.

Instances where access to special Purpose foods should not be considered

- There is no basis for applying access controls to these foods as it would then be seen as crossing the food-medicine interface. Appropriate labelling standards should ensure such products are consumed in line with sound dietary practice and as such they present no public health or food safety issues within the general population.
- Labelling clearly as to individuals that should not consume the food adequately manages potential access issues whilst ensuring availability to individuals with requirements for the particular food. Current labelling requirements adequately cover this.
- It is not necessary to place restrictions on access to this group of foods unless the ingredients pose a significant safety concern to the general population.
- There is a long history with regard to products currently falling under Section 2.9 of 'the Code' (infant formula, baby food, Toddler Milks, sports food, meal replacements etc.) being available in Grocery and Trade outlets and this has set an expectation with the consumer that they are able to access the products when required at their connivance. A grocery store has significantly longer opening hours than a pharmacy and most products should be available through these channels.
- No evidence of a failure in the market which would necessitate restriction to the currently available distribution channels.
- Products which are designed for 'normal' infants or less severe health conditions should be freely available, but appropriately labelled so that their intended use is clear and ensuring the accidental misuse of the product is minimised.
- Consumer choice and ready access to such foods is important to meet consumer needs and to avoid adding significant costs and inconvenience to consumers.
- It would be illogical to be more restrictive with foods covered by part 2.9 of the code, when for the most part they are merely rich in vitamins and protein.

9. If you believe there should be access controls, what sort of controls should these be and at what point should these controls be applied?

Analysis:

The majority of submitters noted that we should refer to their answer for question 8. They also noted that there is a need to address the access controls issue. However, there seems to be much debate about whether or not the controls are appropriate or if there needs to be changes. Many agree that while there should be access controls, they are already in place and

no further changes should occur.

Specific Comments:

- To ensure these products are in keeping with sound dietary practice, it may be necessary to apply some disqualifying criteria e.g. products high in sugar, saturated fat or sugar may be prevented from being marketed as a Special Purpose Food. Standard would incorporate compositional parameters for each specific food category. Current compositional constraints on such categories as formulated supplementary foods would be revisited as currently they do not adequately address dietary needs of the target population.
- The appropriate access controls for specific foods under the Standard should be determined in the assessment and development of the Standard in relation to the need to protect public health of the population and individual groups within the population. It is likely that these foods serving a special dietary purpose will be made available and only accessible to those population subgroups that may require them.
- Access controls further to labelling are not required
- The access controls should be determined for particular foods as part of the relevant standard as part of the risk management process. Some options include 'pharmacy only' 'under medical supervision' 'under health professional advice' and so on. However this would not be practical for all products, e.g. infant formulas.
- Some medical foods should only be available to out-patients to minimise the risk of inappropriate use by non-target consumers.
- The policy should note that access controls are appropriate. The Standard development and risk management process should define what those access controls are and provide for specific circumstances.
- It remains unclear if pharmacies are able to be required to supply foods only by prescription or equivalent. Nonetheless, medical foods such as "hospital-only" foods should only be available to consumers such as out-patients by limiting general access.
- It is not necessary to have access controls for formulated supplementary sports foods (with the exception of appropriate warning statements where necessary.
- There should be no access controls introduced as these will impose on Trade restrictions
- If controls on access over and above directions for use and labelling statements are seen to be appropriate for certain foods, it would question whether it is appropriate that these should be regulated as foods or more appropriately regulated under the TGA.
- It is suggested that no commercial advertisement be permitted for such medical products other than 'HCP' journals.

10. Can you identify any particular issues with the advertising/marketing of special purpose foods? Can you suggest any approaches to address these issues?

Analysis:

Several submitters noted that this should be more appropriately addressed through the National Review of Labelling or through a standards settings approach. However, most submitters noted that the advertising/marketing of special purpose foods should be addressed in this intent. Several submitters gave examples of weight loss products being advertised on TV as well as examples relating to products such as Milo and toddler milks. Advertising/marketing of medical and pharmacy food was also discussed by several

submitters.

Specific Comments:

- There are currently no issues with Formulated Supplementary Foods and Formulated Meal Replacers as these descriptions are not used in advertising and do not form the focus of any labelling or promotional information that is designed to describe the product to the end consumer.
- These products are more commonly promoted as general purpose foods to assist consumers determine where this food would fit into a normal diet, and in the comprehension of its overall health benefits.
- Identifying these products in the same light as general purpose foods assists consumers in disassociating such products with dietary supplements and therapeutic products.
- Policy guidance should provide clarity about the intent and purpose of each of these Special Purpose Foods, and should consider advertising and marketing of these foods in relation to a particular range or category of foods.
- There are specific examples of foods, e.g. Toddler Milks/Formulas which are outside the scope of the prescribed standard for infant formulas, where the current packaging, labelling, representation and display is questionable with respect to giving a false impression to the general public that implies a superior benefit as a general purpose food. They are promoted and marketed to the general public in the public arena, where their specific intent and purpose may be misunderstood or misrepresented, particularly by vulnerable groups including parents.
- Advertising/marketing of special purpose foods would be more appropriately addressed through the National Review of Labelling.
- Special purpose foods which are advertised and marketed to the general population have an unfair marketing advantage over similar foods which are not positioned as special purpose foods.
- Weight loss products are being widely advertised on TV. The Biggest Loser program has developed its own brand of weight loss products which are heavily advertised during the program. This is inappropriate marketing to an audience where many are teenagers and adolescents.
- Formulated supplementary foods for young children or toddler milks are marketed as Stage 3 after infant and carry-on formula (Stages 1 and 2). This implies that toddlers aged 1-3 have a specific physiological need for these products which is not true for the majority of these children. These three types of products are also placed in the same area on supermarket and pharmacy shelves to promote this stage relationship.
- The special purpose foods are exempt from the tighter provisions in other standards regarding the addition of, for example, vitamins and minerals.
- The main issue with advertising and marketing of Special Purpose Foods lies with the current lack of enforcement by the relevant States and Territories.
- Until there is reassurance and suitable actions to be confident that this is happening, there is no need to amend the current advertising/ marketing approach for Special Purpose Food. Once this issue has been adequately addressed, there may be a need to review the current permitted claims for this sector, particularly in relation to formulated supplementary sports foods.
- The advertising and promotion of products directly to children should not be permitted on the grounds that children are unable to interpret the context of special nutrition needs.

- The marketing of infant formula is restricted by the MAIF agreement in Australia and the voluntary NZIFMA Code of Practice in New Zealand. This also restricts the ability and context in which infant formula is promoted.
- Both agreements are based on the local interpretation of the World Health Organisation's International Code of Marketing of Breast-milk Substitutes ("WHO Code").
- Advertising/marketing provisions should be considered as part of the standards setting process, by FSANZ, and that may not be appropriate to consider these in the policy context.
- At present advertising is excessive with some Special Purpose Foods advertising to the general population using a number of points of influence, such as sponsorship deals, and advertising in various media including print and television.
- Given that many special purpose foods will sit right at the food-medicine interface, consistency with provisions regulating the advertising of therapeutic goods is essential, in terms of a level playing field and for helping to ensure their advertising/marketing is evidence based, and occurs in a socially responsible context.
- Advertising is an important method of communicating to groups that may benefit from consuming special purpose foods designed for their needs. An example of this would be the promotion of Up&Go to people who skip breakfast.
- Restrictions on the advertising of some special purpose foods, namely supplementary foods for young children, would create an anti-competitive distortion in the market for toddler/child foods.
- It is important that critical information is not confused with advertising and marketing.
- Therapeutic claims are not permitted in relation to foods. This provision places limits on any statements made in the advertising and marketing of foods intended for particular dietary uses.
- It is recommended that the particular dietary use of a food be stated on the label and in any associated advertising.
- In New Zealand the Fair Trading Act 1986 applies to the advertising and marketing of products including food products. The Fair Trading Act addresses misleading practices in respect to food products available for sale in New Zealand.
- Any Ministerial Council Guidelines for Part 2.9 should not prevent manufacturers developing and adopting codes of practice for the marketing of foods intended for particular dietary uses where appropriate.
- New Zealand recognises that the specific provisions in Standard 2.9.1 for the labelling of infant formula products, and the extension of those provisions under Standard 1.1.1, provide regulatory effect to parts of the World Health Organisation's International Code of Marketing of Breast-Milk Substitutes.

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

Analysis:

Several jurisdiction and Industry submissions raised concerns that Part 2.9 - Special Purpose Foods may undermine the Policy Guidelines for the fortification of foods with Vitamins and Minerals and the Policy Guideline for the addition of Substances other than Vitamins and Minerals if the Special Purpose Food is marketed to the general public. Further they raised issues relating to the need to address the addition of vitamins and minerals to food in Part 2.9.

Most Industry submissions raised issues in relation to the definition of 'at risk' populations and the definition for 'vulnerable' populations. Two industry submitters raised concerns over the impact that changes to Part 2.9 would have on trade and export conditions.

Specific Comments:

- The delineation between general population and 'at risk' groups is not clearly defined in current Policy Guidelines nor Regulation.
- 'At risk groups' do not include those whose circumstances other, than an existing health or physical condition, do not enable them to consume a balanced diet.
- If the Policy Guideline is to adopt its very narrow definition of 'at risk groups' i.e. those with a particular physical or physiological condition or disease/disorders, and infants (under 12 months), policies for foods targeted to the general population need to take into account groups not included in the Special Purpose Foods definition.
- This policy guidelines for 'Addition of Vitamins and Minerals to Foods' and 'Addition of Substances Other than Vitamins and Minerals' must ensure the dietary needs of 'at risk' groups within the general population are met, and are not stifled by the current constraints associated with fortification of general foods.
- As the intent of Special Purpose Foods is to separate them from the General Purpose Foods and regulate appropriately, clarity of intent and application of Standards is required for both manufactures and the general public.
- It is important that any policy guidance carefully considers the trade and export consequences of any changes to the standard.
- The use of such statements needs to be governed by the same evidence-based approach that the Special Purpose Food will deliver the claimed benefit, but clearly any restrictions on the provision of such claims that may be applied to general purpose foods should not apply to special purpose foods.
- The ability of food manufacturers to develop special purpose foods with higher than permitted general food nutrient fortification has the potential to undermine the integrity and intent of the policy guidance and regulation of fortification of foods with Vitamins and Minerals.
- There are instances where manufacturers will deliberately attempt to alter nutritional profiles to meet protein and energy criteria for special purpose foods with the intent of then being able to fortify these foods more generously than if they were to manufacture a general purpose food. The resulting food would then be marketed as a general purpose food (e.g., highly fortified yoghurt).
- It is important that foods that are standardised under Part 2.9 be able to communicate accurately and satisfactorily to consumers, to allow them to make informed choices and to understand that such products are specially developed to meet specific purposes. Consumer information is vital for the purchase and use of these products.

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

Analysis:

In maintaining clarity and consistent risk-based regulatory decisions at the food-medicine interface the submitters agreed that there is a need for more transparency and that there is a need to define those products that are to be regulated as foods and those that are more appropriately regulated by the Therapeutic Goods Administration (TGA). Further the jurisdictions noted that there should be a review process where the TGA has deemed a

product to be a food.

Nine industry submissions and public health submissions had issues regarding the consistency risk- based regulatory decisions where special purpose foods and the food-medicine interface had different serve sizes, where food has much higher serve sizes than medicines. Finally, there was concern around the clarity of special purpose foods that are not the same as medicinal products.

Specific Comments:

- There are likely to be significant issues raised in addressing regulation at the food-medicine interface.
- It is essential to maintain clarity in intent, definition, access and promotion.
- As the moment state and territory jurisdictions have limited ability to question the TGA determination of a product as a food when they feel that the determination is not an appropriate one. Many of these products are sports foods. There will continue to be issues around sports foods because of this and because of the NZ Supplemented Food Regulations.
- Special purpose foods could fulfil the current gap in the food-medicine interface.
- Providing food which is used for medicinal purposes can fulfil particular nutritional requirements and prevent the development of nutritional deficiencies in specific population sub groups. These opportunities are currently not enabled in the Code but could be captured well under the scope of Part 2.9.
- Where nutritional deficiency exists, delivering the nutrient through food has multiple benefits over giving the nutrient as a medicine. Multiple nutrient deficiencies often co-exist, along with lack of energy and macronutrients. A specially formulated food can be designed to meet these multiple needs, and also help establish appropriate eating habits and behaviour.
- Existing nutrient levels appropriate for Special Purpose Foods to adopt are published by the World Health Organisation (WHO). These are specific nutrient recommendations for alleviating risk of multiple micronutrient deficiency in specific age groups or in specific vulnerable population groups.
- Food is the ideal delivery vector for these nutrients but the maximum claimable amounts currently allowed under Part 2.9 of the Code do not match the maximum fortification levels set by WHO and fortification is also limited to specific age groups which do not cover all those most vulnerable.
- The policy intent needs to be reflective of a risk and evidence based, safe food surety, consistently administrated, interpreted and enforced regulatory system which also allows for industry innovation and development.
- This should be then clearly stated in legislation for reference.
- It is suggested that FSANZ work alongside the TGA in helping to clarify and reach a common understanding of a therapeutic claim. The fact that foods cannot currently make a therapeutic claim needs to be included into the Code for clarity.
- There is great concern with regards to the area of therapeutic claims for food products if the proposed Nutrition, Health and Related Claims policy is implemented and will provide comment as required.
- Currently in Australia food-type dietary supplements are not covered by the Food Standards Code or other regulation hence there is a large gap at the food-medicine interface.

- In Australia, foods permitted to add nutrients such as vitamins and minerals are permitted based on proportions of the Recommended Dietary Intake (RDI). This is not the case in NZ where a risk based approach using Upper Levels of safety are proposed for food-type dietary supplements providing a more effective food-medicine interface. It is recommend a similar approach for Foods for Special Purposes.
- No real concern about medicalising the food supply.
- Foods should not be restricted more so than medicines. Foods formulated in section 2.9 of 'the Code' address specific dietary nutrition needs or goals and are applicable to different population groups at different times throughout their lives. Medicines treat disease or conditions where foods maintain good health or general wellbeing.
- There is no question that food maintains good health and that medicine treats disease. Since health is the absence of disease, then food maintains the absence of disease. In that sense and that sense only can food be considered a medicine. It is important therefore that regulatory approaches are similar either side of the interface, and that there is a process that ensures a regular dialogue between the two agencies to ensure a common understanding. This will prevent companies from 'gaming' the regulation and regulations from unnecessarily disturbing the marketplace.
- It is desirable to provide a clear distinction between foods and medicine. The introduction of plant sterols into foods for the general population is an example where this has not been maintained. Controls on advertising, labelling and marketing to ensure Special Purpose Foods are only used by those with special needs which are not met by normal foods.
- The serve sizes of foods are generally much higher than medicines; these larger serve sizes make it difficult for an individual to consume hazardous amounts of nutrients in a sitting. This serve size differential can serve as a convenient differentiation between medicines and food.
- Special purpose foods are not medicinal products.
- These products meet dietary requirements such as providing total nutrition for infants whose mothers are unable or who have chosen (for whatever their reasons) to bottle feed.
- The ingredients are general foods and there are no medical conditions, nor any medicinal substances added to these products.
- Infant formulas produced under Clause 28 of Standard 2.9.1 for specific conditions do not have any medicinal substances. These products have the nutritional status modified. The ingredients are general foods and there are no medical conditions, nor any medicinal substances added to these products.
- The development of consistency in developing criteria for risk-based regulatory decisions at both the food and medicine interfaces is supported. This may extend to permitted claims and information on pack of the product.
- Scientific substantiation requirements for ingredient and labelling permissions should be consistent across the food-medicine interface whilst fostering innovation and product advancement. Consistency permits consumers to receive a consistent message and one that is not misleading.
- Have references in the Standard that exclude those compounds that are sold as medicines. (As in the New Zealand proposed Supplemented Food regulations).
- Exclude alcoholic products, kava and other intoxicating substances. These do not appear to be excluded at the moment.
- Continued recognition of the decision-making system operated by the TGA, FSANZ and

AQIS for determining the appropriate regulatory status of products at the food-medicine interface is necessary. The system needs to continue to evolve as necessary in the future to ensure consistent, risk-based decisions are made.

- Food standards, especially those for Special Purpose Foods, need to be drafted very carefully to ensure their scope does not adventitiously draw in therapeutic goods to be regulated as foods. Where the scope of a food standard is inappropriately broad, it leads to regulatory decisions which are not risk-based and decisions have to be made that are against common sense or conventional wisdom.
- Effective compliance/enforcement mechanisms are necessary on both sides of the food-medicine interface to help ensure consistency in post-market management of products purporting to be of different regulatory status than is required by legislation (i.e. therapeutic goods trying to be positioned as foods, or vice versa).

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

Analysis:

The majority of submitters do not directly discuss foods that are currently regulated under part 2.9 that should not be considered special purpose foods. Some industry submitters note that foods for special medical purposes should not be included under Part 2.9. However, jurisdictions are mainly concerned about special purpose foods that are marketed to the general population.

The majority of industry submitters note that many foods that start out as special purpose foods end up being promoted to the general population. Overall it is suggested that some foods to look at as not special purpose foods include sports foods, Milo style products and toddler milks. Below is further discussion.

Specific Comments:

- When special purpose foods market themselves to the general population as a supplement to the diet to account for poor eating habits and/or as a nutritious snack they can no longer be considered as special purpose foods i.e. foods high in saturated fat, sugar and sodium. Such foods would be considered to contribute to poor dietary practice even though they may have been formulated to address a specific dietary need. Some of these foods targeted at children are marketed as 'nutritious energy'. There is no need for extra energy foods in the diet of health children. Another food marketed at men as a nutritious snack provides 36g sugar in a 500mL service.
- Yes. There are foods that start out as Special Purpose Foods and end up being promoted to the general population, for example, Sports Drinks are promoted to the general population
- One particular product would appear to be a Special Purpose Food that is currently promoted to the general population as a "Nutritional or Functional Energy Drink". The ingredients are non-fat milk powder, water, sugar, malt extract, cocoa, milk fat…fortified with vitamins and minerals and served with milk.
- Some cereals, bars and chocolate-type drops should be considered for review.
- The Review should consider the interface with Standard 2.6.4 Non-alcoholic Formulated Carbonated Beverages.
- Infant foods should not be considered a special purpose food. Infant foods are currently not 'formulated to meet the particular dietary requirements of nutritionally vulnerable groups' but are formulated to be consumed as part of a normal diet. If the proposed

definition remains unchanged then it would be preferred for Standard 2.9.2 to be removed from Part 2.9 and placed elsewhere in Chapter 2 of the Code.

- The Australian infant food category consists of 147 non-cereal based food products and 13 cereal based foods. New Zealand infant food category contains 86 non-cereal based foods and 10 cereal based foods. Under the proposed definition of special purpose foods, over 240 products would not be compliant with Part 2.9.
- Other foods which present as general purpose foods are the toddles milks which are positioned within Standard 2.9.3 as formulated supplementary foods for young children aged 1-3 years. The original intent of these appears to be nutritional support for young children who are sick or convalescing or who have physiological reasons fail to grow and thrive. They are not required by healthy young children who are generally able to obtain their requirements from the family diet. The use of toddler milk for fussy eaters or to meet nutrient requirements is inconsistent with the dietary guidelines which encourage the consumption of a wide variety of foods. In addition it does not help to establish good eating habits.
- The Standards listed under Section 2.9 of 'the Code' and the products manufactured under this section of 'the Code' are appropriately designated.
- The current intent of section 2.9 'Special Purpose Foods' of 'the Code' is to capture all the products in one section which are designed to address certain nutrition needs or goals of different population groups. Products are marketed in a way to indicate suitability for the claimed nutrition purpose via the mandatory labelling statements. The current Standards in section 2.9 of 'the Code' include a wide variety of products targeted at groups with specific dietary needs that may not be met through normal dietary intake. This section of 'the Code' was developed to include a wide variety of food categories addressing many different nutrition goal and needs and population groups exclusively.
- The definition of special purpose foods should include products generally available as well as products with a specific population target as long as there is justification for the product to be marketed as a Special Purpose Food meeting specific consumer nutrition goals or needs.
- It is questioned how the proposed Foods for Special Medical Purposes can fit under a Food Standards Code when products have to be used under medical supervision for the dietary management of individuals with certain conditions or disease states. If it is a requirement for these to be used under medical supervision, this appears to be contrary to the objectives of FSANZ
- It is not considered that it is appropriate or efficient to have a list of foods that will be permitted to be included in Part 2.9. This would stifle future technological advances and put up a barrier to inclusion for appropriate foods.
- The Working Group is encouraged to consider the wider ramifications and further advances; and to look to a policy guide that will allow consumers access to new products into the future.
- International regulations on infant formula products and products for 'young children' (namely Codex and the EU). Addressing these differences will help harmonise Part 2.9 with international standards.

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

Analysis:

There were a wide variety of concerns raised here. The Jurisdictions raised issues regarding

lack of clarity, consumers being misled, and issues related to monitoring special purpose foods for compliance. The industry submissions discussed flexibility to meet market needs, and fortification of the food supply. The majority of submissions (both industry and government) noted that there are public health issues related to special purpose foods. Further discussion is below.

Specific Comments: Industry

- Industry requires flexibility in being able to supply products that meet market needs. Providing the objective related to provision of public health and safety is met, minimal regulatory constraints should be imposed on the composition of Special Purpose Foods. Thus one of the policy principles should be the provision of minimum regulation where there are no risks to public health.
- The current situation leads to unfair market advantage for manufacturers who position foods as special purpose foods but market them as general purpose foods.
- The Consultation document states that the intention is not to remove standards from the Code but to appropriately place them in the Code. However, on page 7 under Industry Impacts the document states that a cost to industry may be reformulation. There would be a cost to industry is some food products currently manufactured as special purposed foods need to reformulate if they were deemed to be general purpose foods.
- Industry should not be restricted in providing Special Purpose Foods specifically for nutritionally vulnerable populations.
- Manufacturers must be provided the opportunity to label and advertise these products in a way that ensures consumers are aware of the purpose the product and how it is to be used.
- Defining foods as having special purposes raises the issue of efficacy, which has not been addressed in the consultation paper. It is in keeping with the current direction of policy development that foods produced for a certain purpose should be required to have support that the food achieves its intended effect, particularly in vulnerable populations. Given the policy guideline for Part 2.9 is expected to overarch more specific policy guidelines where they exist (for example Infant Formula), it is appropriate that guidance on efficacy be broad. An example, based on other policy guidelines, might be: "The purpose of the food is articulated clearly by the manufacturer and the food is in a form consistent with delivering the stated purpose."
- FSANZ should be alerted to the importance of dairy exports of special purpose food applications to the national economies of Australia, and particularly New Zealand.
- Part 2.9 must be harmonised with international standards for milk-based infant formula products, toddler and pre-school milks, both in terms of definitions applied and standards specified, including vitamin and mineral fortification and optional ingredients permitted.
- Pragmatically, non-harmonisation limits the ability of local industry to register/gain approval to market special purpose products in export markets.
- There should be a review of Part 2.9 of the Code to ensure that the standards are up-to-date with current nutrition knowledge.

Consumers

- Consumers will need to readily differentiate special purpose foods from general foods. Regulations need to incorporate labelling provisions that provide clarity as to the type of food and the purpose for which it is intended.
- Terminology that holds little meaning for consumers such as 'formulated supplementary

food' should be replaced with descriptors that more clearly define the food for the consumer.

- It is difficult to comment due to the lack of clarity on the intent and concrete examples of foods that are categorized as Special Purpose Foods.
- It is particularly important that nutrition and diet quality are considered in the overall context, particularly in relation to the current obesity epidemic and rising prevalence of diet- related chronic diseases.
- Consumers may be misled regarding the role of these foods and consequently there is the possibility of misuse of foods e.g. high protein shakes for weight loss etc.
- There should be provision for improved communication to consumers to better identify the nature of the product and its intended use. For example, a formulated supplementary food which is designed to meet the needs of undernourished people with coeliac disease or diabetes cannot currently inform these consumers of its attributes.
- There is a need to provide a broader permission to provide relevant information to consumers and health professionals.
- The restriction on information for bottle feeding mothers is a concern. Consumers need to know how they might safely use the product, which products are right for their child and FSANZ and industry have a responsibility to clearly identify to consumers what they products are for, the nature of the product and its intended use. The current labelling restrictions on infant formula products do not meet this responsibility.
- One issue is the indiscriminate use of Special Purpose Foods which may be dangerous in high doses as a result of insufficient control measures in marketing and retail practice.
- Without an on-going food and nutrition monitoring and surveillance system it is not possible to produce either cross-section or serial data's on consumption to track the impact of these products on nutritional or health status in the contact of the total diet.
- It is difficult to assess the potential for harm from the cumulative effect of a range of highly fortified special purpose foods being consumed by the side public.
- Whilst the intention of the regulation of foods is for special target groups this does not happen in the market, especially not for Formulated Supplementary Foods. It is quite possible because of their minimal "change from normal", that a consumer ends up with a raft of normal looking food products and at the end of breakfast has consumed 100% RDI of a range of nutrients after consuming "normal" looking fortified cereal, fortified yoghurt and/or milk, fortified juice (under 1.3.2) and a piece of fortified toast with fortified yeast extract.

Public Health

- There is an increasing number and amount of vitamins and minerals and other substances being added to the general food supply.
- There is need to monitor the intake of both special purpose foods and fortified general purpose foods so that the cumulative effects intake of substances which are continually being added to the food supply can be better understood.
- The interaction of Nutrition, Health and Related Claims with Special Purpose Foods is an important consideration. The consultation paper states that the health claims policy guideline does apply to special purpose foods. This has potential to impact on foods developed for specific medical purposes so it is suggested that this issue should be considered carefully in developing the policy guidelines. Clarity on this issue will be particularly relevant to future work on the currently reserved Standard 2.9.5 – Medical Foods.

- It is recognised that FSANZ has a regulatory role but there should be appropriate guidelines through Departments of Health for vulnerable groups who would save money by not buying specialty products, when not needed.
- The dietary guidelines for Australian adults and dietary guideline for children and adolescents in Australian provide evidence based information about what the Australian population should at. These guidelines include recommendations for infants, young children, older Australians and those expending relatively high energy levels.
- The dietary guidelines do not provide recommendations for those with serious medical conditions or for the small number of healthy people with specialised nutritional requirements such as elite athletes.
- In this context the positioning and promotion of special purpose foods to meet the needs of the general population is inconsistent with the NHMRC dietary guidelines. This could undermine public health nutrition messages regarding a wide variety of foods and promote dietary patterns inconsistent with the dietary guidelines.
- Issues relevant to public health relate to the lack of monitoring of special purpose foods. There is an unknown cumulative effect of a range of highly fortified food for example with vitamins and minerals. This increases the risk of over-consumption which may have negative public health outcomes and be unnecessarily costly and misleading to the consumer.
- This could undermine public health nutrition messages regarding a wide variety of foods and promote dietary patterns inconstant with the dietary guidelines.
- This question refers directly to the definition and type of products to be Standardised under Part 2.9. It is not agreed with the proposed definition; and as these products are seen as being specially formulated to address specific dietary needs; it is our view that the regulations and processes for food standard setting and approvals are adequate for the Standardisation of Special Purpose Foods.

15. Which policy option do you prefer and what are your reasons for this preference?

Analysis:

Four submissions supported option one however, the majority (22) of submissions supported option two. The Jurisdictions all agreed that option two is the preferred option because it gives FSANZ clear guidance and promotes a more equitable marketplace. However, they did mention there is a need for the definition to be clarified.

Fifteen of the industry submissions supported option two because it seems to give FSANZ more direction. However, they also mentioned that the definition needed to be broadened as in its current state they would not support it. It was indicated that the definition needs to include nutritionally vulnerable groups. Public health organisations agreed that option two is the preferred option.

Four industry submissions supported option one because they believe standards are appropriately placed within Part 2.9 and development of a generic definition should be the responsibility of FSANZ. Specific reasons for each of the preferred options are below.

Specific Comments: Option 1

- The definition provided in this discussion paper is too narrow. This narrow definition would predispose a review of standards 2.9.3 & 2.9.4 even though no evidence has been provided that protection of public health and safety are at risk. Therefore the proposed policy is in conflict with the guiding principles as expressed in the discussion document on page 11.

- To 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.
- Standards are appropriately placed within Part 2.9, with definitions, and development and labelling requirements for particular Special Purpose Foods sufficiently outlined in each Standard.
- Development of a 'generic' definition for a Special Purpose Food should be the responsibility of Food Standards Australia New Zealand (FSANZ).
- A new Policy document is not required.
- Maintain Status Quo
- Other options would mean increased burden to industry in relabelling and possible re-formulation of Toddler milks, introduction of trade barriers with having non harmonised regulations, decrease in and possible withdrawal of innovative products and choice for those consumers wishing to provide nutritional benefits for their toddlers through the use of Toddler Milk. There may be possible nutritional deficiencies arising from the removal of choice for those toddlers.

Option 2

- The absence of policy guidelines for Special Purpose Foods may inhibit FSANZ from making appropriate changes to current standards and to the types of foods covered under the generic term 'Special Purpose Food'.
- There are deficiencies in current standards covered under Part 2.9 ANZFSC and therefore the preferred option would be Option 2 i.e. provide a food regulation policy context on the intent of Part 2.9. This will provide FSANZ with the necessary direction in which to progress a review of standards to be covered under Part 2.9 of Australia and New Zealand Food Standards Council.
- "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)". Possible accommodations include broadening the definition of vulnerable groups to include those 'who cannot or do not meet their dietary requirements due to lifestyle or life stage needs. This would include factors such activity levels (very low or very high), eating patterns and food format preferences, those at risk of physiological conditions or disease (e.g. osteoporosis).
- Providing another appropriate part in the code to capture products that currently are produced to meet the needs of vulnerable groups as outlined in the proposed possible solution.
- Regardless of solutions that may be implemented the issue of minimum kJ & protein requirements for formulated supplementary foods requires addressing. Often those that are not meeting vitamin and mineral requirements are in fact over consuming kJs and possibly protein.
- Policy intent must also consider the impact to export and trade for Australian Food Manufacturers and not unduly place them at disadvantage.
- It is important that policy and regulation does not hamper product innovation to meet specific dietary needs.
- Provision of a food regulation policy context on the intent of Part 2.9 will support consistent and clear enforcement across various jurisdictions.
- This will provide regulatory clarity, promote a more equitable marketplace for industry

and reduce the risks of possible negative health outcomes.

- The current Standard, particularly Standard 2.9.4, should be revised to provide consumers a wider range of products (and allow for innovation within industry) and more certainty about product suitability and performance.
- It is rejected that the assumption that some foods currently captured under Part 2.9 would need to be moved to general purpose foods if the definition would amended as proposed in the paper. This would result in increased burden to industry in relabelling and possible re- formulation of Toddle Milks, Formulated Supplementary Foods and Meal Replacements, introduction of trade barriers with having non-harmonised regulations, a decrease of innovative products on the market and of course decreased choice for consumers.
- An alternative approach to section 2.9 would be to have an overarching definition for Special Purpose Foods which would encompass foods specifically formulated to meet particular dietary requirements or specific nutrition goals or needs of a consumer. Consumers may have specific nutrition goals or Sports goals but not be at risk of being nutritionally vulnerable. Additional there could be a subset of section 2.9 which addresses foods intended for vulnerable populations.
- If this approach was progressed there would be minimal disruption to industry, potential for harmonisation with Food Type Dietary Supplement regulation in New Zealand and minimal impact with regard to re-formulation of foods manufactured according to eh current Standards in this section of 'the Code'.
- Rather than removing some of the foods from Part 2.9, it is suggested that some of the Foods in the general Food Standards Code may need to be shifted into it.
- Consider placing some of the more extensively fortified foods that have been placed 'ad hoc" elsewhere in the code in Part 2.9, in particular formulated caffeinated beverages (Part 2.6.4), electrolyte drinks and formulated beverage (Part 2.6.2) as they are fortified beyond normal food needs.
- Possibly shift kava (Part 2.6.3) as it sits on the food/medicine interface. Even some of the permissions of Part 1.3.2 are beyond what necessary for normal food. They should be scrutinised against the policy and the regulations modified if necessary.
- The intent of Part 2.9 of the Code is to provide standards that prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups. Requirements will be prescribed relative to the particular intended dietary use of the food.
- Remove Standard 2.9.2 from Part 2.9 and place this standard under a more appropriate part of the Code as it is inconsistent with the classification of special purpose foods.
- Any requirements for additional labelling information on special purpose foods are not supported.
- For the purposes of this part of the Code, physiological vulnerability arises only by reasons of life stage, physical disease, physical disorder and disability or convalescence.
- Ministerial Council Guidelines on the intent of Part 2.9 of the Code will provide clarity for the future development of standards for foods for particular dietary uses.
- Either Option 1, but with recognition that further Standard development in Part 2.9 is needed in the area of supplementary foods for children so the range of these types of products manufactured within Australasia for both local consumption and export is covered, or,
- Option 2 but with Policy guidance harmonised with that of other countries, and with clear

Policy guidance regarding the need to cover food applications made orphans by Policy guidance on Part 2.9. Provision must be made for coverage of these products in alternative Standards. The option selected should not increase burden to industry in relabelling and possible re formulation of Toddler Milks, introduction of trade barriers with having non harmonized regulations, decrease in and possible withdrawal of innovative products and choice for those consumers wishing to provide nutritional benefits for their toddlers through the use of Toddler Milk. There may be possible nutritional deficiencies arising from the removal of choice for those Toddlers. It is not support the proposed definition as per page 8 of the consultation paper

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.

Analysis:

Six jurisdiction submissions answered those questions. Of those six, all of these jurisdiction submissions have a consensus that there will be a cost to consumers because they may consume food that is not designed for them due to clever marketing campaigns. A lack of policy on marketing of special purpose foods is considered an issue. These jurisdictions indicated that the marketing of special purpose foods to the general public is sending out negative public health images. Eight industry submissions and three public health submissions discussed their concerns in regards to the relabelling of products. Four of these industry submissions quoted the FSANZ labelling change costs of $2500-$6000 per 'stock keeping unit' (SKU). Other costs concerns raised by industry included costs of reformulation of their products and the economic implementation with regards to imports and exports. No submission discussed the benefits.

Specific Comments:

- Issuing a policy document that contains a definition of a 'special purpose food, that can be seen as being very restrictive in relation to the types of foods to which it applies, may result in exclusion of several foods currently on the market, primarily those foods treated as 'Formulated Supplementary…' type foods. Unless these excluded foods can be accommodated within the provisions of a general food, they may be forced to be removed from the marketplace. This would impose a significant cost burden on industry and would reduce consumer choice in the area of fortified foods that are designed to meet specific dietary needs.
- The cost to the non-target audience of purchasing unnecessary Special Purpose Foods that are marketed to the general population, for example, Follow-on Formula and Toddler milks. Breast milk is recommended, however, if there is a special need to use infant formula, then the introduction of follow-on formulas and toddler milks increased the price of feeding an infant significantly. The cost of feeding an infant for 12 months ranged from approximately $750 for the cheapest formula compared to approximately $1800 for the most expensive product, a difference of over $1000. Toddler milks are $13 to $20 per 900 grams, considerably more expensive than dairy milk.
- Australian produced foods currently on the market both domestically and internationally for which there is significant consumer demand, may no longer be able to be produced. Aside from the economic implications for the domestic and export spheres, the removal of these products may lead to greater reliance on supplements where there is greater potential for mega dosing and adverse effects.
- The inappropriate marketing of special purpose foods undermines current recommendations and guidelines on health eating e.g. the Australian Guide to Healthy

Eating and the Australian Dietary Guidelines, and thus also undermines nutrition education efforts. This is a cost on time and resources for government and community organisations.

- The fact that some manufacturers develop special purpose foods and market them as general purpose foods indicates that there is lack of clarity around the intent of Part 2.9. This creates costs for industry and enforcement agencies in relation to new products whose development may be challenged by enforcement agencies. It also leads to unfair market advantage for manufacturers who position foods as special purpose foods but market them as general purpose foods.
- There may be the risk of negative public health impacts of the inappropriate consumption of special purpose foods by non-target populations.
- As there are no health and safety issues currently with Special Purpose Foods, it is unreasonable to discontinue their permission to exist.
- Changes to the definition of Special purpose Foods that would result in moving Formulated drinks, formulated Supplementary Foods, Meal Replacements or Sports Foods or Drinks into general foods would potentially damage the industry if significant reformulation is required.
- Under the current economic climate this could result in closing down factories, job losses, cancellation of Co-manufacturing contracts and the export of manufacturing operations overseas. There would also be an extreme loss of consumer confidence if products they are used to seeing on the market become further restricted, lose their innovation potential or disappear altogether.
- A change in the labelling and potential re-formulation of Special Purpose Foods could have large cost implication on industry. FSANZ has previously undertaken a study on labelling costs and estimates that a change to labelling will have an indicative cost of $2,500 - $5, 000 per SKU. The cost of requiring labelling changes and the complexity of the changes would easily exceed $1 million and of course the potential brand damage and loss of iconic brands like MILO on the market cannot possibly be estimated and it is expected to not be tolerated by consumers.
- Any changes to either formulation requirements or changes to labelling, even if allowing for more flexible labelling options, different to the current requirements have the potential to increase costs in the implementation period. The cost-benefit for changes need to be carefully considered in the current economic environment and it would also support extended implementation timings to tie in with other proposed changes.
- Lack of policy guidance will continue to create costs in relation to lack of clarity of the intent of products regulated under Part 2.9 of the Food Standards Code, in relation to enforcement action for government and product development that is challenged in relation to enforcement for industry.
- There is a risk of negative public health outcomes and associated costs if the current lack of clarity leads to inappropriate consumption of special purpose foods by non-target consumers.
- If option 2 was adopted, and this resulted in the review of Standards 2.9.3 & 2.9.4., all manufacturers of formulated meal replacements and supplementary foods plus formulated sports foods would have to tie up significant resource to defend products that already exist in the market place. In many cases these foods provide a healthier option to people who feel too rushed for a sit down breakfast, or who are trying to achieve particular sporting goals. Regulatory uncertainty during this time would reduce innovation. Without attractive convenient yet nutritious options, many Australians &

New Zealanders will continue to opt for junk food, which will continue to be freely available

- Adoption of the proposed definition of special purpose foods would mean that Toddler Milks are no longer covered under Part 2.9. The fate of toddler milks is unclear under this scenario, but could mean increased burden to industry in relabelling and possible re formulation of Toddlers Milks, additional trade barriers due to less harmonised regulations, decrease in and possible withdrawal of innovative products and choice for those consumers wishing to provide nutritional benefits for their toddlers through the use of Toddler Milk. There may be possible nutritional deficiencies arising from the removal of choice for those Toddlers.
- The cost to non-target population of purchasing unnecessary special purpose foods marketed to the general population and the potential health cost of inappropriate dietary intake. This would include the potential for increasing energy intake (because of their nature, special purpose foods are high in energy) in an already obese society

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.

Analysis:

Three jurisdictions and some public health organisations raised concerns that the focus on the

'intent' of Part 2.9 will limit the scope to address the issues of concern such as the access, marketing and advertising, addition of vitamins and minerals and other relevant policy guidance.

There appears to be a general preference among the manufactures particularly those that manufacture infant formulas minimum effective regulation and for a self-regulatory system for marketing and advertising. Both food industry and public health organisations are again placing emphasis on harmonisation with international regulatory approaches.

Specific Comments:

- To set the context for determining the intent of the Policy it would be useful to understand the extent of the current and future need for Special Purpose Foods, and if possible consider those 'grey' foods which appear to currently be marketed as 'general purpose foods' which may not be contributing to population health and well-being as the marketing would imply.
- Concerns around the focus on the 'intent' of Part 2.9 will limit the scope to address the issues of concern such as the access, marketing and advertising, addition of vitamins and minerals and other relevant policy guidance.
- Policy guidance should be developed to enable FSANZ to review the content of Part 2.9.
- Various sections within Standard 2.9 (for example, Formulated Meal Replacements and Formulated Supplementary Foods) have a maximum permitted claim per serve for various nutrients however there is often no maximum permitted quantity per serve for the ingredient.
- It is recommended that the maximum permitted claim requirements be removed as this could potentially mislead consumers and appears to serve no useful purpose (as outlined in Standard 2.9.3).
- There needs to be clarification around the regulatory position for probiotic foods. This could be addressed by including a statement into Standard 2.9.3 – Formulated Meal

Replacements and Formulated Supplementary Foods.

- There has been some concern around products being sold in juice bars. There needs to be further investigation as to whether some of the 'super foods' or 'functional foods' can be captured by Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods. This may assist with ensuring a level playing field for industry and provide consumers with appropriate products.
- The intent of this Policy Guideline is not to remove Standards from the Code. However it is strongly question the appropriate fit of Foods for Medical Purposes within Special Purpose Foods in the Food Standards Code, as it is apparent from many of the previously discussed issues around this area – such as restrictions on access, how the products can be advertised and how the products are to be used– that these are issues that are more appropriately managed under Therapeutic Goods Administration.
- Further consideration is requested of this area following feedback from this review as drafting policy guidance for proposed regulatory anomalies such Foods for Medical Purposes does not facilitate clear and consistent regulatory development into the future.
- The concept of "regulation commensurate with risk" be included in the scope of the policy as this is consistent with the COAG policy of minimum effective regulation that would flow from a policy consideration. The imposition of regulatory measures should also be consistent with an outcome-based approach rather than a mandatory prescriptive approach.
- Consideration should be given to the integration of regulation of specially formulated beverages and Special Purpose Foods.
- It is supported that the proposed definition for Special Purpose Foods, as promulgated by the Infant Formula Manufacturers Association of Australia.
- It is suggested an alternative definition should be: a special purpose food is defined as a food that is specially processed or formulated to meet specific dietary requirements or needs that may not be met through dietary intake of natural/general purpose foods.
- It is supported that the permission for labels on special purpose foods to use scientifically substantiated nutrition claims to assist consumers to make an informed choices.
- There has been failure of the current food regulatory system to appropriately regulate labelling of infant formula products (special purpose foods) under Standard 2.9.1, whereby amendments to the 'Code' were conducted in the absence of public consultation.
- In contrast, there is strong evidence that the self-regulation of the marketing of infant formula by industry is working, because of the very few number of breaches that have been found since the voluntary marketing agreements were put in place in Australia and New Zealand.
- The current food regulatory system has restricted exporters' ability to service international markets due to non-harmonisation of definitions and standards with international standards.
- The proposed definition of Special Purpose Foods may not adequately capture the inclusion of Toddler Milks (currently regulated under Standard 2.9.3 – Formulated Supplementary Food for Young Children). Toddlers (aged 1-3 years) could still be regarded as a 'vulnerable' population due to the importance of nutrition during this period of growth and development. It is suggested that 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 may not be able to 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) - Toddlers (1-3 years)"

- Consideration should be given to harmonisation with international regulatory approaches in order to minimize international trade barriers, and to foster the availability of innovative products that are available outside of Australia / NZ to the Australian / NZ consumers.
- Considerable impact with regard to the compositional requirements of these foods and significant barriers to Trade would be created through pursuing an inappropriate non harmonised definition.
- Labelling on special purpose foods to allow the use of scientifically substantiated nutrition and health claims. This will bridge the information gap that currently exists in standard 2.9.1 and enable consumers to make an informed choice.
- Products should feature a clearly legible descriptor as to its supplemented nature on the principal display panel, not just somewhere on the label. A typical consumer only takes a few seconds to decide which variant to buy and is rarely going to read the back.
- To set the context for determining the intent of the Policy it would be useful to understand the extent of the current and future need for special purpose foods. This would require effective monitoring so that future reviews would be more evidence based.
- In the proposed draft policy principles, under the definition of special purpose foods, there are a number of key elements for the proposed definition of special purpose foods.
- The second point of these key elements raises the issue of nutritional vulnerability which claims to arise from situations where people are unable to meet their normal dietary requirements. Unable is an inappropriate word in this context as it would include issues of food security and instances where people are disinclined to eat a healthy diet. It is important to then clarify what the actual inability stems from.
- Also in the proposed draft policy principles, the second point under higher order principles makes reference to any written policy guidelines formulated by the food regulation council. Any relevant food and nutrition policy e.g. Dietary Guidelines, should also be included as a matter of course.

18. Additional Comments

Analysis:

Of the thirty two submissions, only thirteen submitters made additional comments. Of these, four were from jurisdictions, eight were from industry and one was from a public health organisation. Three jurisdiction submissions noted that it would be useful to monitor the consumption of some special purpose foods. Four industry and one public health submissions were concerned about the time given for review of all submissions by interested parties. Other additional comments are listed below.

Specific Comments:

- It would be useful to monitor the consumption of some special purpose foods. This information could be collected as part of a consumer survey to study the types of food consumed, why they are consumed and by whom. Some information may be valuable for national nutrition surveys. However these do not usually cover young children less than 2 years. This would help to establish the extent of consumption of foods that are marketed as general purpose foods and assist with establishing appropriate access controls.
- It would have been useful to include information about the type of products intended to be included in Part 2.9 could be further described.

- The current approach and inclusion of a restrictive definition in policy guidance do not allow for sufficient consideration of the foods currently covered by Part 2.9.
- Given the different risks and purposes associated with the foods currently in Part 2.9, it may be appropriate that they are dealt with differently within Part 2.9 or within other parts of the Code, and through the standards development process.
- However both foods specially formulated for vulnerable populations and foods specially formulated for specific purposes for the general population need to be recognised in the policy guidelines, so that appropriate ways of dealing with both of these can be developed.
- Preferred approach: That definition is restricted to the confines of the Code; and that both categories of special purpose foods are considered concurrently so that all impacts, including regulatory impacts, are transparent to consumers, government and industry groups.
- There are concerns that there seems to be limited time for a review of all submissions by interested parties.
- It is urged to FRSC to ensure that this policy development provides a best practice policy guideline for use into the future. Such a guideline will anticipate technological developments to allow for the improvement of the food supply. A best practice policy statement will not hinder the adoption of new ingredients, foods or technological advancements.
- The policy should include a statement in regards to consistent application of the latest information on safe and appropriate levels of vitamins and minerals. When compared the permitted claim levels under standard 2.9.3 and 2.9.4. (adult foods only). Whilst most levels permitted for a one day quantity for sports foods equal those in 4 servings of a supplementary food or meal replacement (quite a reasonable assumption) there are many different ratios that make less sense on the face of it. This may well be historic rather than anything else. See below. Another possible anomaly is that Vitamin K is only permitted in meal replacements (reasoning unknown). Modelling of diets during the review process is recommended.
- Although it is not part of the scope of this document, Part 2.9 of the Code should be fully reviewed and updated accordingly to meet current population nutritional requirements and fortification levels.