Attachment 10

Summary of Submissions to the Draft Assessment Report
Application A470 – Formulated Beverages

FSANZ received 30 submissions in response to the Draft Assessment Report on Application A470 – Formulated Beverages, during the 6-week public consultation period of 25 May to 6 July 2005. Two late submissions were also received. A summary of submitter comments is provided in the table below.

Three regulatory options were presented in the Draft Assessment Report:

- Option 1 – Maintain *status quo* i.e. no explicit permissions for formulated beverages in the Code;
- Option 2 – Amend the Code to permit the addition of a defined set of vitamins and minerals to formulated beverages excluding cordials, in addition to a restriction on the total sugar content; and
- Option 3 – Amend the Code to permit the addition of vitamins and minerals to formulated beverages and cordials as requested by the Applicant without any other specific compositional requirements.

No.	Submitter	Submission Comments
1	**Auckland Regional Public Health Service** Kate Sladden/ Christine Cook	**Support Option 1** **Regulatory options** • Advise support for Option 1 is based on the understanding that the repeal of the New Zealand *Dietary Supplements Regulations 1985* (NZDSR) proceeds. • Argue formulated beverages should not be permitted and that the existing 'loophole' that allows formulated beverages should be closed. • Acknowledge the disadvantages Australian beverage manufacturers are experiencing with importation of formulated beverages from New Zealand under the Trans Tasman Mutual Recognition Arrangement (TTMRA). Note however in-principle agreement from New Zealand government to repeal food aspects of the NZDSR. Therefore believe the 'loop-hole' should not be used as the basis for developing a new standard for formulated beverages in the *Australia New Zealand Food Standards Code* (the Code).

No.	Submitter	Submission Comments
		Fortification policy guideline *Health benefit/deficiency* • Argue formulated beverages do not appear to satisfactorily meet criteria for a 'deficiency' or 'health benefit'. o Highlight that neither the New Zealand Children's Nutrition Survey nor the 1997 National Nutrition Survey show any appreciable risk of inadequate vitamin C intake. Also note there is no conclusive 'scientific evidence' that supplementation with vitamin C delivers a 'health benefit'. *Appropriateness of food vehicle* • Do not believe fortification of foods/beverages that are fundamentally nutritionally poor is appropriate. Argue such an approach adds to consumer confusion and encourages consumption of unhealthy food/beverage choices. <u>Reference quantity/serving size</u> • Suggest the 600 ml reference quantity request is an example of 'super sizing'. • Argue the justification for the large serving size (i.e. thirst quenching/to aid hydration) is unconvincing as water is freely available in communities and there is no evidence that the population is dehydrated. **Total sugar and energy content of formulated beverages** *Risk of overweight and obesity* • Note there is extensive evidence that sugary drinks play a role in promoting weight gain in children (Taylor et al 2005). o Appreciate this risk has been acknowledged by FSANZ by proposing to restrict the amount of sugar in formulated beverages to 7.5 g/100 ml (which equates to 45 g sugar/600 ml reference quantity). However advise there is a high probability consumers will focus on the added vitamins and minerals and be unaware they are consuming a large quantity of sugar i.e. more than from a can of soft drink. • Report consumers of formulated beverages are unaware of their energy content and the resulting potential for passive over-consumption. • Recommend a further restriction on the amount of sugar in formulated beverages to not greater than 3 g/100 ml as part of Option 2, should the Application proceed,. <u>Dental health</u> • Note the 600 ml serving size compared to other standard serving sizes (355 ml can, 250 ml tetra pack) increases the risk to dental health as it may be consumed over a longer period of time.

No.	Submitter	Submission Comments
		Labelling *Vitamin and mineral content claims* • Recommend claims related to vitamin and mineral content be restricted to inclusion of contents in the nutrition information panel (NIP) only as part of Option 2, should the Application proceed. **Potential to mislead consumers** • Disagree that Option 2 will prevent consumers from being misled regarding the nutritional quality of the product. o Believe FSANZ's 2003 consumer research, which supports this statement, is contentious. • Suggest the fact that formulated beverages are being fortified with vitamins that the majority of the population already consume in adequate amounts is in itself misleading as it implies dietary deficiency. • Believe it is conceivable that consumers may believe that a beverage fortified with a wide array of vitamins could be used as a substitute for nutrient rich foods such as vegetables and fruit. **Risk management** • State that vitamin C should not be treated as a separate case. • Recommend that if the Application proceeds, risk management strategies to protect vulnerable individuals from excessive intake of micronutrients should be explicit, as part of Option 2. **References** • Taylor R, Scragg R, Quigley R. Do sugary drinks contribute to obesity in children? A report prepared by the Scientific Committee of the Agencies for Nutrition Action. Wellington; ANA: 2005.

No.	Submitter	Submission Comments
2	**Australian Consumers Association (ACA)** Clare Hughes	**Do not support any option** **General comments** • Consider this Application to be about trade issues not about improving public health. • Consider the assessment of this Application has not been consistent with FSANZ's primary objectives. • Acknowledge FSANZ must have regard to trade issues but comment the recommendations are driven by trade interests and only has 'regard to' public health and safety and consumer objectives that should be the basis for assessment. • Appreciate the current inconsistency between the Australian and New Zealand industries for formulated beverages needs to be rectified, however do not believe the current recommendations will achieve this. • Consider the assessment report highlights formulated beverages are more to do with creating a marketing opportunity for manufacturers than a strategic public health strategy to address specific vitamin and mineral deficiencies. **Fortification policy guideline** • Consider the proposed sugar restriction does not adequately address the specific principle of voluntary fortification that 'permissions to fortify should not promote increased consumption of foods high in salt, sugar or fat'. • Note the approach seems inconsistent and perhaps counterproductive with the health promotion message to consume two serves of fruit and five serves of vegetables a day, as consumers may be encouraged to drink formulated beverages as an alternative to fruit and vegetables. *Appropriateness of food vehicle* • Consider formulated beverages are not an appropriate vehicle for delivering vitamins and minerals. o formulated beverages are high in sugar and do not provide the dietary fibre and other beneficial phytonutrients present in fruit and vegetables. • Believe consumers can already meet their daily vitamin and mineral needs through consumption of a balanced diet. • Believe formulated beverages should not be seen as a significant source of vitamins and minerals. If a consumer's diet is already poor, then consuming a formulated beverage will not be sufficient to improve it. Conversely, if a consumers diet is adequate there is no need to consume a formulated beverage. **Target group** • Consider formulated beverages will also have appeal to younger consumers (<16 years) who are attracted by their fashionable image. • Argue it is inevitable that marketing of these beverages will appeal to children – bright colours associated with the labelling, packaging and the beverage itself.

No.	Submitter	Submission Comments
		Composition of formulated beverages *Artificial sweeteners* • Consider it likely that manufacturers will use artificial sweeteners to sweeten formulated beverages and still meet the sugar restrictions. • Suggest that the implications of increased consumption of artificial sweeteners be reconsidered in light of the intense sweetener survey FSANZ completed in 2003. <u>Electrolytes</u> • Believe that if products are marketed as sports waters or using words like hydration and fluid replacement, then there must be appropriate levels of electrolytes, consistent with levels in sports drinks. **Risk assessment** • Believe dietary inadequacy of the target population should be assessed, rather than determining if there is deficiency in the general population. For example, it is irrelevant if elderly are deficient in particular vitamins or minerals, as they are not likely to be the target market for formulated beverages. *Vitamins and minerals* • Do not support the permissions for the addition of beta-carotene, and vitamins D and E, as there is sufficient risk of adverse health effects for these fat-soluble nutrients to be rejected. • Believe the risks associated with the addition of iron and iodine for sensitive subpopulations have not been appropriately managed, and believe FSANZ should not permit the addition of iron at the levels proposed, if at all. o Note that while individuals may not be diagnosed with haemochromatosis until sufficient iron has accumulated, regular consumption of formulated beverages may lead to earlier onset of adverse symptoms. *Dietary modelling* • Consider that in the 10 years since the 1995 NNS, the food supply has changed dramatically, so much so that it is likely that the data is no longer representative of Australian's consumption patterns. **Total sugar and energy content** • Support principle of restricting sugar content of formulated beverages. However, not satisfied that the restriction is sufficiently low given the large 600 ml serving size. • Highlight the Dietary Guidelines advise 'consume only moderate amounts of sugars and foods containing sugars'. Note if a consumer were to drink one 600 ml serve of a formulated beverage they would be consuming 45g of sugar which is more than the intake of sugar from one can of soft drink; for example a 375 ml can of Coca Cola provides 39.8 g sugar. • Consider that to suggest that it is appropriate for a consumer to get 50% of one day's sugar intake from one beverage whose primary purpose is hydration is an underestimation of the fact that consumers are likely to consume far more that the remaining 50% from their meals, snacks and other beverages.

No.	Submitter	Submission Comments
		Risk of overweight and obesity • Note sugary beverages such as soft drinks have been associated with increased energy intake, which in turn is associated with obesity. • Believe the risk of overweight and obesity has not been given adequate consideration, as consumption of formulated beverages may contribute to excess total energy consumption. • Believe the restriction to 50% daily intake reference value is not sufficient to minimise the likelihood of formulated beverages contributing to excess energy consumption, which in turn is linked to overweight and obesity. **Labelling** • Suggest that not requiring additional labelling requirements for these products shows lack of attention to the need to provide consumers with information that will allow them to manage any potential health risk associated with consumption, or assess their suitability for children and pregnant women. • As the marketing of these products is influencing consumer choice, ACA believe formulated beverages should carry advisory statements such as: o 'formulated beverages may only be of assistance if your dietary intake of vitamins and minerals is inadequate' (noting however that it is unlikely that the vitamins and minerals in formulated beverages will be sufficient to make the total diet adequate); o 'consuming formulated beverages does not replace a healthy diet'; o 'this beverage should not be considered as equivalent to a serve of fruit or vegetables'; and/or o 'not suitable for children' where levels of vitamins and minerals in a formulated beverages present a health risk for children. • Believe there must be statements advising the presence of artificial sweetener and the impact on over-consumption on health. **Potential to mislead consumers** • Consider that FSANZ should not underestimate the extent to which consumer demand for formulated beverages has been perpetuated by the marketing of these products. The very mention of the presence of vitamins and minerals creates the impression that it is a 'healthy' product. • Suggest parents may purchase these products for their children because they think they are a healthier alternative to fruit juice, water and soft drink because of the added vitamins and minerals. **Risk management** • In some areas, do not agree with FSANZ conclusions to the lack of public health risks or with the recommended risk management approach or lack thereof. • Believe FSANZ has not adequately addressed the identified risks and need to put safeguards in place to protect at risk consumers, particularly children. For example, use of children's RDI rather than adults and no permissions given if addition of a vitamin or minerals is found to present a risk for children.

No.	Submitter	Submission Comments
		• Believe voluntary fortification with iodine and folate should not be permitted if there is mandatory folate and iodine fortification. Similarly, if in the future, mandatory fortification is extended to other nutrients this must results in a removal of permissions to voluntarily fortify with that nutrient. o If both voluntary and mandatory fortification of iodine and folate were allowed, the approach will become less controlled and it will be more difficult to determine appropriate levels for mandatory fortification as the extent of voluntary fortification may vary and lead to over consumption of these nutrients. o It will also undermine the public health strategy associated with mandatory fortification. **Monitoring and surveillance** • Highlight that this Application provides another reason why consumption data needs to be updated with commitment to ongoing monitoring and surveillance. • Note it will be particularly important to monitor the impact of formulated beverages on consumption of vitamins and minerals. **Impact analysis** • Concerned that the recommendations will not improve the situation for consumers, if New Zealand manufacturers continue to have a choice between producing to the NZDSR or the FSANZ standard. **Other comments** *Formulated beverage products* • Comment ACA are aware of three other Solis beverages with added vitamins and minerals that would be classified as formulated beverages, in addition to the two Solis products identified in the DAR. o Suggest these products should be within the scope of the Application noting they contain medicinal herbs which are being considered by the Food Regulation Standing Committee.

No.	Submitter	Submission Comments
3	**Australian Food and Grocery Council (AFGC)** Kim Leighton	**Support modified Option 2** **General comments** • Fully endorse the government policy for minimum effective regulation. • Endorse the objectives of FSANZ in the protection of public health and safety, and the use of adequate labelling to inform consumers. **Regulatory options** <u>Option 1</u> • Reject Option 1 as the current standard fails to address inequity in Australia-New Zealand trade, as it prohibits Australian manufacturers from manufacturing a product for which there is public demand and need and thus prohibits Australian manufacturers from competing. <u>Option 2</u> • Support a modified Option 2, as AFGC disputes the risk assessment for the seven requested vitamins and minerals that have not been allowed. • Consider the proposed approach has regard to promoting fair-trading in food and promoting consistency between domestic and international food standards. • Consider a formulated beverage standard would enable the New Zealand Government to repeal the *New Zealand Dietary Supplements Regulations* (1985). **Fortification policy guideline** <u>Health benefit/deficiency</u> • Support the Policy Guideline regarding voluntary fortification, and note FSANZ should have regard to the specific order policy principles in considering this application: o consider formulated beverages fortified to a minimum level of 25% RDI per serve will deliver a *health benefit* both collectively and individually for each of the 16 vitamins and minerals proposed; and o believe it could be argued that the intended purpose of the Application is in response to the specific needs *(deficiency or inadequate intake)* of a target population, providing for people who use such foods due to lifestyle needs or other special dietary requirements. **Definition** • Consider the definition of formulated beverages to be restricted in that it does not provide opportunity for the further development of formulated foods nor does it allow for the future development of a standard that is more closely aligned with the NZDSR.

No.	Submitter	Submission Comments
		Composition of formulated beverages Percent fruit juice • Note it would be inconsistent with the formulated beverages definition if the juice content were greater than 50%. • Disagree with the proposition that the fruit juice content needs to be limited to 24% to prevent confusion with fruit drinks and fruit juice that has added vitamins for the purpose of restoration. • Consider that enforcement agencies and consumers would be able to distinguish between the two, and that the restriction is unnecessarily restrictive and inconsistent with the principal of minimum effective regulation. Exclusion of cordial • Agree in principal that cordials are not an appropriate vehicle for fortification due to their energy content and the potential risk that use may lead to conflict with nutritional guidelines supporting the consumption of water. o Note however concerns that this conclusion is not based on a demonstrated causal relationship, rather it is implied from data showing children drink cordial. Suggest that this does not demonstrate that if parents had the opportunity to purchase fortified cordial that children would drink less water. **Reference quantity/serving size** • Recommend further consideration be given regarding the 600 ml reference quantity on the following basis: o varying volume of formulated beverages in the current market; o reference quantities for other fortified beverages (modified milk, fruit and vegetable juices) currently use a 200 ml reference quantity; o a 600 ml quantity may be too large for some groups of the population; and o a reference quantity of 500 ml would make it more convenient for consumers to calculate their intake, being half a litre. *Total sugar and energy content of formulated beverages* • Consider the issue of obesity needs to be considered in relation to both the total energy content of the product and the activity of the intended population. • Note there is precedence for regulating the presence of carbohydrate and placing requirements on the amount of energy derived from protein in the Formulated Supplementary Sports Food Standard. • Raise concerns regarding the practicality of the sugar restriction, as there is potential for variation in fruit sugars in fruit juices and differences in the sugar composition. • Recommend an alternative approach be considered of restricting the total energy in the product, and providing for the use of artificial sweeteners. • Recommend the limitation on sugar content should not apply, as the target population is physically active and in need of rehydration and/or energy, rather than the sedentary population where total energy consumption is a contributing factor to weight gain.

No.	Submitter	Submission Comments
		Risk assessment **Vitamin and minerals** • Support the findings of the DAR risk assessment for the 16 vitamins and minerals proposed under Option 2. • Reject conclusions excluding permissions for the following seven vitamins and minerals – vitamin A, copper, iodine[1], iron[1], molybdenum, manganese and zinc. • Recommend reconsideration of the evidence of risk and potential benefits in relation to six of these vitamins and minerals (excluding molybdenum) including: o vitamin A (187.5µg/600 ml) – note the evidence based on the tolerable upper intake level recommended by the European Commission indicates no population group will exceed the safe upper level; o copper (0.75 mg/600 ml) – note supported by dietary modelling and clinical advice to *at risk* individuals does not include restriction of copper intake; o iodine (37.5µg/600 ml) – note supported by dietary modelling and predicted increase is modest and unlikely to reach levels associated with adverse effects in *at risk* populations; o iron (3 mg/600 ml) – note iron poses no safety concerns for healthy population, will benefit individuals at risk of deficiency, and for individuals with a genetic disorder, clinical guidelines do not recommend restriction of iron intake from food. o manganese – recommend FSANZ reconsider the process of risk assessment of manganese. Also note validity of data on intake is uncertain; o zinc – recommend inclusion of zinc provided it is in combination with copper. Note the zinc:copper ration eliminates the risk of copper deficiency produced by zinc supplementation. Also recommend FSANZ include the zinc:copper ratio in the dietary modelling. • Acknowledge there is insufficient data on human trials and clinical studies on the dietary intakes of molybdenum yet note it is being used in clinical trials for the treatment of metastatic cancer and Wilson's disease. Note there is no reported incidence of it causing ill health at low dose. Suggest there is not reason to exclude the use of low doses based either on ill effect or lack of evidence of a health benefit. • Recommend further consideration of the lack of any evidence that consumers are experiencing adverse health or nutritional outcomes from exposure to these vitamins and minerals. <u>Dietary modelling</u> • Concerned that the use of dietary modelling and food composition data, based on UK and USA data, is only a rough approximation and does not accurately reflect Australian/New Zealand populations or food supply. **Impact analysis** • Consider providing formulated beverages in the marketplace may be of benefit to consumers who have allergies to milk or soy,

[1] Note the proposed recommendation in the DAR included permissions for both iodine and iron.

No.	Submitter	Submission Comments
		providing increased informed choice for consumers. ***Other comments*** Drafting • Recommend the proposed drafting be reconsidered as it is inflexible and does not achieve the objectives of an outcomes based standard. Furthermore it does not provide opportunity for further development of formulated foods, nor for the rationalisation of the Code. Structure of Standard • Argue against the development of a formulated beverage permission under the non-alcoholic beverages standard 2.6. • Recommend the development of a new commodity standard under Chapter 2 with broad overarching requirements that reflect the principles and outcomes of formulated foods, such as explicit prohibition of additions to alcohol and specifying the maximum levels of total sugar or fat permitted. • Suggest water-based flavoured beverages could form a subcategory of this new standard, and formulated sports foods, electrolyte drinks and energy drinks could also be included as subcategories. • The above would allow other forms of formulated products to be developed in the future, e.g. beverages based on infusions of herbs or tea, or use of modified milk, soy or coconut milk. • Suggest the use of food additives be made a subcategory under a new standard for formulated foods, or alternatively as a category under non-alcoholic drinks, rather than making it a subcategory of water-based flavoured drinks.
4	**Australian Fruit Juice Association (AFJA)** Rolf Schufft	**Support modified Option 2** ***General comments*** • Support the Australian Beverages Council Ltd Application with the following provisions: o fruit juice and fruit drink be included as part of the non-alcoholic beverages represented in the Application; and o the maximum vitamin C (ascorbic acid) that may be claimed in these products is 50% RDI based on 200 ml serving. - Note under Standard 1.3.2 fruit juices are allowed only 120 mg vitamin C per serve which is equivalent to 300% RDI per 200 ml serve. Whereas the quantity of vitamin C contained in fruit drinks is dependent on the fruit juice content of the drink. Advise in the case of a fruit drink with 24% fruit content (the proposed maximum for formulated beverages) this would equate to 72% RDI per serve. Believe the 100% RDI claim is inappropriate as most formulated beverages will have juice contents less than 24%.

No.	Submitter	Submission Comments
5	**Coles Myer Ltd** Helen Mair	***<u>Option 1 with an amendment, but modified Option 2 next preferred option</u>*** **Regulatory options** <u>Option 1</u> • Suggest Option 1, in conjunction with an amendment to the TTMRA to prevent entry of formulated beverages into Australia, may be a viable choice. Note however a further review of the NZDSR and the Code would be required in unison to move towards a joint food standards system. o Propose that this would address fair trade issues and would not be likely to prevent the improvement of nutritional status for those that are deficient. *Option 2* • Support Option 2 however note further risk assessment is required. Also suggest additional provisions should apply. o Consider such changes to the Code would only provide more clarity and enable the application of the Code to be more feasible and manageable for retailers, manufacturers and enforcers. **Target group** • Suggest those subpopulations identified to be deficient in particular nutrients are not likely to find formulated beverages appealing e.g. vitamin D deficient dark-skinned veiled women or the elderly. • Propose formulated beverages tend to appeal to the 'fashionably health conscious' who are influenced in their beliefs by the media, peer groups, celebrities, marketing etc which often provide information that is incorrect and/or misleading. **Definition** • Propose the inclusion of juice and milk under the definition of formulated beverages to prevent these products being perceived as nutritionally inferior which is not in line with the Dietary Guidelines. **Composition of formulated beverages** • Propose the following provisions be considered in the progression of Option 2: o limit the number of added vitamins/minerals for any one product to a defined number i.e. 4-6 from the allowable list; o include biologically active substances/non-culinary herbs on a risk analysis basis; o exclude permission for caffeine[1]; o exclude permission for carbon dioxide[2] unless there is a restriction on kilojoule, sodium and sugar content of final product in line with the Dietary Guidelines. Note this would be acceptable from a 'minimise harm' perspective, as an alternative to soft drinks;

[1] The Applicant is not requesting caffeine or carbon dioxide as an ingredient.

No.	Submitter	Submission Comments
		○ restrict the kilojoule, sugar[1] and sodium content of final product in line with the Dietary Guidelines. ○ include of soluble fibre for enhanced calcium uptake and improve fibre consumption levels of the population. Percent fruit juice • Note it is unlikely consumers will be able to distinguish between 24 and 25% fruit juice as constituting different categories of product. **Risk assessment** Vitamins and minerals • Recommend a review of the inclusion of vitamins and minerals with known toxicity levels in the list of allowable additions noting that formulated beverages will most appeal to those that are likely to perceive the inclusion as 'more is better' who are likely to already be taking a variety of supplementary products and/or actively seeking other concentrated sources to consume - therefore skewing the balance of nutrient intake with possible adverse consequences. • Caution that adult consumers to which formulated beverages greatly appeal lack knowledge of potential adverse reactions/toxicity from vitamins and minerals and are less likely to be suffering from deficiency and more likely to already be taking supplements. ○ Question the inclusion of selenium, iron which have toxic levels or cause adverse outcomes e.g. vitamin E can interfere with vitamin K activity, based on deficiencies identified within the population. • Highlight the importance of considering adverse outcomes from certain vitamin and mineral interactions with drugs (for example vitamin E, C, D iron, magnesium, and zinc with warfarin, vitamin B6 and folic acid with Phenobarbital, vitamin C with amphetamines) when assessing the inclusion of non-culinary herbs/ biologically active substances, which are also associated with drug interactions and medical precautions. • Believe the level of vitamin C (100%RDI) may pose a potential issue in relation to cumulation of vitamin C from different sources including other foods and beverages in addition to supplements often at high doses. • Note excessive vitamin C consumption has been associated with kidney stones, osmotic diarrhoea and rebound scurvy (not only in adults but also in infants born to mothers taking high doses of vitamin C). Furthermore, osmotic diarrhoea from vitamin C may possibly be one of the causes of irritable bowel syndrome in the Australian population. ***Total sugar and energy content of formulated beverages*** • Suggest the sweetness of the beverage not just the sugar and kilojoule content needs consideration in relation to obesity as constant consumption of sweet foods conditions the palate to have a preference for sweet foods thereby potentially encouraging poor food selection choices. **Labelling** • Do not support the application of generic labelling requirements.

[1] Note a limit of total sugar was recommended as part of the DAR.

No.	Submitter	Submission Comments
		• Support the inclusion of warning statements and the requirement to clearly indicate on the front of pack that the product is fortified with nutrients. o Suggest the inclusion of warning statements for children and pregnancy as products are likely to appeal to both these groups; or alternatively reduce the quantity of permitted vitamins and minerals to ensure safety of these groups or legislate formulated beverages within the supplementary foods/sports foods standard so warning statements apply. o Recommend requirement for clear indication of added vitamins/ minerals/biologically active substances on the front of the pack to prevent inadvertent consumption of the product by those that have a medical condition that would be compromised by the consumption of the product, and those on medications that may be adversely effected by consumption of the product. Comment that the medical profession are not always savvy about food products and consequently are not likely to advise relevant patients to avoid these products. o Recommend that it is made clear to manufacturers that limits and amounts declared on the label relate to the finished product at the end of shelf-life not the amount added to cover nutrient interactions with other product ingredients/additives and degradations. Note this will also facilitate enforcement. **Risk assessment** • Argue that the risk assessment does not seem to have considered the imbalance issue of vitamins and minerals in the context of the total intake across the general population. • Suggest that given the characteristics of the target market, formulated beverages are likely to be consumed on their own, that is not part of a meal and probably on an empty stomach i.e. as a hydrator during activity or as a 'pick me up' the vitamins and minerals present are not diluted, protected or affected by other food components. <u>Stability</u> • Note vitamins and minerals interact with each other and other food ingredients, and are more likely to do so when in solution. Furthermore the stability of vitamins and minerals within a product is variable and affected by a number of factors (time, temperature, light, pH). **Potential to mislead consumers** • Note in many cases 'more is better' and 'you can't be hurt by anything that is natural/vitamins/minerals' is the message. Therefore it is important that the availability and composition of formulated beverages be stipulated and supported by substantiated and accurate information.

No.	Submitter	Submission Comments
6	**Complementary Healthcare Council** Allan Crosthwaite	***Support modified Option 2*** ***Purpose*** • Do not support formulated beverages being sold as general-purpose foods. • Contend they have a specific purpose i.e. vitamin and mineral supplementation. ***Risk assessment*** Vitamins and minerals • Note a number of the ingredients proposed for inclusion in formulated beverages including vitamin A and selenium are restricted under the *Therapeutic Goods Act* due to their potential toxicity. • Given the expansion of the market of fortified foods suggest that consumers may not be aware of how much they really consume on a daily basis. o Suggest consideration of the appropriateness of 'one day quantity' limits and issues associated with cumulative toxicity. Bioavailability • Recommend the development of any new standard ensures the food industry is responsible for analytical method development and method validation and bioavailability (to substantiate efficacy). Stability • Note some vitamins in aqueous solutions may be highly unstable. • Consider the issue of vitamin and mineral stability over the shelf life of a formulated beverage a major omission of the DAR which undermines the arguments presented regarding formulated beverages meeting consumer nutritional or health requirements. • Note fortification can only be useful if the food contains effective amounts and is ingested at regular intervals over suitable periods of time. Furthermore the nutrient must be present at the time of ingestion at a known content and must be bioavailable. • Suggest that without stability information on the ingredient, it is difficult to determine that the vitamin or mineral is effectively being delivered to the consumer. • Recommend the development of any new standard ensures the food industry is responsible for stability studies to substantiate allocated shelf-life on an ongoing basis. ***Labelling*** • Do not support the application of generic labelling requirements to formulated beverages. • Consider these requirements inadequate unless and until the food industry can demonstrate, in a transparent way, product stability.

No.	Submitter	Submission Comments
		• Strongly recommend a mandatory requirement for the food industry to ensure label claims are met throughout the shelf life of the product. o Recommend the development of any new standard ensures the food industry is responsible for label claim verification (e.g. analysis of multi-micronutrients in a complex matrix). • Comment that the DAR does not address how FSANZ and the relevant governments will implement the required manufacturing standards to ensure label claims over the shelf life of the product. Also note the DAR does not address the question of failure to meet label claims. <u>Health claims</u> • Raise concerns formulated beverages may be perceived by manufacturers to have implied health benefits and therefore be tempted to make health claims. • Note similar type therapeutic vitamin/mineral products listed under the *Therapeutic Goods Act* sold in powder form to be mixed with water are allowed to make health and therapeutic claims. • Suggest the DAR has not adequately addressed compliance issues. • Do not have confidence that compliance with the Code will be monitored or enforced ***<u>Potential to mislead consumers</u>*** • Consider the potential to mislead consumers has not been adequately addressed. Note there are inadequate controls over manufacturing procedures substantiation of content, stability and bioavailability over the shelf life of formulated beverages. State the consumer must know that if they choose to supplement using formulated beverages they are safe in doing so. • Note people who take nutritional supplements make a conscious decision to do so for a specific purpose and, therefore are generally prepared to read the label to learn about and accept the risk of potential contraindications. Hence a consumer who wishes to increase their nutrient intake wants to know exactly how much they take and need to be confident the product is stable and contains what it says on the label. Contend at present foods cannot provide this. ***<u>Regulatory impact</u>*** • Note the complementary healthcare industry is currently subject to considerable costs to meet the requirements of the *Therapeutic Goods Act* to achieve content, stability and bioavailability outcomes. Therefore expect the cost to the food industry should be similar. Note these costs would inevitably be passed onto consumers.

No.	Submitter	Submission Comments
7	**Dairy Australia** *Jacinta Orr*	**Support Option 2*** **Regulatory options** • Consider restricting the inclusion of vitamins and minerals to milk is in disaccord with the recommendation of the Application being based on 'promotion of fair trading' and the desirability of the food industry to be working 'efficiently and competitively'. • Recommend a full, expedited review of Standard 1.3.2 – Vitamins and Minerals to enable a degree of consistency across core food groups and to be consistent with national nutrition policies, including permissions to allow the same vitamins and minerals to milk as proposed for formulated beverages. <u>Option 1</u> • Note Option 1 does not put an end to the untenable situation of having sugar-sweetened formulated beverages being lawfully manufactured in New Zealand and sold in Australia. <u>Option 2</u> • Favour Option 2, but note strong reservations. <u>Option 3</u> • Strongly oppose Option 3, as consider this option to be associated with great risk of overexposure and possible harm, and is not in the interests of public health or safety. **Fortification policy guideline** **Appropriateness of food vehicle** • Consider formulated beverages to be a nutritionally poor food vehicle. • Believe that milk is a more suitable vehicle for fortification than water-based, sugar-sweetened drinks. • Consider milk to be a nutritious drink and highly appropriate food vehicle for fortification, however is only permitted to have vitamins A, D and calcium added. • Consider the addition of vitamins and minerals to formulated beverages is inconsistent with the Policy Guideline that states 'permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand'. • Consider the possible high consumption of formulated beverages is not consistent with dietary guidelines that state 'eat only a moderate amount of sugars and foods containing added sugars'. • Believe it would be more consistent with national nutrition policies and the Policy Guideline if the nutrients outlined on Option 2 were permitted to be added to plain water and milk, rather than formulated beverages.

* Denotes support with some reservations

No.	Submitter	Submission Comments
		Substitution/replacement • Cite studies which have shown that sweetened drinks displace milk from children's and adolescents' diets (Frary et al 2004, Committee on School Health 2004, Marshall et al 2005, Nielsen et al 2004, Whatley et al 2005). • Note substitution of milk by sugar-sweetened drinks is of concern because of subsequent lower intakes of nutrients. **Purpose** • Challenge the purpose of the product being for hydration. Note plain water is appropriate for optimal hydration and is consistent with nationally endorsed guidance on healthy eating. • Highlight the Dietary Guidelines for Australians Teaching Notes advise consumers to 'substitute plain water or soda water for soft drinks, sweetened fruit drinks, cordials and sweet alcoholic drinks'. **Risk assessment** **Bioavailability** • Adding vitamins and minerals to formulated beverages does not guarantee nutritional equivalence to naturally occurring sources. • Cite Heaney et al (2005) who concluded that calcium bioavailability was uneven between fortified products and not equal to cows' milk. • Note even if calcium salts are shown to have a similar bioavailability to milk, it cannot be assumed that they will have an equally beneficial effect in terms of bone health. Dietary modelling • Note modelling on total energy intake would be advantageous. **Total sugar and energy content of formulated beverages** Risk of overweight and obesity • Consider formulated beverages, with the suggested large portion size, have the potential to make a large contribution to the total energy intake of the community. • Believe that a restriction on sugar is essential. Also suggest consideration of total energy intake is required. • Note the proposed sugar content equates to 45g sugar per 600 ml serving, which may contribute ~5-10% of total energy intake in adolescent- and adult- men and women respectively, who consume one sugar-sweetened formulated beverage per day. • Cite US data indicating that adolescent males ingest much higher amounts of soft drink, representing ~26% of their total average energy intake (Committee on School Health, 2004). • Note findings from a recent Australian study that children and adolescents consumed non-core beverages in excess, obtaining 30.7% and 36.0% of their daily beverage energy respectively. Children aged 2-4 years who were obese appeared to obtain energy from these beverages than their health weight counterparts (Bell et al, 2005).

No.	Submitter	Submission Comments
		• Refer to a Newspoll survey commissioned by Dairy Australia showed that consumers would purchase additional fruit/flavoured drinks over and above the drinks they usually consume. • Suggest formulated beverages have a large portion size which may increase over time, as per the US experience (Committee on School Health 2004, Neilsen et al 2004), thereby encouraging increased consumption and contributing to total energy intake. • Express concern regarding over consumption when energy is ingested in liquid form. Note Wymelbeke et al (2004) reported that food intake was not modified for the energy content of the ingested fluids. **Labelling** <u>Vitamin and mineral content claims</u> • Highlight inequity of source claims as formulated beverages will be permitted to make 'good source' claims for 16 vitamins and minerals whereas milk can only claim 'good source' for calcium, vitamin B12 and iodine, and 'source' for magnesium, riboflavin and vitamin C. **Potential to mislead consumers** • Suggest use of percentage RDI and 'source' claims may misled consumers to perceive that sweetened drinks are a healthy addition to the diet. • Note consumers may be misled that they are absorbing the same amount of a nutrient as from a natural source of the nutrient, when often they would absorb significantly less. • Dairy Australia is apprehensive that sugar-sweetened beverages, with the requested level of calcium fortification, could be perceived by consumers, and moreover marketed, as an alternative to cows' milk causing potential for consumer misinformation. • Note consumers may perceive formulated beverages as a more healthy beverage than is reality if these beverages are permitted to make 'good source' claims for the 16 vitamins and minerals, when compared to milk which can only make 'good source' claims for 3 nutrients. *References* • Bell et al. Contribution of 'noncore' foods and beverages to the energy intake and weight status of Australian children. European Journal of Clinical Nutrition, 2005;59:639-45. • Committee on School Health. Soft drinks in schools. Pediatrics, 2004;113:152-4. • Frary CD et al. Children and adolescent's choices of foods and beverages high in added sugars are associated with key intakes of key nutrients and food groups. Journal of Adolescent Health, 2004;34:56-63. • Heaney et al. Not all calcium-fortified beverages are equal. Nutrition Today, 2005;40:39-44. • Heaney et al. Calcium fortification systems differ in bioavailability. Journal of the American Dietetic Association, 2005;105:807-10.

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		• Marshall et al. Diet quality in young children is influenced by beverage consumption. Journal of the American College of Nutrition, 2005;24:65-75. • Nielsen et al. Changes in beverage intake between 1977 and 2001. American Journal of Preventative Medicine, 2004;27:205-10. • Whatley et al. Beverage consumption patterns in elementary school aged children across a two-year period. Journal of the American College of Nutrition, 2005;24:93-8. • Wymelbeke et al. Influence of repeated consumption of beverages containing sucrose or intense sweeteners on food intake. European Journal of Clinical Nutrition, 2004;58:154-61. • Other references provided with submission.
8	**Dietitians Association of Australia (DAA)** Sue Cassidy	**Do not support any option** **Regulatory options** • Acknowledge purported disadvantage Australian beverage manufacturers are experiencing with the importation of formulated beverages from New Zealand under the TTMRA however believe this should not be considered as the New Zealand Government has foreshadowed changes to the NZDSR including a preference for fortified foods, currently regulated as 'dietary supplements' to be regulated under the Code. o Suggest acknowledging formulated beverages in the Code may undermine the potential to revoke the current changes foreshadowed by the New Zealand Government. **Fortification policy guideline** • ***Believe the addition of vitamin C at 100% RDI on the premise of market fairness does not follow policy guidance.*** *Appropriateness of food vehicle* • Do not believe that fortification of foods which are intrinsically nutritionally poor is a valid remedy for addressing vitamin and mineral deficiencies in a population. **Health benefit/inadequacy** • Believe the recommended option represented in the report is not entirely within the fortification policy guidance. For example, vitamin C and several other vitamins do not meet the criteria for addressing a 'health benefit' or 'deficiency' in the community. **Target Group** • Note the incidental target group appear to be children and teenagers.

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		Risk Assessment *Vitamins and minerals* • Argue formulated beverages should not be permitted in the Australian market because of the potential risks associated with iodine, iron (and sugar). • Recommend the maximum permitted claimable quantities be changed to maximum permitted quantities, noting manufacturers will add more than the amount claimed to avoid having levels that are less than the amount stated in the nutrition information panel. o Express concern this could contribute to even higher and more excessive intakes of certain nutrients. o Suggest a margin of +/- 5% around the claimed quantity could be specified to allow a margin of error. • Recommend vitamin C be added at a maximum level of 25% RDI to encourage use of fruits and other whole foods that are good sources of vitamin C and provide other essential micronutrients. *Substitution/replacement* • Raise concerns that formulated beverages may replace plain water consumption by some consumers, particularly teenagers. • Cite a review by St-Onge which provides evidence that the consumption of soft drink has been accompanied by a decrease in milk consumption which may partly explain the rise in paediatric body weights. **Total sugar and energy content** • Note that despite a sugar limit, one 600 ml serving will still provide approximately 50% of the reference daily intake of sugar. • Suggest that as formulated beverages will be marketed as a healthy alternative to other sweetened drinks such as cordials or soft drinks, it is feasible some individuals will have more than one serving each day and as such formulated beverages could contribute to excess energy consumption. • Highlight evidence showing energy from sugar-sweetened drinks adds to total energy intake and does not displace energy from other drinks. Also note there is less of a compensatory adjustment for energy after consuming energy from drinks compared with foods. • Cite a recent report by the FAO and WHO which recognised a high intake of sugar-sweetened beverages may promote weight gain. **Labelling** • Due to potential for formulated beverages to contribute to the current increase in childhood obesity and replace milk or water in the diet, recommend mandatory warning statements which advise against regarding formulated beverages as a substitute for a healthy diet or as a healthy alternative to plain water (or wording to that effect). *Vitamin and mineral content claims* • As a further risk management strategy, propose claims related to vitamin and mineral content be restricted to the inclusion of contents in the NIP only.

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		Potential to mislead consumers • Raise concerns that the addition of vitamins and minerals to formulated beverages may create the perception they are healthy alternatives to milk. **Risk management** • Seek clarification as to the nature of risk management strategies that would be considered necessary to protect vulnerable individuals such as those who are homozygous for hereditary haemochromatosis. **References** • Poppitt SD, Prentice Am. Energy density and its role in the control of food intake: evidence from metabolic and community studies. Appetite. 1996;26:153-174. • Mattes RD. Dietary compensation by humans for supplemental energy provided as ethanol or carbohydrates in fluids. Physiological Behaviour. 1996;59:179-187. • Joint WHO/FAO Expert Consultation. Diet, nutrition and the prevention of chronic diseases. Geneva: World Health Organisation, 2003. • St-Onge M-P, Keller KL, Heymsfield SB. Changes in childhood food consumption patterns: a cause for concern in light of increasing body weights. American Journal of Clinical Nutrition. 2003;78:1068-1073.
9	**The Environmental Health Association (Australia)** Phillip Oorjitham	**Support modified Option 2** **Purpose** • Support the classification of formulated beverages as a general-purpose food. **Composition** • *Question whether this proposal would apply to powder added to water.* Percent fruit juice • Reject the argument that the fruit juice content be limited to 24% to prevent confusion with fruit drinks and fruit juice that has added vitamins for the purpose of restoration, as the declarations, advertising and marketing of these products would be different. • Note the fruit juice content will be limited by the total sugar or energy content. Consider that manufacturers should be given the flexibility to use any percentage of fruit content provided it meets this limitation. • Note formulated beverages are only a small fraction of total daily diet and the standard should not be made so prescriptive as to limit fruit content. Exclusion of cordial • Support the proposal not to permit fortification of ready-to-drink cordials on grounds that the product is primarily marketed to children.

No.	Submitter	Submission Comments
		Food additives • Support food additives permissions for formulated beverages to be made as a category under non-alcoholic drinks in Schedule 1 of Standard 1.3.1. • Question in removing ready-to-drink cordials from the list of permitted foods, whether there is a need to retain the proposed levels of preservatives for the remaining products in the market. • Given alternatives and available technologies, such as hot-fill or UHT packaging, question whether is it necessary to retain permissions for sulphates and benzoates? **Reference quantity/serving size** • Query the need for the reference value to be 600 ml, rather than a lesser value of 500 ml. **Risk assessment** **Vitamins and minerals** • Support the range and levels of the proposed 16 vitamins and minerals. • Support the findings that these 16 vitamins and minerals pose no public health and safety concerns and there is a potential benefit in terms of addressing a nutrition or health need. • Note that even though there is a lack of available data for certain vitamins or minerals, there is data to suggest a potential benefit, e.g. molybdenum is being used in trials for the treatment of metastatic cancer and Wilson disease and there is no significant risk from consumption. Question why it is not being permitted. Dietary modelling • Raise concerns that the use of dietary modelling and food consumption data, based on UK and USA data, is only a rough approximation and does not accurately reflect Australian population or food supply. • Note the lack of available Australian data highlights the need for a comprehensive and current National Dietary Survey and food composition data to enable the regulator to undertake assessments. **Total sugar and energy content** • Accept that obesity is a potential public health concern and that increased levels of consumption of sugars may contribute to weight gain. • Consider it overly simplistic to base the standard on limiting the total sugar content when carbohydrates and proteins also contribute to energy. • Note if the objective is to reduce the risk of weight gain, then it should be based on energy per serve not on the sugar content. • Support the limitation of 800 kJ energy per 600 ml serve, which is equivalent to a total sugars content of approximately 7.5 g per 100 ml. • Note on this basis an adult consuming four lots of 600 ml bottles of product providing 25% RDI for selected vitamins and minerals would have 100% of the RDI fir vitamins and minerals but only 27% of the RDI for energy.

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		Impact analysis • Note under the current arrangement regarding NZDSR and TTMRA, Australian consumers are exposed to the risk of an unregulated market and Australian manufactures are unable to develop a competitive product. • Query whether the fact that formulated beverages have been in the marketplace for sometime can be taken as evidence that the demonstrated public health risk is actually low.
10	**Fonterra** Mara Fisher	**Support Option 2*** *Regulatory options* Option 1 • *Do not support Option 1 as it is unduly restrictive and is inequitable against dairy.* Option 2 • Support Option 2, as it takes into account public health and safety, while encouraging food innovation to satisfy consumer demands and nutritional requirements. • Note strong reservations in that Option 2 is not a consistent and equitable result for industry, as dairy foods are restricted to add calcium and vitamins A and D only. Believe if these permissions are not extended to dairy, this will result in unfair and unhealthy bias towards non-dairy products. Option 3 • Agree that Option 3 is inappropriate in the interests of protection of consumer health and safety. **Fortification policy guideline** **Appropriateness of Food Vehicle** • Caution against adding nutrients to sugar-sweetened and flavoured drinks. • Consider the promotion of high energy and artificial drinks as healthy, due to the addition of specified nutrients, should not be encouraged. • Consider the specified nutrients should only be added to plain water and milk at this stage. • Believe if it is found appropriate for formulated beverages to be fortified with selected nutrients, similar permissions should be extended to other nutritional beverages such as milk. • Suggest the proposal would result in an outcome that is inconsistent with the Policy Guideline, as the restrictions to fortify dairy beverages combined with increased permissions to fortify other beverages, would promote a consumption pattern inconsistent with the nutrition policies and guidelines of Australia and New Zealand.

No.	Submitter	Submission Comments
		Risk assessment Substitution/replacement *Consider the risks and issues for public health and safety have not adequately taken into account the substitution of milk beverages and water that may result from the additional permissions.* Bioavailability • Suggest consideration should be given to the bioavailability of added nutrients so that consumers are not given a misleading impression. • Note fortification of formulated beverages does not guarantee nutritional equivalence to the naturally occurring source. **Total sugar and energy content** • Identify obesity and excess weight gain as growing issues in Australia and New Zealand. **Labelling** *Vitamin and mineral content claims* • Consider 'good source' claims should not be permitted on sweetened, flavoured water-based beverages unless they are also permitted on milk beverages.
11	**Food Products Association (FPA)** Allen Matthys	**Support Option 3** **Regulatory options** • Support the production of formulated beverages in Australia and New Zealand without the limitation of sugar or juice content. **Composition** Percent fruit juice • Believe there is no technological justification for the proposed level. • Note the regulation would prevent imports into Australia and New Zealand that exceed 25% juice and contain vitamins and minerals that are not there solely for restoration due to losses during processing. Also note this policy is inconsistent with recommendations for fortification by the WHO and UNICEF. **Risk assessment** Vitamins and minerals • Request modification to allow for fortification with all 23 requested nutrients, and to allow for more flexible fortification levels to meet public health needs and reduce restrictions on international trade.

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		• Contend there is no scientific basis for limiting nutrient additions from 23 to 16. • Consider the 25% RDI limit per 600 ml (except for vitamin C) may limit future product innovation to meet public health and individual needs. **Total sugar and energy content** • Contend there is neither a health justification nor any scientific basis for restricting the total sugar content. • State the rationale underpinning the proposed limit is based solely on the premise there is 'potential for the consumption of formulated beverages to increase the sugar and energy intakes of the population'. • Believe there are no good or bad foods but good and bad diets and there are people who are sedentary and active. If a person consumes more total calories than they expend during their daily activities, they risk weight gain – this is independent of food sources. **Labelling** <u>Vitamin and mineral content claims</u> • Note the USFDA has established standards for 'good source'(≥10% daily value) and 'excellent source' (≥ 20% daily value) based on a reference amount of 240 ml. • Contend the permissions are about 60% lower when compared with comparable US beverages.
12	**International Council of Beverages Association (ICBA)** Alain Beaumont	**Support modified Option 2** **Regulatory options** • Support promulgation of a standard that would allow the production in Australia of formulated beverages without the limitations on sugar or juice content and the restriction on cordials. **Composition** <u>Maximum juice content</u> • State ICBA cannot find a technological reason to support the proposed level which is based on the local minimum level of juice before vitamin restoration is permitted under current regulations. • Note this would prevent imports of products into Australia and New Zealand that exceed 25% juice and contain vitamins and minerals beyond restoration which is counter to recommendations for fortification by leading authorities such as WHO and UNICEF.

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		Exclusion of cordial • Note cordials in Australia are concentrates sold at a retail level, which are usually dilutable at a 1:4, or 1:5 ratio and mostly contain fruit juice. Also note cordials are popular with families as economical drinks and are often purchased by socio-economically disadvantaged groups. • Suggest that since these groups might benefit most from beverages enhanced with vitamins and minerals, the proposed restriction seems at odds with public health goals. *Total sugar and energy content* • Do not believe there is a health justification nor is there any scientific basis for restricting the level of total sugar. • Suggest the consumption of sugars from beverages should be considered in the context that it is calories that count – not the proportions of fat, CHO and protein in the diet when it comes to body weight control. • Point out that there are no good or bad foods but there are good and bad diets and there are people who are sedentary and those who are active. Furthermore if a person overindulges in any type of food and does not exercise they risk weight gain. o Recommend moderation and exercise – not restriction of a sugar content in any specific food or beverage to avoid this. • Refer to UNICEF's supporting statement for fortifying food staples such as sugar. Note sugar is sometimes used as a vehicle for fortification for example in Guatemala. • Note many countries allow for the production of vitamin and mineral enhanced beverages without restricting sugar content. **Impact analysis** • Caution that the proposal may violate international trade, as it would restrict the importation of a water-based beverage with 8% brix level or higher. • Believe the proposal would prevent exports of a fortified concentrate packed for retail sale to Australia and New Zealand.

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13	**Kraft Foods Ltd** Dr Allan Poynton	**Support modified Option 2** *Regulatory Options* <u>Option 1</u> • Reject Option 1 for the following reasons: o maintains the inequality of manufacturers in New Zealand being able to produce products in a format not available to Australian manufacturers; o closes off an area for innovation and development; and o reduces opportunities for international trade. <u>Option 2</u> • Support Option 2 for the following reasons: o removes an inequality between the regulations in New Zealand and Australia; o provides an opportunity to trade formulated beverages between Australia and other countries where formulated beverages are used both for hydration and to support the vitamin and mineral requirements; and o provides further opportunity for innovation. • Commend FSANZ on its recommendation of Option 2, and the considerable amount of work which went into collating and evaluating the critical safety information of the vitamins and minerals considered. <u>Option 3</u> • Reject Option 3 for the following reasons: o permits extending beyond current knowledge of the range of vitamins and minerals with the potential for causing harm; and o unscrupulous or poorly-informed manufacturers might take advantage of the wider permissions, which might result in products with adverse effects and therefore negatively impact on the reputation of the food industry in the eyes of the consumer. **Purpose** • Support classification of formulated beverages as a general-purpose food. **Composition** *Percent fruit juice* • Support maximum limit of 24% fruit ingredients.

No.	Submitter	Submission Comments
		Food additives • Support permission for a range of food additives which support health and wellbeing. *Exclusion of cordials* • Support exclusion of cordials as formulated beverages. **Reference quantity/serving size** • Suggest reference quantity should be 500 ml rather than 600 ml, to allow 'source' claims to be made for a serve size of 230 ml (a normal drinking glass). **Risk assessment** *Vitamins and minerals* • Recommend zinc be permitted, noting recommendation on page 353 of DAR that zinc be added at a level of 3 mg per 600 ml. • Recommend vitamin A be permitted, as consider the argument for exclusion is inappropriate as the risk is to young children, where these beverages are not targeted to this age group. **Total sugar and energy content** • Support restriction of total sugar content of formulated beverages to 7.5 g/100 ml. **Labelling** • Support application of generic labelling requirements to formulated beverages. **Other comments** <u>Products</u> • Presented information on a beverage in powdered form called TANG[1] which is sold in South East Asia as a formulated beverage.

[1] Note powdered forms of beverage are outside the scope of this Application.

No.	Submitter	Submission Comments
14	**National Foods Ltd** Janine Waller	**Support modified Option 2** *General Comments* • Supportive of fortification where there is an evident need and/or health benefit, and the food vehicle is nutritionally sound. • Consider the provision of a fair and equitable regulatory system should be considered at the forefront of the decision-making process for this Application. • As a minimum, request a review of Standard 1.3.2 to: o address the inequities between food groups and permitted vitamins and minerals added, particularly for dairy foods; o create a fair, equitable and competitive playing field for manufacturers; o ensure consumers' choice is not mandated by the regulators. • Consider that in trying to address the trans-Tasman regulatory differences that apply for formulated beverages, the evident inequities between regulations of foods and permitted vitamins and minerals added (Standard 1.3.2) are yet again deferred by FSANZ, and that these inequities can no longer be ignored. • Suggest regulations with inequities do not allow the objectives of 'desirability of an efficient and internationally competitive food industry' and 'the promotion of fair-trading in food' to be met (Policy Guideline High Order Policy Principles). • Note that approval of this Application would allow the addition of 16 vitamins and minerals, which is more than any other food or beverage listed under this Standard. • Consider this Application has the potential to create further inequities between fruit drinks containing less or greater than 25% fruit ingredients, and fruit juices, and to promote sugary water and fruit drinks as superior beverages to other nutrient dense fluids, such as milk. *Regulatory Options* <u>Option 1</u> • Note Option 1 fails to address the trans-Tasman inequities in formulated beverages. <u>Option 2</u> • Note Option 2 considers total sugar as the limiting nutrient criteria but fails to differentiate between 'naturally occurring' verse 'added' sugar, nor the impact of total calories and portion size. • Suggest Option 2 has the potential to exacerbate the inequities in Standard 1.3.2 by differentiating between the number of vitamins and minerals permitted in fruit drinks with ≤24% fruit ingredients verses those with ≥25% fruit ingredients or fruit juices. <u>Option 3</u>

No.	Submitter	Submission Comments
		• Believe Option 3 does not regulate the range of vitamins and minerals added, the food vehicles to which they can be added, nor the limiting nutrient criteria. **Fortification policy guideline** **Appropriateness of Food Vehicle** • Comment that the Policy Guideline states that 'permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand'. • Note that the Australian Dietary Guidelines recommend plain water and milk as the best fluids for children, where these products would be in conflict with this recommendation. • Comment that for adults, the beverage of choice is plain water as it can hydrate without adding additional energy to the diet. Milk is recognised for its nutritional benefits. • Note milk is a nutrient-dense food vehicle which aligns with the recommendations from the Australian Dietary Guidelines and Australian Guide to Health Eating. **Target Group** • Consider this Application is looking at promoting sugary water and sugary fruit drinks for hydration to adults, however children could fall into the scope of the target group. **Definition** • Recommend the addition of milk to the mix of beverages for consideration under formulated beverages. **Composition of formulated beverages** <u>Percent fruit juice</u> • Recommend the removal of the 'maximum limitation of percent fruit ingredients. **Reference quantity/serving size** • Recommend reviewing the proposed portion size (reference quantity). • Note the reference quantity of 600 ml is in excess of that prescribed for other beverages such as milk, fruit drink, fruit juice (i.e. 200 ml). A quantity of this magnitude adds to the overall caloric intake. **Risk assessment** **Dietary modelling** • Consider basing an application on dietary data nearing nine years old is unacceptable, as population data needs to be accurate and current to make substantially sound evidence based decisions.

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		Total sugar and energy content • Recommend the removal of criterion for sugar in favour of criteria for total calories and portion size • Cite recent Australian research which shows that over 30% of energy intake for children and adolescents comes from non-core beverages (i.e. all beverages except water and milk), (Bell et al, 2005). • Note fruit/cordial drinks were listed in the top five food groups contributing to energy intake in children from foods eaten at school (Bell & Swinburn, 2004). • Refer to data from 73,000 Americans aged 2 years and over from 1977-2001 which show a 135% increase in energy intake from sweetened beverages, equating to a net increase of 278 calories per day (Neilson and Popkin, 2004). o Note the percent of calories from fruit drinks doubled, and energy intake from milk was reduced by 38%. Also the trend in increased sweetened beverage consumption was characterised by consumption of larger portions and more servings per day. • Recommend the nutrient criteria for formulated beverages be governed by total calories and portion size rather than total sugar, given overall caloric intake appears to be the main contributor to health concerns such as obesity. Note this is consistent with current nutrient guidelines in schools whereby sugar criteria has been replaced by criteria for energy and portion size (NSWSCA, 2005). • Note the figure for total sugar of 7.5 g/100 ml does not differentiate between 'naturally occurring' verse 'added sugars'. *References* • Bell AC et al. Contribution of 'noncore' foods and beverages to the energy intake and weight of Australian children. European Journal of Clinical Nutrition, 2005;59:639-45. • Bell AC & Swinburn BA. What are the key food groups to target for preventing obesity and improving nutrition in schools? European Journal of Clinical Nutrition, 2004;58(2):258-63. • Neilsen SJ & Popkin MB. Changes in beverage intake between 1977 and 2001. American Journal of Preventative Medicine, 2005;27(3):205-10. • NSWSCA. Health kids products – Healthy Kids nutrient criteria. NSW School Canteen Association 2005. • Other references provided with submission.

No.	Submitter	Submission Comments
15	**NSW Food Authority** Kelly Boulton	**Support Option 2** **General comments** • Advise that whilst the Application was strongly opposed at IAR (by the NSW Health Food Branch), the revision of the Application to remove for example caffeinated[1] and carbonated drinks has influenced the Authority's position. • Note that the Ministerial Council has since adopted policy which addresses fortification of foods with vitamins and minerals which has particular relevance to this proposed permission. **Regulatory Options** • Remain concerned about the impact of the NZDSR. • Express disappointment FSANZ has assessed that New Zealand companies could elect to produce formulated beverages under the NZDSR under Option 2 as support was in part premised on the understanding the New Zealand legislation will be repealed on the commencement of this new permission. Note however the Authority is not prepared to support Option 3 purely for the benefit of enabling the NZDSR to be repealed.[2] **Total sugar and energy content** • Acknowledge the proposed upper limit for sugar (7.5 g/100 ml) is a positive step to ensuring consistency with national and state policies however note formulated beverages are generally available in packages 500 ml or larger which provides a substantial amount of sugar that is greater then national nutrition guidelines levels. • Recommend an upper limit be set according to serving size.
16	**NSW Health** Edwina Macoun/ Rhonda Matthews	**Support Option 1** **General comments** • Do not support the voluntary fortification of formulated beverages with vitamins and minerals as there is no convincing evidence this will bestow a public health benefit. • Maintain the issues are based on free trade and marketing opportunities rather than public health. • Consider there is potential for detrimental public health effects associated with an over-fortified food supply, consumer confusion, potential for toxicity and undesirable changes in food consumption behaviours.

[1] Note the permission for caffeine was never sought by the Applicant.
[2] The repeal of the NZDSR is not within FSANZ nor does Option 3 state that the repeal

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		• Highlight the complex relationships between food and nutrients that influence absorption, metabolism and retention of nutrients. Advise the addition of vitamins and minerals to formulated beverages will not bestow the same health benefits that are possible by consuming a wide range of nutritious foods, especially plant foods that contain phytochemicals. <u>Policy Precedent</u> • Suggest consideration be given to looking at the impact on the overall food supply and likely trends over time rather than assessing each request for voluntary fortification in isolation. • Note that by setting a precedent with formulated beverages, it is likely others will seek approval in the future. Even if the approved amounts are limited to 25% RDI eventually a broad range of foods will be supplemented with additional nutrients thereby putting consumers at risk of toxicity and creating consumer confusion. • Note a decision made on the basis of fair trading and market forces will set a precedent for future applications, which is not beneficial from a health perspective. **Fortification policy guideline** • Note a number of vitamins and minerals did not demonstrate either a nutritional need or a potential to deliver a health benefit. Hence on nutritional grounds (and the need to fulfil the policy principle) there is no basis to support the addition of these nutrients to formulated beverages. • Maintain permission for addition of a broad range of vitamins and minerals to formulated beverages should be based on the evidence of need or potential health benefit and not primarily on the basis they are allowed in other sections of the Code. Nor should they be allowed because the evidence suggests they will do no harm as this is not a Specific Order Policy Principle. **Total sugar and energy content** <u>Risk of overweight and obesity</u> • Note the following: o Australia and New Zealand are currently facing a rising prevalence of obesity; o the contribution of additional sugar to the diet from sugar-containing beverages is a contributing factor to rising energy intakes and obesity; and o the World Health Organization rate the evidence implicating a high intake of sugar-sweetened drinks in promoting weight gain as 'moderately strong'. • Do not concur that the proposed upper limit of 7.5 g/100 ml will minimise the potential risk of increased energy and sugar intakes in the population. • Suggest the 45 g sugar (765 kJ) from a 600 ml bottle is a substantial amount of sugar and inconsistent with national and state policy goals to promote healthier weight. • State moderating sugar intake is a matter of national policy, which is addressed by the Australian Dietary Guidelines and the National Obesity Task Force. • Note reports suggesting Australia is second to the US in consumption of beverages with added sugar and concern for an epidemic of childhood obesity in Australia.

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		○ Recommend limitation not encouragement of sugar containing beverages is required in the interests of reduced energy intakes, public health and promotion of healthy weight. • Raise concerns that formulated beverages are already being targeted at children with anecdotal evidence suggesting there are several brands being heavily marketed to schools in NSW. Refer to the Australian Dietary Guidelines for Children and Adolescents recommendation that children and adolescents 'consume only moderate amounts of sugar and foods containing sugars'. • Do not support any substance being added to formulated beverages which may make them appear to be more 'healthy' or stimulate increased consumption. • Cite analysis of the 1995 National Nutrition Survey data which show non-alcoholic beverages (including juices, soft drinks, mineral waters and sports waters) contribute almost half (43-47%) of the total added sugar intake of Australian children and adolescents. ○ Suggest the data indicates beverages are contributing significant amounts of added sugar to the diets of young people and that the aim should be to reduce this rather than maintaining the status quo (or increasing it). *Dental health* • Note sweetened acidic beverages also contribute to dental erosion. **Risk assessment** • Note FSANZ's risk assessment is very rigorous and extensive but is essentially dismissed on the basis of 'fair trading and minimum effective regulation'. • Express concern that a small amount of information regarding market advantage appears to override over 247 pages of extensive public health nutrition analysis. *Vitamins and minerals* • Question the rationale for the addition of vitamin C at 100% RDI as opposed to a maximum 25% for other permitted vitamins and minerals despite no deficiency or health gain. • Maintain vitamin C is not in short supply in our food system and there is no apparent reason to allow 100% RDI to be permitted. <u>Bioavailability</u> • Suggest consumers may expect the vitamin or mineral in the product has appropriate bioavailability. • Note the bioavailability of vitamins and minerals proposed to be added to formulated beverages are virtually impossible to assess with any degree of accuracy and that it may be that may of the vitamins and minerals will be poorly absorbed because of the low pH of the beverage, presence of other substances or consumption of other foods at the same time. **Potential to mislead consumers** • Refer to the Applicant's suggestion that the request is in response to consumer demand for these products, yet note the Applicant provides no evidence in this regard.

No.	Submitter	Submission Comments
		• Raise concerns that there is an opportunity for consumers to be misled and note further research would be valuable in this regard. o Recommend that given limited research has been conducted on consumers response to formulated beverages, how they perceive them, likely consumption patterns and what beverage type they would replace them with, this research should be undertaken prior to a decision being made on this Application. • Believe it is likely that formulated beverages with a broad range of added vitamins and minerals will be marketed to those who have an interest in making a healthy choice. o Note however consumers who voluntarily seek a formulated beverage with the promise of increasing vitamin and mineral intake, should not be encouraged or misled into compromising their nutrition by consuming additional sugar (or fat or salt). • Highlight limited consumer awareness regarding issues of over-consumption. o Raise concerns in relation to findings from FSANZ's consumer research on FTDS which indicate a positive consumer view of supplemented products and a lack of awareness of any associated risks with over-consumption. • Caution that there is potential for consumers to mistakenly regard formulated beverages as suitable substitutes for 'core' foods such as meat, milk, fruit and vegetables because they contain vitamins and minerals found in these foods (e.g. calcium, iron and vitamin C). • Note many consumers are unaware of the broad range of nutrients and health benefits to be gained from consuming core foods that go beyond the presence of a particular vitamin or mineral. Suggest further research would be required to assess whether formulated beverages will be viewed as a substitute for core foods. • Believe if formulated beverages are approved, there will be stimulated marketing to promote these beverages to increase market share with the addition of vitamins and minerals a perceived selling point. **Labelling** • Note the FSANZ consumer research identified consumers did want labels that distinguish between foods that intrinsically contain certain nutrients and those that contain extrinsic or 'added' nutrients. Hence if formulated beverages are approved, consider it would be appropriate that labelling should indicate that the vitamins and minerals have been added to the product. **Impact analysis** • Counter the suggestion that consumers will benefit from allowing formulated beverages because they will have increased choice given consumers are already faced with a wide and bewildering array of beverage choices. Contend the main beneficiary of formulated beverages approval in Australia will be manufacturers and not consumers. **Other comments** *Nutrition Education* • Argue that by allowing vitamins and minerals to be added to foods and beverages that they are not intrinsic to, will in time make education virtually impossible.

No.	Submitter	Submission Comments
17	**New Zealand Food Safety Authority (NZFSA)** Carole Inkster	**Support Option 2** **General comments** • Note during the establishment period of the Joint Therapeutics Agency between Australia and New Zealand, dietary supplements and the NZDSR is being reviewed by New Zealand. • Anticipate food products currently regulated under the NZDSR are likely to be regulated at some future time under the Code. **Regulatory options** • Note Option 2 would provide for a range of FTDS drinks to be regulated. • Believe Option 3 has the potential to promote increased obesity and poor dental health. • Note Option 3 goes against the FSANZ guiding principle of protecting public health and safety. **Purpose** • Agree with classification of formulated beverages as a general-purpose food. **Composition** <u>Exclusion of cordials</u> • Agree cordials are not appropriate food vehicles for fortification because of their high sugar content and lack of control over composition as consumed. *Food additives* • Agree with the food additives requested. • Suggest however that as permissions already exist in Standard 1.3.1 in the relevant non-alcoholic beverages categories no specific category is needed. **Risk assessment** • Support further discussions around the exclusion of zinc and request clarification of data sources and values used. o For example Table 22 (pg 352 DAR) the mean intake at baseline differ from the 1995 National Nutrition Survey for the age groups 2-3 yrs and 4-8 yrs. Advise that using these figures changes the percentage UL at both baseline and scenario 2 which makes a significant difference in terms of risk for the 4-8 yrs age group. o Comment that *Milo,* which is made with milk, is a popular beverage with children contains a greater quantity of zinc by volume than is requested for formulated beverages. Suggest the inconsistency does not appear justified and needs to be reconsidered. • Cite the New Zealand Children's' Nutrition Survey which shows large proportions of girls, particularly 11-14 years, have an inadequate zinc intake.

No.	Submitter	Submission Comments
		• Support further dialogue around the interpretation of 'health benefit', particularly FSANZ's understanding of the term 'health status' and what will be covered by this. o Note discussions around health benefit in nutrition assessment focus on reduction of chronic disease risk, with little explanation of increased health status. **Total sugar and energy content** • Agree with limitation on sugar content to reduce public health risks in the areas of obesity and dental health. **Labelling** • Agree there is no need for specific labelling requirements i.e. formulated beverages should be covered by the generic labelling requirements contained in Chapter 1 of the Code. • Agree there is no need for a prescribed name – clause 1(b) of Standard 1.2.2 will ensure a formulated beverage is named or described adequately. Furthermore information in the ingredients list and NIP will provide information to consumers.
18	**New Zealand Juice & Beverage Association** John Robertson	**Support modified Option 2** **Composition** *Percent fruit juice* • Acknowledge the Application requested water-based, flavoured beverages which precludes fruit juices however that given the health benefits associated with fruit juices it should enable the addition of fruit juice up to at least 50%. <u>Exclusion of cordials</u> • Contend there is no justification for the exclusion of cordials. **Total sugar and energy content** • Contend there is no justification for limiting the sugar concentration. • Cite findings from the New Zealand Children's Survey showing total calorific intake from beverages (including juices, cordials, powdered drinks, sports drinks, energy drinks) was no more than 6%. o Question how given this low % contribution, soft drink consumption could be viewed as an important risk factor in the development of obesity in school aged children. **Risk assessment** • Fully support the list of vitamins and minerals approved for use in the DAR.

No.	Submitter	Submission Comments
		Impact analysis • Advise if the sugar limitation was imposed it would prevent the following products (currently made under the NZDSR) from being manufactured[1]: o Gforce o E2
19	**Nutrition Australia** Nola Caffin	**Prefer Option 1 but support modified Option 2** **General Comments** • Believe the comment period should be extended for significant and far-reaching issues of public health (as was done for Proposal P293). Suggest organisations such as NA are disadvantaged in the consultation process as the relevant people are generally in positions where preparing submissions is not part of the core responsibilities unlike industry and larger organisations. • Express concern the Application is about marketing opportunities rather than health benefits. Note for the general population, the nutrients required for good health can be obtained from foods available in the Australian food supply. • Support fortification only in accordance with Codex Principles i.e. o restoration where nutrients have been lost in processing; o restoration for nutritional equivalence of a substitute food; and o where there is a demonstrated public health nutritional need. • Believe consideration of the Application should not have taken place until the inconsistencies between Australia and New Zealand regulations had been resolved. • Suggest the NZDSR have been exploited and that New Zealand had foreshadowed changes. Also note formation of a joint Therapeutic Goods Agency. Believe these processes should have been completed before this Application is considered. **Regulatory options** • Note Option 1 is the preferred option however because the trade inequalities between Australia and New Zealand are the main and valid reasons for this Application and because these products are already available in Australia NA support a modified Option 2 with respect to juice/sugar content but note this only addresses some of the concerns). • Note there is no consistency in international regulations for products such as formulated beverages.

[1] under the Code but not the NZDSR unless these were repealed.

No.	Submitter	Submission Comments
		Fortification policy guideline *Appropriateness of food vehicle* • Question the evidence that vitamin and minerals consumed in the form of formulated beverage will provide the expected health benefit to consumers. **Target group** • Believe children will be consumers of formulated beverages which will continue to displace more suitable options such as milk and water. **Purpose** • Raise concerns on how formulated beverages will be marketed and used. Suggest that if they are marketed as dietary supplements with health benefits then this takes them out of the category of general-purpose foods like breakfast cereals etc that are fortified. • Concerned that allowing formulated beverages as general-purpose foods will open up the floodgates to other products wishing to increase the range of vitamins and minerals added to them. **Composition** <u>Percent fruit juice</u> • Recommend the fruit juice content should be no more than 5% and no added sugar to restrict the sugar and energy content of formulated beverages. o Suggest non-nutritive sweeteners could be used if there is a taste problem (due to the addition of vitamins and minerals) as a result of lowered fruit juice content. • Recognise the regulatory reasons for limiting fruit juice content but do not believe a consumer can be expected to distinguish between a general purpose fruit drink containing and a formulated beverage containing 25% and 24% fruit ingredients. <u>Exclusion of cordials</u> • Agree with decision to exclude cordials. **Total sugar and energy content** • Disagree that the proposed restriction provides adequate protection against excessive consumption of food high in sugar. • Note a serving size of 600 ml means a formulated beverage would contain at least 720 kJ per serve (assuming no energy contribution from protein or fat) which provides more sugar and kilojoules than a 375 ml can of soft drink. o Contend this is not in line with the policy guidance regarding the promotion of increased consumption of foods high in sugar and the need for consistency with nutrition policy and guidelines. • Highlight the need for consistency with sugar, fat and salt criteria for nutrition, health and related claims.

No.	Submitter	Submission Comments
		• Agree there could be increased consumption of formulated beverages and hence energy due to their increased nutritional attractiveness. • Cite references highlighting as little as one soft drink per day has been linked with an 83% increased risk of developing diabetes in women and a 1.6 increased risk of developing obesity in children. <u>Dental health</u> • Raise some concerns of formulated beverages being promoted as an aid to hydration. Note emerging but significant issue of tooth erosion as a result of consuming sugary drinks for rehydration. Advise that dehydration reduces protective saliva flow and tooth erosion is now being seen in young people actively involved in sport who otherwise have excellent teeth. **Other comments** *Advertising* • Raise concerns as to how formulated beverages are to be marketed. Quote a recent media article highlighting an advertisement for a fortified breakfast cereal which 'only tells you part of the story'. Appreciate FSANZ has no control over product advertising however suggest this issue should be considered when deciding whether specific labelling requirements are warranted.
20	**PB Foods Ltd** Monica Witsch	**Support Option 2*** **General comments** • Generally support issues raised in the Dairy Australia submission (see above). • Recommend a review of this Application considering the addition of vitamins and minerals across the core food groups under Standard 1.3.2 in line with the fortification policy guidance. • Believe it is highly inequitable that milk and modified milks, nutritious vehicles for fortification, can only have vitamins A, D, and calcium added as general-purpose foods. **Composition** • Believe it would be more consistent with national nutrition policies if the proposed nutrients were permitted to be added to plain water and milk, rather than only to sugar-sweetened, flavoured drinks. **Risk assessment** • Express concerns about the wide range of vitamins and minerals which Option 2 would permit to be added to a nutritionally poor vehicle of sugar-sweetened and flavoured beverages only[1].

[1] can be added to artificially sweetened beverages

No.	Submitter	Submission Comments
		Potential to mislead consumers • Fearful that given the permission for 'good source' claims for all 16 vitamins and minerals that consumers may perceive formulated beverages as a healthy addition to the diet and a possible substitute for milk. Note that if associated claims are fair and reasonable, there would be support to allow them in a wide variety of foods including milk drinks to protect public health and encourage consumption where Australians may be deficient.
21	**QLD Health** Gary Bielby **Health**	**Do not support any option but modified Option 2 next preferred option** **General comments** • Support fortification only in accordance with Codex Principles, i.e. for reasons of demonstrated public health need, nutritional equivalence and restoration. • Believe that formulated beverages are unnecessary for good health, as all nutrients required for good health can generally be obtained from a nutritionally balanced diet. **Regulatory options** • Do not support any of the proposed Options as they stand. • Acknowledge that because inequitable trade is the main reason for the Application and formulated beverages are already available in the market, some suitable Option may be developed. • Advise the next preferred option is a modified version of Option 2 that would address: o the high level of sugar in formulated beverages; and o specific labelling requirements. • Note the major issue is that New Zealand has failed to repeal their Dietary Supplement Regulations, and thus there is inequity for Australian and New Zealand businesses. • Consider it preferable if this issue was resolved via the repeal of these regulations rather than Australia having to continually amend the Food Standards Code to accommodate the exploitation of a loophole by some New Zealand manufacturers. **Fortification policy guideline** **Health Benefit** • Do not agree that the potential health benefits of formulated beverages outweigh the costs, where the cost of obesity in Australia is $1.3 billion and rising fast. • Consider it unlikely that any increased nutrient intake provided by these beverages would outweigh their role in obesity and its associated chronic diseases, as supported by the US experience. • Note even if there is evidence of deficiency, formulated beverages are not a desirable means of obtaining nutrients. • Request evidence that the vitamins and minerals consumed in the form of formulated beverages will provide the expected health benefit to consumers, when compared with their original food source.

No.	Submitter	Submission Comments
		• Consider it surprising that fat-soluble vitamins have been allowed, considering that the body accumulates rather than excretes fat-soluble vitamins. **Purpose** • Recommend consideration of formulated beverages as special purpose or supplemental foods. **Composition** <u>Exclusion of cordials</u> • Agree with the decision to exclude cordials. **Total sugar and energy content** • Express concern regarding the sugar content of formulated beverages, particularly as they are products supposedly created to enhance health. • Note the sugar content restriction allows an excessive amount of sugar and energy in these products, and therefore does not comply with the Policy Guideline regarding the promotion of increased consumption of foods high in sugar and the need for consistency with nutrition policy and guidelines. • Note that when determined, the nutrition and health claims (P293) criteria for sugar, fat and salt need to be consistent with criteria used for this Application. • Advise the proposed sugar content combined with the reference serving size would mean that a formulated beverage would contain at least 720 kJ per serve and 9 teaspoons of sugar. This is more calories that a 375 ml can of soft drink, and would contribute significantly to the serves of "extra foods" for all age groups and genders as described in the *Australian Guide to Health Eating*. <u>Risk of overweight and obesity</u> • Note one soft drink per day has been linked with an 83% increased risk of developing diabetes in women (Schulze et al, 2004), and a 1.6 increased risk of developing obesity among children (Swinburn et al, 2002). • Do not agree that the proposed restriction of sugar content for formulated beverages provides adequate risk management of obesity and its association with chronic disease, especially in children. <u>Dental health</u> • Note little consideration given to the impact on oral health. **Risk Assessment** <u>Vitamins and minerals</u> • Consider that formulated beverages as described are multi- vitamin and mineral supplements in liquid form as opposed to pill/tablet form.

No.	Submitter	Submission Comments
		• Question whether it is appropriate to allow voluntary fortification of nutrients that are currently under consideration for mandatory fortification (i.e. iodine and folate)? • Consider the potential harm of formulated beverages for people with undiagnosed haemochromatosis and long-term iodine deficiency has been too easily dismissed in favour of potential health gains to the broader population. *Dietary modelling* • Question how appropriate it is to use RDIs developed in 1991, now that the draft NRVs for Australia and New Zealand are available. • Express concern regarding the use of out of date dietary data, namely the NNS, and support the initiation of a comprehensive national nutrition monitoring and surveillance program. **Labelling** • Suggest consideration of a prescribed name in conjunction with classification of formulated beverages as special purpose. • Consider labelling should be required to assist consumers in making an informed choice. • Suggest further measures (in addition to exclusion of cordials) are required to protect children and teenagers from consumption of formulated beverages, e.g. labelling formulated beverages as 'not recommended for children', or labelling to indicate that the RDI relates to adults. • Concerned about the similarity of formulated beverages to therapeutic goods. o Consider that there needs to be labelling requirements to the effect that 'dietary supplements are only of use if intake is inadequate', so that consumers are not misled to believe that formulated beverages are necessary for health. • Highlight problem of how these products are promoted and advertised, note this issue requires consideration when deciding whether specific labelling requirements are warranted. **Potential to mislead consumers** • Do not believe that the proposed compositional restriction on the amount of sugar in formulated beverages is enough to minimise the risk of consumers being misled as to the nutritional quality of the fortified food. *Impact Analysis* • Believe the impact on nutrition and dietetic educators should also be considered, as well as the impact on the health system. • Consider that little acknowledgement is given to the cost for government and non-government organisations to provide consumer education. In addition, few jurisdictions have adequate public health and community nutrition staff to provide any nutrition education services. • Suggest the contribution of these sorts of products to the obesity crisis and related chronic diseases should not be underestimated.

No.	Submitter	Submission Comments
		• Queensland Health does not agree with FSANZ's conclusion that the potential health benefits of formulated beverages outweighing the costs. The National Obesity Taskforce has determined that the cost of obesity in Australia is $1.3 billion and rising fast. The Taskforce also determined that poor nutrition, inadequate physical activity and obesity account for more than 10% of the burden of disease in Australia and equal tobacco as being the most important avoidable cause of ill health in Australia. • Acknowledge that formulated beverages are not the sole contributor to the obesity crisis in Australia, it is unlikely that any increased nutrient intake provided by these beverages would outweigh their role in obesity and its associated chronic diseases. The experience of the US supports this view, as the growth of these products in the US as described in this application is paralleled by continued increases in rates of obesity and chronic disease among the US population. Even if a range of vitamins and minerals are lacking in 3% or more of the population (which is a clinically significant figure and probably not significant when considering the whole population) as described in this application, formulated beverages (i.e. sweetened beverages) are not a desirable means of obtaining extra nutrients.
22	**Jennifer Savenake**	**Do no support any option** **General comments** • Recommend a review of the conditions (qualifying and disqualifying) for 'source' and 'good source' claims, if formulated beverages are approved to ensure consistency with the intent of the fortification implementation framework. **Regulatory options** <u>Option 1</u> • Acknowledge possible disparity between Australian and New Zealand manufacturers of formulated beverages under the TTMRA however note only 4 of the 20 products in the 2005 review were New Zealand imports. • Comment that formulated beverages can be manufactured under Standard 2.9.4. Also comment that this is considered to be incongruous with the intent of part 2.9 of the Code, which is designed for foods that are prepared for at risk groups whose dietary requirement cannot be satisfied by a normal diet. Note the policy guidance does not apply to part 2.9 as it was presumed 'at risk' groups may have different requirements, yet the conditions for voluntary fortification include clinical or sub-clinical evidence of deficiency or deficiency is likely to develop. Suggest it is incongruous that the intended population (and approval of added vitamins and minerals based on deficiency or possible deficiency data) means this 'at risk' group is not meeting their requirements by a normal diet.

No.	Submitter	Submission Comments
		Option 2 • Consider it incongruous with protecting public health and safety to create regulations on the basis of efficiency and competitiveness with another system which is not based on risk based methodology. It also undermines consumer confidence in the sound scientific risk management strategies practiced by FSANZ. • Believe Option 2 may still represent a technical barrier to trade as the levels of sugar and vitamins permitted are lower than what is allowed under the NZDSR. • Note New Zealand manufacturers will continue to produce formulated beverages, which will remain inconsistent with the Code. Option 3 • Argue Option 3 is unacceptable as it is not based on risk management practice to protect public health and safety. **Fortification policy guideline** • Contend the Application is not consistent with the intent of the policy which suggests limiting fortification so that it does not promote consumptions/habits inconsistent with national nutritional guidelines. *Appropriateness of food vehicle* • In view of the possible adverse effects on health regarding obesity and dental health with the growth of formulated beverages, consider formulated beverages are inappropriate vehicles for fortification in terms of protecting and promoting health therefore they do not meet the Policy Guideline. **Risk assessment** *Vitamins and minerals* • Recognise FSANZ has used international data on EAR and RDI due to the current review of the Australian and New Zealand NRV however note the draft NRV have AI for a number of nutrients which are proposed to be added to formulated beverages. • If formulated beverages are approved, recommend the addition of vitamins and minerals is consistent with Australian and New Zealand NRV; and the role of AI is considered. Dietary modelling • Question whether these nutrients should be added to the food supply when there is no composition data and no intake data on which to make safety assessments. **Total sugar and energy content** • If formulated beverages are approved, recommend lower sugar levels than 50% of the daily reference value.

No.	Submitter	Submission Comments
		Overweight and obesity • Note trends from industry intelligence that fortified water market is new and expanding and formulated beverages will be consumed in addition to other beverages. o Suggest this translates to additional energy intake in a population, which already had existing obesity risks. • Express concern regarding the apparent thirst quenching 'healthy' image these products will portray while providing between 5-10% estimated energy requirements (based on sedentary to moderate activity in reference weights for adolescents and adults 19-30 yrs from Draft NRV and 45g or 50% daily reference intake. • Suggest the addition of vitamins and minerals to sweetened beverages could be seen as adversely affecting existing public health initiatives by promoting the consumption of sweetened beverages which have been shown to contribute to increased obesity. Cite numerous studies to support this. Dental health • Suggest the addition of vitamins and minerals to sweetened beverages could be seen as adversely affecting existing public health initiatives by promoting the consumption of sweetened beverages which have been shown to contribute to dental caries. • Comment that the reference 600 ml serving size compared to other standard serving sizes (e.g. 355 ml can 250 ml tetra pack) increases the risk of dental caries as the larger volume is likely to be consumed over a longer period of time. **Labelling** *Claims* • Acknowledge FSANZ has used international data on EAR and RDI due to the current review of Australian and New Zealand NRV however note the draft NRV for Australia have AI for a number of nutrients proposed to be added. o Question how a 'source' or 'good source' claim could be made on RDI when there is insufficient data to set an RDI or if there is insufficient data to set an EAR whether these nutrients should be added to the food supply. • If formulated beverages are approved, recommend a review of conditions (i.e. qualifying and disqualifying) be undertaken for 'source' and 'good source' claims to ensure consistency with the intent of the policy guidance. **Potential to mislead consumers** • Note the health claims Proposal P293 which suggests qualifying and disqualifying criteria for claims including nutrition content claims. Also note from FSANZ's fortification implementation framework that vitamin and mineral claims have been excluded from the Proposal at this stage. o Suggest this labelling could promote formulated beverages as better nutrition than they represent. • Refer to FSANZ's consumer research on FTDS which indicated consumers could be misled as to the nutritional quality of formulated beverages. • Acknowledge that whilst compositional restriction on the amount of sugar and removal of cordial go some way to addressing consumer misunderstanding there remains the possibility these products will be marketed in a way that consumers perceive them to be 'healthy' and while they contain added vitamins and minerals and fluid they contain no other nutrition benefits.

No.	Submitter	Submission Comments
		• Advise that without addressing bioavailability, any claim of 'source' or 'good source' on formulated beverages could be misleading as the average consumer would expect that if the product stated this claim they should benefit from the presence of the vitamin or mineral. **Monitoring and surveillance** • Note the policy guidance mentions the need for ongoing monitoring and surveillance of the impact of additional vitamins and minerals to the food supply, which although outside the scope of FSANZ's responsibility needs to be referred to the appropriate body when considering this Application. • If formulated beverages are approved, recommend monitoring and surveillance issues be addressed. **Other comment**s *Food-medicine interface* • Recommend further clarification of food-drug interface if formulated beverages are approved. • Raise concerns that the options presented do not adequately address the ambiguity of products that fall within the food-drug interface. • Highlight the need for consistency with the TGA so therapeutic goods are not included in foods in order to bypass TGA approval and be seen as a 'soft' option. • Notes the 'grey area' between soluble or liquid multivitamin preparations and formulated beverages and that the work on guidelines for assessing the regulatory status of a product at the interface has not been clarified. <u>Education</u> • Note comments from FTDS consumer research that 'the addition of more information on labels will not be meaningful unless accompanied by education'. o Express concern as to who should provide and fund such education. o Question whether governments should pay for education that provides a market benefit to manufacturers at the expense of more important public health messages such as promoting breastfeeding or fruit and vegetables. o Note education provided by manufacturers could be seen as biased and lack credibility. Suggest it is possible that the division of funding and provision of education may be appropriate. • Highlight recent concerns from consumers in relation to foods with added vitamins and minerals and other dubious nutritional content advertising their health benefits. **References** • www.parentsjury.org.au • Ludwig DS, Peterson KE, Gortmaker SL. Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis. Lancet. 2001;357 (9255):505-8.

No.	Submitter	Submission Comments
		• Bell AC & Swinburn BA. What are the key food groups to target for preventing obesity and improving nutrition in schools? European Journal of Clinical Nutrition, 2004;58(2):258-63. • Welsh JA, Cogswell ME, Rogers S, Rockett H, Mei Z, Grummer-Strawn LM. Overweight among low-income preschool children associated with the consumption of sweet drinks: Missouri,1999-2002. Pediatrics. 2005;115(2):223-229. • Schulze MB, Manson JE, Ludwig DS, Coldwitz GA, Stampfer MJ, Willett WC, Hu FB. Sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes in young and middle-aged women. JAMA. 2004:292(8):927-34. • Bell AC et al. Contribution of 'noncore' foods and beverages to the energy intake and weight of Australian children. European Journal of Clinical Nutrition, 2005;59:639-45.
23	**SA Department of Health**	**Support Option 1** **General comments** • Raise concern that the Application will set a policy precedent that will open the floodgates for applications for fortification. • Note that a broad range of fortified foods could potentially lead to problems of toxicity, increased consumer confusion and misleading claims as well as higher consumption of inappropriate foods leading to dietary related illness. • Strongly oppose the addition of vitamins and minerals to formulated beverages on the basis it does not adequately protect public health and safety and may promote misleading conduct in relation to promotion of such foods. • Consider public health, in the broader sense, relates to the burden of diet related disease, including obesity. Therefore fortification of beverages which can contain high amounts of sugar, is not considered supportive of protecting public health of the broader community. • Contend there is a lack of evidence from the Applicant regarding the impact of formulated beverages on the Australian diet including what they will displace, and the impact on dental health and other diet related diseases. **Fortification policy guideline** • Suggest the acceptance of formulated beverages as suitable candidates for fortification appears in direct conflict with the NHMRC Dietary Guidelines. • Consider fortified beverages encourage fluid intake inconsistent with the Guidelines which recommend water and milk as the primary consumption with limited consumption of fruit juice. <u>Health benefit/deficiency</u> • Note there appears to be no evidence that formulated beverages would adequately address a deficiency in the specified nutrients in the population. • Note that whilst there are population subgroups that benefit from the intake of higher levels of specific vitamins and minerals, there is no evidence to suggest the fortification of beverages will benefit the overall health of the population. Suggest specific requirements can be more appropriately met by the consumption of vitamin and mineral supplements. **Risk assessment**

No.	Submitter	Submission Comments
		Vitamins and minerals • Note information from the Australian Market Survey 2005 indicates that the maximum recommended daily intake on the labels of formulated beverages range from 600-3600 ml per day for adults. Note at the upper limit of 3600 ml this would equate to 150% RDI for many vitamins and minerals. • Suggest that as general purpose foods with no restricted marketing, it is not inconceivable that children consuming formulated beverages at their maximum recommended level would have an intake far exceeding their RDI. <u>Bioavailability</u> • Note from the DAR that bioavailability is uncertain and cannot be fully assessed. • Suggest that without bioavailability data, there is no evidence that fortified beverages will address deficiencies or provide health benefits to the general population. *Dietary modelling* • Consider the food consumption data used for the intake assessment derived from the 1995 NNS is insufficient to give a true representation of Australian's current dietary intake of vitamins and minerals. • Believe it is difficult to deduce from this data, inadequate intake levels and question the accuracy and relevance of 10-year-old data. **Total sugar and energy content** • Note the proposed limitation of 7.5 g/100 ml for a 600 ml serving size equates to 45g of sugar which is half the daily intake reference value listed in Standard 1.2.8. • Consider a limit for one 600 ml serve that equates to half the daily intake for the average adult is extremely high, as these products may be aimed at vulnerable populations such as children. • Suggest there is little justification for this limit apart from the fact that it would allow the majority of formulated beverages already on the market to remain unchanged. *Risk of overweight and obesity* • Do not agree with FSANZ's assessment that the upper limit will minimise the potential risk of increased energy intake and suggest it is inconsistent with national dietary goals promoting healthy weight. • Note the sugar restriction equates to 270 g per 3.6 litres and equals 4320 kJ which is a significant contribution to energy intakes. • Cite findings from Ludwig et al 2001 that support intake of sugary drinks leads to higher incidences of obesity. <u>Dental health</u> • Note the sugar restriction equates to 270g per 3.6 litres and equals 4320 kJ which is a major adverse impact on dental health. • Highlight findings from a SADS study that report dental caries in children under 6 years of age has risen 40% since 2000.

No.	Submitter	Submission Comments
		Labelling • Raise concerns that formulated beverages will be promoted as a general-purpose food with no specific labelling or warning statements, which enables them to be openly marketed to children and other vulnerable population groups. • Note Formulated Caffeinated Beverages have particular labelling requirements and are specifically aimed at adults, unlike formulated beverages. • Note while the current inclusion of some formulated beverages as Formulated Supplementary Sports Foods Standard is inappropriate, the specific labelling requirements and warning statements for these products restricts their marketing. *Nutrition claims* • Consider consumers are likely to be misled as to the nutritional quality of fortified beverages, especially where 'source' claims are made. *Health claims* • Suggest the introduction of the new nutrition, health and related claims Standard in the future will potentially broaden the claims made on fortified beverages and hence further mislead the consumer and encourage higher intake levels. **Risk management** • Consider the inclusion of a selection of vitamins and minerals on the basis of their current inclusion in the FCB standard without any other evidence of health benefit is inappropriate **References** • Ludwig DS, Peterson KE, Gortmaker SL. Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis. Lancet. 2001;357(9255):505-8. • SADS Report

No.	Submitter	Submission Comments
24	**Dr Rosemary Stanton** **Stanton**	**Support Option 1** **General comments** • Raise concerns that valid scientific concerns from six groups with no vested interest and concerned purely with public health held no sway against the ten submissions (at initial assessment) from industry groups or companies with vested interest in changing the regulations. Note submissions from public health/professionals cited evidence of possible adverse effects on dental health and obesity, which are particularly important if the addition of vitamins and minerals increases consumption of sugar-flavoured beverages, which is presumably why industry submissions favour relaxing regulations. • Note at times industry and public health concerns can overlap but where there is conflict between commercial considerations and protection of public health, public health should have first call. **Regulatory Option**s • Recognise that the soft drink industry believe the current prohibition on adding vitamins and minerals to beverages favours production by companies in New Zealand however believes from a public health perspective it is not valid to argue that if one country does something, others should also be permitted. o Consider such thinking leads to lowering of standards and is not in consumers interests. o Suggest it would be more relevant to work towards prohibiting current practices in New Zealand. • Argue the provision of formulated beverages is not something consumers have requested rather it is a marketing exercise by industry. Refers to 40 years work in the area of sports nutrition and note there is no established public health need for such beverage, even among sportspeople **Fortification policy guideline** *Appropriateness of food vehicle* • Suggest adding vitamins and minerals to products that are not core foods could create problems if these are substituted for core foods. <u>Health benefit/deficiency</u> • State there is no evidence that adding the proposed vitamins and minerals to formulated beverages would overcome any possible deficiencies in Australia. • Note any possible deficiencies (except for vitamin D) would be better addressed by encouraging people to choose from the wide rang of highly nutritious products available as depicted in the core food groups of the AGHE. Advise this is one of the reasons for projects set up by SIGNAL and the Department of Health and Ageing to increase consumption of fruits and vegetables as in the current 2 plus 5 campaign.

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		• Note the Beverages Council claim these drinks are *added* to the regular diet. Believe that with no evidence that the proposed vitamins and minerals are needed or would address any possible problems in particular groups in the community, the extra kilojoules provided by adding these drinks to the regular diet is a backward step in a country trying to grapple with unprecedented levels of excess weight in adults and children. **Composition** • Believe water-based flavoured beverages ('basically soft drinks') fit into the category defined in the Australian Guide to Healthy Eating (AGHE) as 'extras' noting formulated beverages have: o no intrinsic value in the diet; o potential negative health effects e.g. dental health; and o extra sugars in the diet adds kilojoules which could impact on excess weight. **Risk assessment** *Displacement/substitution* • Argue that since adequate milk consumption is a problem for many Australian children, competition from formulated beverages is undesirable. Also cites studies in other countries showing milk consumption is inversely related to consumption of sweetened beverages. • Suggest that if vitamins and minerals are added to formulated beverages, it is possible that the soft drink industry will later apply for permissions to other soft drinks, including those with higher levels of sugar, those with artificial sweeteners and drinks with a mixture of sugar and artificial sweeteners. o Caution that the objections raised in her submission would be magnified given these products are widely sold and consumption is already at levels considered undesirable in obesity-prone populations. **Total sugar and energy content** • Contend Option 2 does not deliver benefits by restricting the Application to drinks with less than 7.5% sugar/100 ml. Note that whilst it may reflect the current level in some imported products some scientific rationale is required. • Also note dental health is not solved by simply restricting sugars to 7.5% as the acidity of formulated beverages is a problem. *Risk of overweight and obesity* • Highlight the consumption of sweetened liquids has been implicated in excess weight. Reference several studies pointing out the body does not appear to recognise satiety from liquid sources. • Suggest that rather than trying to increase sweetened drinks, the aim should be to decrease them, noting evidence that this can prevent weight increase in children and may decrease in obesity.

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		Dental health • Advise acidity is a major problem for dental health including decay and erosion whether drinks are sweetened with a large or lesser amount of sugar or contain artificial sweeteners. Also highlights evidence that the association between acidity of drinks and dental problems is not well understood by children. **Labelling** *Vitamin and mineral content claims* • Suggest that if formulated beverages are marketed as a 'good source' of particular vitamins and minerals, it is likely consumers may purchase formulated beverages in preference to other products which provide a more balanced intake of nutrients. For example, formulated beverages with added calcium will not be nutritionally equivalent to fat-reduce milk. <u>Health claims</u> • Recognise if the Application is successful, the Applicant wants to be able to make health claims in marketing formulated beverages. Also mentions food industry claims that health claims are likely to increase sales noting this presumably will lead to more formulated beverages being consumed. • Highlight the criteria required for health claims: to qualify a product would need to include a natural content of nutrient(s) and the disqualifying criteria would include high levels of sugar, salt or saturated fat. Also note other disqualifying criteria may be relevant for some products. **Impact analysis** • Warn there is a potential public health cost if Australians believe that by consuming formulated beverages they need be less concerned about their intake of foods such as fruit and vegetables. • Highlight widespread contact with parents who assume they can compensate for children's low consumption of fruit and vegetables with vitamin C tablets. Suggest it is reasonable to consider marketing and advertising the vitamin and mineral content of formulated beverages could have a similar effect. Also cautions that anything that may adversely impact on Australians recognition of the importance of getting nutrients from core foods such as fruits and vegetables could have undesirable effects on public health and nutrition. • State there is no scientific evidence that consumers would benefit from a 'greater product choice'. Furthermore note that since the expansion of product choice, consumption of healthful products such as fruits and vegetables has fallen. **References** • Ludwig DS, Peterson KE, Gortmaker SL. Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis. Lancet. 2001;357(9255):505-8. • Schulze MB, Manson JE, Ludwig DS, Coldwitz GA, Stampfer MJ, Willett WC, Hu FB. Sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes in young and middle-aged women. JAMA. 2004:292(8):927-34.

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		• Mattes RD. Dietary compensation by humans for supplemental energy provided as ethanol or carbohydrate fluids. Physol Behav. 1996;59:179-187. • Harnack L, Stang J, Story M. Soft drink consumption among US children and adolescents: nutritional consequences. J Am Diet Assoc. 1999;9:436-441. • James, J. Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. BMJ. 2004;328(7450):1237. • Moynihan P, Petersen PE. Diet, nutrition and the prevention of dental diseases - review. Public Health Nutrition. 2004;7(1A):201-26. • Gillis LJ, Bar-Or O. Food away from home, sugar-sweetened drink consumption and juvenile obesity. Int J Paediatr Dent. 2003:13(6):425-33. • Sirimaharaj V, Brearley Messer L, Morgan MV. Acidic diet and dental erosion among athletes. Aust Dent J. 2002;47(3):228-36. • mrdjenovic G, Levitsky DA. Nutritional and energetic consequences of sweetened drink consumption in 6- to 13-year-old children. J Pediatr. 2003;142(6):604-10.
25	**Cecile Storrie**	**Do not support any option** **General comments** • Boycotts products which have added vitamins with the exception of iodised salt. • Advises that when manufacturers add vitamins it upsets calculations for a balanced diet. • Suggests a 'plain food' label for food which has no additions to save consumers time and hassle.
26	**Therapeutic Goods Administration** Fiona Cumming	**Support Option 2*** **General comments** • Comment that the Application raises some concerns about the safe and appropriate use of formulated beverages for a number of reasons. • Suggest that the net benefit of permitting the addition of vitamins and minerals to formulated beverages is that formulated beverages are likely to be viewed by consumers as having nutritional advantages over other soft drinks, and may be perceived as being a significant source of vitamins and minerals in the diet. • Consider it is necessary for public health and safety reasons to place limits on the quantity of some of these nutrients that can safely to added to a reference quantity of a formulated beverage.

No.	Submitter	Submission Comments
		Risk assessment *Bioavailability* • State that this Application provides no sureties for the stability and bioavailability of the vitamins and minerals in formulated beverages or the safe use of these products. • Note when vitamins and mineral supplements are presented in medicinal form they: o must be manufactured in accordance with a Code of Good Manufacturing Practice; o may only be formulated from approved forms of each vitamin and mineral; o must meet stringent quality standards; and o must be labelled with clear instructions for use and, in some cases, with warnings as well. Believe all these provisions are necessary to ensure the effective delivery of the vitamins and minerals, and to help ensure a product's safe use. **Potential to mislead consumers** • Advise it is imperative that formulated beverages are not presented in any way that could lead consumers to believe they have therapeutic benefits. • Recommend that as they are proposed to be regulated as foods, formulated beverages must be clearly presented for food use only. • Consider it could be misleading to consumers who view formulated beverages as a significant source of vitamins and minerals as the quantity which may be added is necessarily limited to 10-25% RDI per reference quantity (and 100% for vitamin C) which may not be nutritionally significant.
27	**Unilever Australasia** Julie Newlands	**Support modified Option 2** **General comments** • Note as a member company of the AFGC and participant in the AFGC working group on this Application, support the comments in the AFGC submission (see above). o In particular, support comments about the inflexible drafting proposed. o Note the development within Standard 2.6 is inconsistent with how other fortified foods have been regulated and adds complexity to the overall structure of the Code. • Request further consideration of Application in a more consistent manner to other fortified foods and/or beverages that are currently regulated to ensure the Code is structured in a more logical manner. • Request the NZDSR are reviewed to ensure the proposed formulated beverage definition proves to be at least a part solution to this broader issue.

No.	Submitter	Submission Comments
		Definition • Consider the proposed definition and permitted ingredients extremely prescriptive and sets up a situation where only beverages that meet the definition of a fruit juice drink are permitted to be fortified, yet this has a much broader potential applicability for water-based beverages. o Suggest this will stifle product innovation. o Note potential ingredients identified for addition to formulated beverages for the purpose of adding flavour or variety, such as vegetable juices, herbs, spices, tea components, dairy components will require a subsequent application to change the definition.
28	**Victorian Department of Human Services** Victor Di Paola	**Support Option 2*** **Target group** • Note concern that one or more manufacturers will be specifically targeting formulated beverages to children. **Fortification policy guideline** • Consider the Application does not comply with the voluntary fortification policy guidelines. • Believe the removal of a number of vitamins and minerals from consideration and imposing a limit on total sugars ensure Option 2 (if accepted) will achieve compliance with both the voluntary fortification policy guidelines and the national dietary guidelines. **Risk Assessment** *Dietary modelling* • Note that the national dietary intake data referenced in the DAR is out of date and therefore unreliable. **Impact analysis** • Note the possibility there may be a dietary benefit if consumers move away from consuming soft drinks and consume formulated beverages due to the lower sugar intake.

No.	Submitter	Submission Comments
29	**WA Food Advisory Committee, WA Department of Health** Paul Van Buynder	**Support Option 1** **General comments** • Note the Application has not provided sufficient evidence that formulated beverages protect public health and safety or bestow public health of consumers. • Recommend the Application does not progress until FRSC develops policy guidance on the fortification of food and food-type dietary supplements. • Believe this would provide consistency in food regulations and greater public health safety, meet risk concerns and enhance consumer confidence in products in both the Australian and New Zealand markets. **Regulatory options** • Consider the recommendation for Option 2 is predominately based on trade and marketing issues and the opportunities they represent. **Fortification policy guideline** *Appropriateness of food vehicle* • Refer to public health nutrition policy, Australian Dietary Guidelines and the Australian Guide to Healthy Eating, which states fluids should comprise water and milk. <u>Health benefit/deficiency</u> • Comment that no nutritional needs or health benefit was identified for beta-carotene, vitamin C, thiamin, niacin, pantothenic acid, vitamin B12, manganese or phosphorus although all but vitamin A are to be permitted. • Suggest that without additional information on a healthy diet, the addition of formulated beverages to the diet is unlikely to rectify clinical or sub-clinical deficiencies. **Reference quantity/serving size** • Believe further consideration of safety should be given to the recommended serving sizes, as described by manufacturers of formulated beverages. **Risk assessment** • Believe further consideration of safety should be given to the following: o usual dietary intake; o additional fortified food consumption and/or dietary supplements.

No.	Submitter	Submission Comments
		Bioavailability • Comment that the bioavailability of added vitamins and minerals in formulated beverages should be considered if they are to overcome clinical or sub-clinical deficiencies, or increase low-level intakes. *Dietary modelling* • State the dietary modelling was severely restricted by lack of in formation on food consumption. **Total sugar and energy content of formulated beverages** • Note the restriction of sugar was designed to minimise the risks of increased energy and sugar intake however state that the addition of 45 g of sugar (765 kJ) in a 600 ml serve or larger is not consistent with Australian Dietary Guidelines to moderate consumption of sugar. *Risk of overweight and obesity* • Suggest that the amount of sugar be viewed in the context of the increasing consumption of beverages containing sugar and links to obesity. Also note the growing body of evidence linking sugar intake to obesity. **Labelling** • Highlight possible risks to children and pregnant women of over consumption when the above factors are considered and warning statements on labels are not mandatory. **Potential to mislead consumers** • Suggest consumer perceptions on the value of added vitamins and minerals to foods with little other nutritional value could result in the impression of dietary adequacy from consumption of these beverages. **Other comments** *Education* • Note FSANZ research into formulated beverages and support the suggestion that enhanced education programs are required to assist consumers in deciphering label information and making informed decisions. However note the responsibility and costs of consumer education must take a holistic view incorporating industry, Commonwealth and State resources. • Welcome any advice from FSANZ on what additional resources are available which may be earmarked to undertake education.

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30	**Zenica BioPlus Pty Ltd** Gary Incledon	**No option specified** **Risk Assessment** <u>Vitamins and minerals</u> • Note the Nutrition Assessment recognised the 'nutrition and health need' for adding zinc to formulated beverages. • Consider the extrapolation method for children based entirely on body weights (compared to adults), results in lower UL's for children than has been reported elsewhere (e.g. FAO/WHO Human Vitamin and Mineral Requirements report). • Note the zinc UL used for children up to 8 years of age (7-12 mg/day) results in an assessment that 'children up to 8 years of age are predicted to exceed the UL at the high level of dietary intake for baseline and Scenario 2'. • Consider the conclusion that zinc intakes for children aged 2-3 years exceed the UL's, therefore posing sufficient risk to disallow zinc to be added to formulated beverages for the general population, is giving disproportionate influence to this age group which is not referred to as a current or potential target for formulated beverages nor likely to consume formulated beverages. • Recommend the UL used for children should be revised to the level used in the FAO/WHO Report, i.e. 23-28 mg/day. • Demonstrate that applying the FAO/WHO UL's, result in none of the zinc intakes for any age group exceed the UL at baseline or scenario 2 (detailed in submission). Conclude, zinc could be permitted to be added to a formulated beverage at a level of 25% RDI per 600 ml serve. **References** • Human Vitamin and Mineral Requirements – Report of a joint World Health Organisation/Food and Agriculture Organisation of the United Nations Expert Consultation. http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/004/Y2809E/y2809e00.htm • Trace Elements in Human Nutrition and Health – World Health Organisation, Geneva (prepared in collaboration with the Food and Agriculture Organisation of the United Nations and the International Atomic Energy Agency.

Late submissions

1	***Food Technology Association of Victoria Inc*** *David Gill*	**Support Option 2** **Regulatory options** • The majority opinion of the Technical Sub Committee was to accept Option 2. • A minority of the Committee expressed an opinion that Option 3 should be accepted for the following reasons: o that an equitable situation would then exist between Australia and New Zealand and the NZDSR could be withdrawn; and o that manufacturers and market forces should determine the viability of products and not prescriptive Standards. • The whole Committee supported the request for the NZDSR to be rescinded with the introduction of the new Standard.
2	***New Zealand Dietetic Association*** Carole Gibb	**Support Option 2** • Believe that a thorough impact analysis has been conducted on the nutritional impact of Option 2 and agree that the health and safety of consumers is protected through limits on the level of fortification to ensure safe levels of consumption, and by excluding specific nutrients that could be potentially hazardous, or where their safety cannot be verified.