Attachment 7

Dietary Modelling Methodologies for Nutrient Intake Assessment Application A470 – Formulated Beverages

Introduction

An application was received by FSANZ requesting that a standard to be added to the Food Standards Code (the Code) for formulated beverages (FB), with an FB being a water–based, non-alcoholic flavoured drink with added vitamins and minerals. It was requested that the FB standard allow for the addition of vitamins and minerals at concentrations sufficient to allow claims of 'source of' or 'good source of'.

A dietary intake assessment was deemed necessary in order to determine the impact of permitting a range of nutrients to be added to FB. The impact was assessed in two ways:

1. determining whether the added nutrients would pose a risk to public health and safety; and
2. determining whether there is 'nutrient inadequacy' in the population, or whether there would be a 'health benefit' from allowing the addition of vitamins and minerals to FB. For example, would consumption of these products address the identified nutrient inadequacy, assuming they replaced specified beverages.

In order to assess safety, estimated intakes of the nutrients were compared with an upper level of intake (UL). To assess whether there is likely to be any inadequacy, the estimated dietary intakes were compared to estimated average requirements (EARs). Where inadequacy or potential health benefits for a nutrient of permitting FB with added vitamins and minerals were identified, nutrient intakes were then compared to the EAR to determine whether the consumption of FB has the capacity to address the inadequacy or provide a health benefit.

Results of the dietary intake assessments for nutrients can be found in other attachments. Attachment 6 Risk Assessment - Micronutrients, includes estimated intakes for nutrients and comparison with the ULs. Attachment 5 – Nutrition Assessment includes estimated intakes and comparison with EARs and an outline of the percentage of the population below this standard. These attachments also highlight specific information that was relevant to the modelling for each nutrient.

The methodologies and results for the exposure assessments for the food additives are at Attachment 8 – Risk Assessment - Food Additives.

Background

FB are currently sold in New Zealand under Dietary Supplements regulations. These products contain nutrients such as pantothenic acid and vitamin C. FB are not currently permitted to be manufactured in Australia and then sold on the Australian market, however, they can be imported from New Zealand under the Trans Tasman Mutual Recognition Arrangement (TTMRA) and sold on the Australian market.

The Applicant requested that FB be permitted to contain nutrients at the maximum claimable level of 25% of the recommended dietary intake (RDI) (except for vitamin C which is at 100% of the RDI). The Applicant provided a list of the requested quantities of vitamins and minerals in a reference quantity (600 ml) of FB. These concentrations were converted to mg/100 g, µg/100 g or mg/kg concentrations for use in the DIAMOND program. The requested nutrient concentrations are listed in Table 1.

Table 1: Proposed concentration levels of nutrients in formulated beverages, as requested by the Applicant

Type of Nutrient	Nutrient Name	Concentration Level to be used in FB	
		(units/600 ml)	units/100 g
Vitamin	Vitamin A (µg)	187.5	31.3
	Thiamin (mg)	0.275	0.046
	Riboflavin (mg)	0.425	0.071
	Niacin (mg)	2.5	0.42
	Folate (µg folic acid)	50	8.3
	Vitamin B_6 (mg pyridoxine)	0.4	0.07
	Vitamin B_{12} (µg)	0.5	0.08
	Vitamin C (mg)	40	6.7
	Vitamin D (µg)	2.5	0.42
	Vitamin E (mg)	2.5	0.42
	Biotin (µg)	7.5	1.25
	Pantothenic Acid (mg)	1.25	0.21
Mineral	Calcium (mg)	200	33
	Chromium (µg)	50	8.3
	Copper (mg)	0.75	0.13
	Iodine (µg)	37.5	6.3
	Iron (mg)	3	0.5
	Magnesium (mg)	80	13.3
	Manganese (mg)	1.25	0.21
	Molybdenum (µg)	62.5	10.4
	Phosphorus (mg)	250	41.7
	Selenium (µg)	17.5	2.9
	Zinc (mg)	3	0.5

Dietary intake assessment provided by the Applicant

The Application did not provide any estimates of nutrient intakes resulting from the consumption of FB. Therefore, FSANZ conducted dietary intake assessments for the nutrients requested.

Dietary modelling

The dietary intake assessments were conducted using dietary modelling techniques that combine food consumption data with food composition data to estimate the intake of the nutrient from the diet. The dietary intake assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary intake = nutrient concentration x food consumption

The intakes were estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with either naturally occurring nutrient levels, levels of nutrient fortification and/or proposed levels of use of the nutrients in foods.

The requested nutrients were assessed in two separate ways:

1. To assess the safety of the nutrient intakes – estimated nutrient intakes were compared to ULs (see results in Attachment 6 – Risk Assessment - Micronutrients).
2. Nutrients were assessed against the fortification policy. Where it may be determined that there is a need for additional levels of the nutrients in the diet due to inadequate intakes, or where it may be determined that fortification would provide a health benefit, intakes were compared to EARs (see results in Attachment 5 – Nutrition Assessment).

Where no UL had been set for a nutrient or where there were no safety concerns, no modelling to assess safety was conducted. Additionally, for some nutrients there were insufficient concentration data, therefore, modelling was unable to be conduced for these nutrients.

Dietary survey data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

It is recognised that nutrient intakes in a 24-hour period are not representative of nutrient intakes over a longer period of time.

For both NNSs, a second day of food consumption information was collected from approximately 10% of respondents for Australia and 15% for New Zealand. FSANZ can take into account second day nutrient intakes by using factors for adjusting the first day intake to gain a more accurate reflection of what daily nutrient intakes would be across a population over a longer period of time. This information has been used for the majority of the intake assessments for nutrients in this Application. Second day adjustments will have little or no impact on estimated mean nutrient intakes, but would likely reduce estimated one-day 95th percentile nutrient intakes.

Second day nutrient adjustments were not calculated for some population groups for retinol (Australians aged 14 years and above and New Zealanders aged 19 years and above) or for some population groups for Vitamin D (for Australians aged 4-18 years) since an adjustment factor could not be obtained for these nutrient/age group combinations due to small consumer numbers of foods containing retinol. Second day nutrient adjustments were also not calculated for iodine (Australia and New Zealand) and selenium (Australia only). This is because iodine was not included in the NNS of either country and selenium was not included in the Australian NNS. Therefore, the nutrient intakes were calculated using a different methodology in DIAMOND. This methodology does not include a component for adjusting estimated intakes as it only includes consumption data from the first 24-hour recall.

Conducting dietary modelling based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food and the resulting estimated intake of a nutrient. However, it should be noted that limitations exist within the NNS data. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected.

Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since 1995/1997 (Cook et al, 2001). However, there is uncertainty associated with the consumption of foods that may have changed in consumption since 1995 or 1997 or that have been introduced to the market since 1995/1997.

Additionally, there may be more foods on the market now that are fortified than was the case in 1995 or 1997 when the food composition databases for the NNSs were established, therefore, some of the baseline nutrient intakes for some nutrients may not take this into consideration.

Additional food consumption data or other relevant data

The 1995 and 1997 NNSs did not report any consumption of FB. Market share data were therefore required to enable dietary modelling to be conducted for this Application. The Applicant provided a report (Leatherhead Food International, 2003) that detailed the consumption of functional soft drinks in an international context. Using German data on the percentage of the soft drinks market held by functional soft drinks (4.1%), FSANZ assumed that formulated beverages will replace 5% of the non-alcoholic beverages market (excluding milk). These data were only used in the assessment of nutrient intakes not food additive exposures. How these data were used will be discussed below in more detail in "Scenarios for nutrient dietary modelling".

The Applicant also provided data on the types of beverages that are likely to be replaced by FB. These data were used in the assessment of nutrients and food additives.

No other information was required or identified for the purpose of using in the dietary intake estimates.

Scenarios for nutrient dietary modelling

For nutrients, three different scenarios were examined:

1. Baseline

'Baseline' nutrient assessments, based on the 1995/1997 NNSs' food consumption data, were conducted to estimate current nutrient intakes before permission before FB are permitted to be manufactured and sold in both Australia and New Zealand with added vitamins and minerals.

For the baseline assessment of folic acid, it was assumed that only breakfast cereals contained folic acid. The levels of folic acid in breakfast cereals were determined using the labelled quantities of folate in the cereals.

Baseline estimates were estimated for the nutritional inadequacy/health benefit assessment (see Attachment 5) and for the safety assessment (see Attachment 6).

2. Market Share Scenario (Scenario 1)

Scenario 1 assessed the impact on nutrient intakes over the long term and across the population. In this scenario, it was assumed that 5% of all non-alcoholic beverages (excluding milk and milk based beverages) would be replaced with FB.

The foods substituted include tea and coffee, cordials, carbonated drinks, fruit juices, fruit juice drinks, sports drinks, bottled water and tap water (as used as a beverage or to make up a beverage).

This scenario was used for the nutritional benefit assessment only (see Attachment 5). For assessing nutrient inadequacy or a health benefit, estimated nutrient intakes are compared to an EAR. For this type of modelling, the data used for the assessment and the assumptions made need to be as realistic as possible, so as to not overestimate intakes and therefore underestimate the extent of any possible level of deficiency.

3. 100% Substitution Scenario (Scenario 2)

Scenario 2 assessed nutrient intakes when people remove specified beverages from their diet and include formulated beverages in the place of these beverages. The food groups substituted were cordials (excluding those made up from powder), carbonated drinks, fruit juice drinks, sports drinks and bottled water.

This scenario was used for the safety assessment (see Attachment 6). For assessing the safety of nutrient intakes, estimated nutrient intakes are compared to ULs. For this type of modelling, a 'worst case' approach is normally taken in order to determine the upper end of possible nutrient intakes and therefore the likelihood of potential safety concerns.

There were several nutrients that were only assessed against the UL for the added sources of the nutrient. This was due to the ULs being applicable only to supplementary sources of the nutrient in the diet. These nutrients included folic acid, niacin (nicotinic acid) and magnesium. For scenario 2 for these nutrients, nutrient intakes from FB were included in the estimated intakes from added sources in the diet.

Population groups assessed

The dietary intake estimates were conducted for both the Australian and New Zealand populations and compared to EARs and/or RDIs and/or ULs, where relevant. Depending on the nutrient, the age groups listed against one of these reference health standards may differ from the age groups listed for another reference health standard. For many nutrients, there are different EARs and/or RDIs for males and females. Consequently, nutrient intakes were estimated for both males and females for all nutrients for comparison against the EAR and RDI. Generally, the ULs were not different for males and females for the nutrients examined in this application. Consequently, for comparison against ULs, nutrient intakes have been calculated for different age groups but not genders.

Nutrient concentration levels

The levels of nutrients in foods used in the intake assessments at baseline were from the nutrient datasets developed for each of the NNSs. Vitamin B_6, Vitamin B_{12}, Vitamin D, Vitamin E, manganese and copper were not examined in the 1995 Australian NNS. Therefore, in order to estimate intakes for the Australian population for these nutrients, the concentration data from the 1997 New Zealand NNS were matched to the most appropriate Australian food code and these values were used to estimate dietary intakes for the Australian population groups. Where no data from the New Zealand NNS were directly applicable for Australian NNS foods, nutrient concentration data, predominantly from the United States, were used.

US data were used as they were easily and freely accessible from the United States Department of Agriculture (USDA) website (http://www.nal.usda.gov/fnic/foodcomp/search/).

For the majority of nutrients, concentrations were assigned to each individual food from the NNSs in DIAMOND. Scenario concentrations for foods nominated as replacement beverages for FB were added by FSANZ and replaced the baseline concentration for the particular scenario being run. For example, food code 11330101 Fruit Drink, Apple from the 1995 Australian NNS has a calcium concentration of 3 mg/100 g at 'Baseline', 5 mg/100 g for Scenario 1, and 33 mg/100 g for Scenario 2, assuming apple drink was replaced by a FB for Scenario 1 and 2 according to assumptions discussed earlier.

The Applicant provided concentrations of nutrients in FB in units/reference quantity (600 ml). These were converted to mg/100 g or µg/100 g concentrations, or mg/kg concentrations for use in the DIAMOND program, depending on the dietary intake assessment methodology used.

Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry. As a consequence, some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997. Since the data were collected for the NNSs, there has been an increase in the range of products that are fortified with nutrients. Therefore, if fortified foods have appeared on the market since 1995/1997, these foods were not taken into consideration in the nutrient intake assessment. An exception to this was the assessment for folic acid where it was assumed that only breakfast cereals are fortified with folic acid and that the level of folic acid in the breakfast cereal is equal to the labelled quantity of folate for those products. For nicotinic acid and magnesium, it was assumed that there were no foods with added sources of these nutrients at baseline.

For some nutrients, the form of the nutrient used in the assessment against the EAR or RDI differs from that used in the assessment against the UL. For example, total folates have been compared to the EAR while folic acid has been compared to the UL.

In the assessments for iodine (for Australia and New Zealand) and selenium (Australia only), analytical data from sources such as food composition data and surveys were used for the dietary intake assessment (see Appendix 1).

The concentrations of iodine in foods were only available from a limited number of sources. For Australia, the intake estimate was based primarily on unpublished 22nd Australian Total Diet Survey (TDS) data. For New Zealand, the intake estimate was based primarily on the data from the 2003/2004 New Zealand TDS and then the 1997/1998 New Zealand TDS. However, where data gaps existed in the Australian data, New Zealand data were used, and visa versa. Following the use of the most recent TDS data, unpublished data from the Australian or New Zealand food composition programs were used for the respective countries. If data gaps still existed, international food composition data (German and UK) were used. For Australia, information from A493 – Iodine as a Processing Aid was also used.

The concentrations for selenium for the Australian intake assessments were all based on survey data collected from a number of sources around Australia for proposal P157 – Metal Contaminants in Foods.

There were no food composition data available to enable a comprehensive dietary intake assessment to be conducted for chromium, molybdenum, biotin and pantothenic acid. Whilst there are small amounts of data available, these data were either not from Australian or New Zealand sources, were not extensive enough across the whole diet or were not in the correct format or had not been assessed for accuracy. Therefore, these nutrients were not able to be assessed in the dietary modelling.

How were the estimated dietary intakes calculated?

The DIAMOND program allows nutrient concentrations to be assigned to individual foods in the DIAMOND program within the 'nutrient intake model' (NIM). There were two nutrients (selenium for Australia only and iodine for both Australia and New Zealand) for which no nutrient concentration data were set up in the NIM in DIAMOND. Consequently, a 'chemical intake model' (CIM) was used in the assessment of these nutrients. In a CIM, foods are grouped according to raw commodity classification codes and analytical data are assigned to relevant raw commodity classification codes (see Appendix 1). This means that instead of individual foods in from the NNS being assigned an individual nutrient concentration level (as in the NIM), one concentration is used to represent a single raw commodity, which may be made up of one or more individual foods from the NNS. This means there is less variation in the nutrient concentrations for a food in the CIM. Where analytical information was available on individual raw commodities and these concentrations differed from that of the broader raw commodity group, the more specific nutrient concentrations were used. For example, the raw commodity group DF Dried Fruit has an iodine concentration of 13 μg/kg while DF0269 Dried Grapes has an iodine concentration of 17 μg/kg.

The intake of each nutrient was calculated for each individual in the NNSs using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of the nutrient by the amount of food that an individual consumed from that group in order to estimate the intake of the nutrient from each food. Once this has been completed for all of the foods containing the nutrient, the total amount of the nutrient consumed from all foods is summed for each individual. Population statistics (mean and high percentile intakes) are then derived from the individuals' ranked intakes.

For both NNSs, a second day of food consumption information was collected from approximately 10% of respondents for Australia and 15% for New Zealand. To take into account second day nutrient intakes, factors are calculated for adjusting the first day intake to gain a more accurate reflection of daily nutrient intakes over a longer period of time. The adjustment factor is calculated by taking into account several factors including each persons day 1 intake, the mean intake from the group on day 1, the standard deviation from the day 1 sample and the between person standard deviation from the day 2 sample. (For more information on the methodology of adjusting for second day intakes, see the Technical Paper on the National Nutrition Survey: Confidentialised Unit Record File (ABS, 1998). The nutrient adjustment factor is applied to each individuals' intake before population statistics are derived.

Where estimated intakes are expressed as a percentage of the reference health standard, each individual's adjusted nutrient intake is calculated as a percentage of the reference health standard (using the intake in units per day), the results are then ranked, and population statistics derived.

The percentage of each population group over or under a reference health standard was calculated by assessing each individuals' intake for a nutrient, and comparing it with the level of the relevant standard, then counting the number of respondents above or below the standard, then calculating that as a percent of the total number of respondents in the age/gender group being assessed.

Uncertainties in the nutrient intake assessments

Where there are uncertainties in the data used for dietary intake assessments, assumptions normally have to be made. Some of the uncertainly associated with the intake estimates for nutrients are outlined below.

It is not known what beverages consumers will actually substitute with an FB. Whilst the Applicant provided some information on the products currently on the market that would be substituted with FB, there is uncertainty about what consumers will actually do when given the choice between a beverage they may normally consume and an FB. Additionally, it is not known exactly what volume of FB people are consuming, as there are no data in the NNSs and no survey data available.

Assumptions in the nutrient dietary modelling

The aim of the dietary intake assessments was to make as realistic an estimate of dietary intake as possible. However, where significant uncertainties existed in the data, conservative assumptions were generally used to ensure that the dietary intake assessment did not underestimate intake. This was the case when the percent market share held by FB in Scenario 1 was rounded to be 5%, and when the maximum claimable concentrations of the nutrients in the FB were used in the dietary modelling.

Assumptions made in the dietary modelling include:

- consumption of foods as recorded in the NNS represent current food consumption patterns; in the 100% substitution scenario, if a consumer drank one or more types of substituted beverages, all of these beverages will be substituted with an FB product
- consumers always select the FB containing nutrient being assessed;
- consumers do not alter their food consumption habits besides to substitute non-FB with an FB;
- consumers do not increase/decrease their consumption of foods/food groups upon FB becoming available;
- all of the nutrients in the FB are absorbed by the body;
- endogenous production of nutrients (where relevant) has not been included in the dietary intake assessment;

naturally occurring sources of nutrients have been included in the dietary intake assessment for most of the nutrients. This was not relevant for the assessment of added sources of niacin (nicotinic acid) and magnesium and for the assessment of folic acid;

concentrations of nutrients in the FB are the maximum claimable amounts, (which may be smaller than the added amounts as highlighted in the Application);

for iodine assessments, where the concentration of iodine in a food was reported as being less than the Limit of Detection (LOD) or Limit of Reporting (LOR), then the iodine concentration of the food was equal to half of the LOD or LOR value. The LOD is the lowest concentration of a chemical that can be qualitatively detected using a specified laboratory method and/or item of laboratory equipment (i.e. its presence can be detected but not quantified). The LOR used in this assessment has been established at the Limit of Quantification (LOQ) which is the lowest concentration of a chemical that can be detected and quantified, with an acceptable degree of certainty, using the specified laboratory method;

where there were no Australian nutrient concentration data for specific food groups, it was assumed that New Zealand data were representative of these food groups, and vice versa for New Zealand. (Many of the New Zealand food composition data and the data in the New Zealand NNS are based on Australian food composition data);

where Australian or New Zealand concentration data were not available for certain foods, it was assumed that other international data (from either the UK, Germany or the US) were representative of the Australian and New Zealand concentrations in these foods;

where a food was not included in the intake assessment (which is mostly applicable to the CIMs), it was assumed to contain a zero concentration of the nutrient being assessed;

there is a 5% market share for the use of FB in the Australian and New Zealand non-alcoholic beverage (excluding milks) market for scenario 1;

for the nutrients assessed using a CIM, where a food has a specified nutrient concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. iodine in carrot which is used to make a carrot cake or coleslaw;

there is no consumption of iodine through discretionary salt use (since NNSs did not measure discretionary salt use);

there are no reductions in nutrient concentrations from food preparation or due to cooking;

for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. milk, yoghurt); and

there is no contribution to nutrient intakes through the use of complementary medicines (Australia) or dietary supplements (New Zealand).

These assumptions are likely to lead to conservative estimates of dietary intake for nutrients.

Limitations of the dietary modelling

Whilst for the majority of nutrients an adjusted nutrient intake was able to be calculated using second day 24-hour recalls from the NNSs, for a small number of nutrients this was not possible. A limitation of estimating dietary intake over a period of time associated with the dietary modelling for these few nutrients is that 24-hour dietary survey data lead to over-estimates of habitual nutrient intakes for high consumers of those nutrients.

For example, daily food consumption amounts for occasionally consumed foods based on 24 hour food consumption data would be higher than daily food consumption amounts for those foods based on a longer period of time; for example, seafood.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry. As a consequence, another limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997. Since the data were collected for the NNSs, there has been an increase in the range of products that are fortified with nutrients. Consequently, the nutrient databases from the NNSs may not be entirely representative of the nutrient levels in some foods that are now on the market.

There are no data in DIAMOND on the use of complementary medicines (Australia) or dietary supplements (New Zealand). Consequently, these could not be included in the dietary intake assessment. This will underestimate nutrient intakes for those people in the population who take vitamin or mineral supplements. This is a particularly relevant limitation for those nutrients that are assessed for safety against the ULs that are derived for supplemental or added sources in the diet.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic intake estimate. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand National Nutrition Survey so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary intake assessments because population weights were not used.

The recently approved application A493 (Iodine as a Processing Aid) that deals with the application of an iodine sanitiser wash to foods can cause the presence of additional iodine in foods due to residual iodine from the wash. These additional iodine concentrations have not been taken into consideration when assessing iodine intakes for this application. Calcium in fortified foods (such as orange juice and biscuits) have not been taken into account in the estimated intakes of calcium.

References

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Attachment 8

Risk Assessment – Food Additives
Application 470 – Formulated Beverages

Summary and conclusions

A risk assessment has been conducted on 57 food additives/additive groups requested by the Applicant to be added to formulated beverages. All of these food additives are currently permitted in Standard 1.3.1 – Food Additives.

Hazard identification and characterisation

FSANZ has not performed an independent hazard identification and characterisation of the 57 food additives, but has relied upon the assessment reports from the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA has established numerical Acceptable Daily Intakes (ADIs)[1] for some, and established an ADI 'not specified'[2] for many in this group. For several, there was not enough data available to perform an assessment.

Dietary exposure assessment

Dietary exposure assessments were conducted only on those food additives with a numerical ADI, i.e., those where there was a potential for safety concerns if the exposure significantly increased. For the majority of the food additives, the dietary exposure either did not change or changed very little when formulated beverages were included in the modelling.

Risk Characterisation

Food additives which have an ADI 'not specified' or and ADI which is sufficiently high to allow GMP use for the additive in food

For the additives with an ADI 'not specified'. dietary exposure assessments were not conducted, since these food additives are considered to have low toxicity and would not be expected to pose a public health and safety risk as a result of their use in formulated beverages.

Food additives, which have a numerical ADI

For the additives for which a numerical ADI existed, dietary exposure assessments were conducted. The risk characterisation concluded that the addition of the following food additives to formulated beverages at the requested concentration would pose no additional public health and safety risk: tartrazine, quinoline yellow, sunset yellow, azorubine, amaranth, ponceau 4R, allura red, indigotine, brilliant blue, fast green, brilliant black, brown HT, sorbates, sulphites, calcium disodium EDTA, sucrose acetate isobutyrate, glycerol ester of wood rosin, and dioctyl sodium succinate.

In the case of annatto, benzoates, acesulphame potassium (ace K), saccharin and alitame, the dietary exposure assessment predicted that there could be an increase in exposure as a result of their use in formulated beverages. This apparent increase is the result of the assumptions made about which beverages were substituted with formulated beverages in the dietary model used, and the current permissions in these particular beverages. Even taking into account these apparent increases in exposure, no public health and safety concerns were raised.

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[1] JECFA defined the ADI *as an estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk*

[2] JECFA defined the term '*ADI not specified' to mean that, on the basis of available data (chemical, biochemical, toxicological, and other), the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not represent a hazard to health.*

Overall conclusion of the risk assessment

On the basis of currently available information, even using very conservative modelling, it can be concluded that, the addition of the requested 57 food additives/additive groups to formulated beverages would not raise any public health and safety concerns.

Introduction
This Attachment details the risk assessment for those food additives proposed for use in formulated beverages (FBs).

The Applicant requested that 57 food additives/food additive groups be approved for use in FBs including colourings, intense sweeteners, preservatives, emulsifiers, modifying agents and flavourings. The additives and the maximum concentration levels to be used in FBs are shown in Table 1. Many of the requested concentrations are the same as those used in similar beverages, such as water-based flavoured drinks and fruit juice-based beverages.

Hazard identification and characterisation
FSANZ has not performed an independent hazard identification and characterisation of the requested food additives, but has relied upon the assessment reports from the FAO/WHO Joint Expert Committee on Food Additives (JECFA).

JECFA has assessed various food additives and for some of them established Acceptable Daily Intakes (ADIs). For others, not enough data was available to perform an assessment, and others have an ADI 'not specified'. The principles used by JECFA for assessing food additives are available in Environmental Health Criteria 70 (WHO, 1987a).

In the context in which JECFA uses it, the ADI is defined as an estimate (by JECFA) of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk.

There are occasions when JECFA considers the use of an ADI in numerical terms not to be appropriate. This situation arises when the estimated exposure to the additive is expected to be well below any numerical value that would ordinarily be assigned to it. Under such circumstances, JECFA uses the term ADI 'not specified'. The Committee defines this term to mean that, on the basis of available data (chemical, biochemical, toxicological, and other), the total daily exposure to the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health.

Table 1: Food Additives requested by the Applicant to be added to formulated beverages

Schedule 1[$]	Maximum proposed concentration levels to be used in FBs (mg/kg)	Schedule 2	Maximum proposed concentration levels to be used in FBs (mg/kg)
123 Amaranth	30	951 Aspartame	GMP
160b Annatto	10	955 Sucralose	GMP
200-203 Sorbic acid and sorbates	400	957 Thaumatin	GMP
210-213 Benzoic acid and benzoates	400	961 Neotame	GMP
220-225 Sulphur dioxide and sulphites	115		
242 Dimethyl dicarbonate	250		
281-282 Propionates	GMP		
385 Calcium disodium EDTA	33		
444 Sucrose acetate isobutyrate	200		
445 Glycerol ester of wood rosin	100		
480 Dioctyl sodium sulphosuccinate	10		
950 Acesulphame potassium	300		
954 Saccharin	80		
956 Alitame	40		
Schedule 3		**Schedule 4**	
100 Curcumins	GMP	102 Tartrazine	70
101 Riboflavins	GMP	104 Quinoline yellow	70
103 Alkanet (& Alkannin)	GMP	110 Sunset yellow	70
120 Cochineal and carmines	GMP	122 Azorubine	70
140 Chlorophylls	GMP	124 Ponceau 4R	70
141 Chlorophylls, copper complexes	GMP	129 Allura red	70
150a Caramel I – plain	GMP	132 Indigotine	70
150b Caramel II - caustic sulphite process	GMP	133 Brilliant blue	70
150c Caramel III - ammonia process	GMP	142 Green S	70
150d Caramel IV - ammonia sulphite process	GMP	143 Fast green	70
153 Vegetable carbon	GMP	151 Brilliant black	70
160a Carotenes	GMP	155 Brown HT	70
160c Paprika oleoresins	GMP		
160d Lycopene	GMP		
160e Carotenal, b-apo-8'-	GMP		
160f Carotenoic acid, b-apo-8'-, methyl or ethyl esters	GMP		
161a Flavoxanthin	GMP		
161b Lutein	GMP		
161c Kryptoxanthin	GMP		
161d Rubixanthin	GMP		
161e Violoxanthin	GMP		
161f Rhodoxanthin	GMP		
162 Beet Red	GMP		
163 Anthocyanins	GMP		
164 Saffron, crocetin and crocin	GMP		
171 Titanium dioxide	GMP		
172 Iron oxides	GMP		

$ The schedule number reflects to the various schedules in Standard 1.3.1 – Food Additives.

Dietary modelling

The dietary exposure assessments were conducted using dietary modelling techniques that combine food consumption data with food chemical concentration data to estimate the exposure to the food chemical from the diet. The dietary exposure assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary exposure = food chemical concentration x food consumption

The exposures were estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with both current and proposed levels of use of the food chemicals in the foods.

Food consumption data from the 1995 Australian NNS and the 1997 New Zealand NNS were used for the dietary modelling, along with concentration data for the food additives from a variety of sources (including the Code, manufacturers' use data and analytical data from surveys). Populations were assessed as a whole as well as for children aged 2-6 years for Australia. Modelling was conducted to estimated exposures to food additives at baseline (i.e. current exposures) and following the consumption of FBs. Due to the uncertainties in some of the data used for the assessment, certain assumptions needed to be made. These assumptions are likely to lead overall, to a conservative estimate for food additive dietary exposures, in particular the assumption that all beverages in the specified types of beverages will be substituted by a FB and that all foods within a food groups will contain the additive being assessed.

Specific details of how the dietary modelling was conducted can be found at Appendix 1 to this attachment.

What food additives were assessed?

There were 57 additives/additive groups requested by the Applicant to be added to FBs. Of these, dietary modelling was conducted for 23 additive/additive groups, essentially those which have a numerical ADI. For the other additives, the ADI was either 'not specified' or sufficiently high such that the use of the food additive was not limited on the basis of safety considerations. In these cases, the additives are allowed to be used in food according to GMP, on the basis that the additive is very unlikely to be used at a level which would cause safety concerns.

Details of these 23 additives where dietary modelling was performed are shown in Table 2.

Table 2: Food Additives for which dietary exposure assessments were conducted

Schedule 1	Schedule 4
123 Amaranth	102 Tartrazine
160b Annatto	104 Quinoline yellow
200-203 Sorbic acid and sorbates	110 Sunset yellow
210-213 Benzoic acid and benzoates	122 Azorubine
220-225 Sulphur dioxide and sulphites	124 Ponceau 4R
385 Calcium disodium EDTA	129 Allura red
444 Sucrose acetate isobutyrate	132 Indigotine
445 Glycerol ester of wood rosin	133 Brilliant blue
480 Dioctyl sodium sulphosuccinate	143 Fast green
950 Acesulphame potassium	151 Brilliant black
954 Saccharin	155 Brown HT
956 Alitame	

Risk assessment of individual food additives, where dietary modelling was conducted

102 – Tartrazine (Schedule 4)

Hazard identification and Characterisation

Tartrazine was evaluated by the JECFA in 1964, and an ADI of 0-7.5 mg/kg bw was allocated (WHO, 1965). The report did not explain the basis on which the ADI was established.

Dietary exposure assessment

For the baseline estimate of exposure, some food groups were assumed to have concentrations at the maximum permitted level (MPLs) from Standard 1.3.1 – Food Additives in the Code. Some foods were assigned an analytical concentration from the South Australian (SA) food colours survey (South Australia Department of Health, personal communication). Based on information found in the FSANZ Food Additive Database, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 7.1.1 Plain breads, 11.4 Tabletop sweeteners, 12.1.2 Reduced sodium salt mixture, 12.1.3 Salt substitutes, 14.1.3.2 Kola soft drinks and some category 4 foods (Fruits and vegetables) do not contain food colours. Tartrazine is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of tartrazine was present in bottled waters assuming these are replaced with FBs containing tartrazine at that concentration. Kola drinks also contained tartrazine at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to tartrazine between the baseline and the 'FB' scenario.

Table 3: Estimated dietary exposure to 102 – Tartrazine

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13800	1.3 (15)	4.0 (55)
		"FB"	13808	1.3 (20)	4.0 (55)
	2-6 yrs	Baseline	987	2.9 (40)	7.3 (95)
		"FB"	987	2.9 (40)	7.3 (95)
New Zealand	15+	Baseline	4608	1.1 (15)	3.3 (45)
		"FB"	4610	1.1 (15)	3.3 (45)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation

The addition of tartrazine to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to tartrazine below the ADI.

In conclusion, the addition of tartrazine to FB would not pose a public health and safety risk.

104 – Quinoline Yellow (Schedule 4)

Hazard identification and Characterisation
Quinoline yellow was evaluated by the JECFA in 1984, and an ADI of 0-10 mg/kg bw was allocated (WHO, 1984c). JECFA based the ADI for quinoline yellow on data from a long-term study in mice, where no adverse effects were observed at the highest dose tested. A safety factor of 150 was used.

Dietary exposure assessment
For the baseline estimate of exposure, food groups were assumed to have concentrations at the MPLs. The SA food colours survey did not analyse foods for quinoline yellow, therefore there were no actual concentrations that could be used to make the estimated exposures more realistic. No manufacturers' use data were available. Based on information found in the Food Additive Database, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 7.1.1 Plain breads and some category 4 foods (Fruits and vegetables) do not contain food colours. Quinoline yellow is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of quinoline yellow was present in bottled waters assuming these are replaced with FBs containing quinoline yellow at that concentration.

There is no change in estimated dietary exposure to quinoline yellow between the baseline and the 'FB' scenario.

Table 4: Estimated dietary exposure to 104 – Quinoline yellow

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13809	2.4 (25)	6.8 (70)
		"FB"	13810	2.4 (25)	6.8 (70)
	2-6 yrs	Baseline	987	6.2 (60)	12.8 (130)
		"FB"	987	6.2 (60)	12.8 (130)
New Zealand	15+	Baseline	4610	1.8 (20)	4.6 (45)
		"FB"	4610	1.8 (20)	4.6 (45)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation

The addition of quinoline yellow to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed, with the exception of 2-6 year olds at the 95th percentile exposure, have estimated exposures to quinoline yellow below the ADI. Exposure for high consumers of quinoline yellow for 2-6 year olds is estimated to only marginally exceed the ADI (130%).

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of quinoline yellow, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured yellow, and alternative yellow colours could be used. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain quinoline yellow is <1%, which also suggests that the above model is highly conservative. Also, all food groups are assumed to contain quinoline yellow at the MPL, which would not be the case in reality. However, no manufacturers use data were available to refine the exposure estimates. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

In conclusion, the addition of quinoline yellow to FB would not pose a public health and safety risk.

110 – Sunset Yellow (Schedule 4)

Hazard identification and Characterisation
Sunset yellow was evaluated by the JECFA in 1982, and an ADI of 0-2.5 mg/kg bw was allocated (WHO, 1982). JECFA based the ADI for sunset yellow on the absence of adverse effects observed at the highest dose in long-term studies in rats and dogs. A safety factor of 250 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Some foods were assigned an analytical concentration from the SA food colours survey (South Australia Department of Health, personal communication). Based on information found in the Food Additive Database and manufacturer use levels used in the food additive review (ANZFA, 1998, ANZFA, 1999), it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 2.2.1.2 Butter products, 2.2.1.3 Margarine, 7.1.1 Plain breads, 8.2 Processed meat in whole cuts, 8.3 Processed comminuted meat, 8.4 Edible casings, 11.4 Tabletop sweeteners, 12.1.2 Reduced sodium salt mixture, 12.1.3 Salt substitutes, 14.1.3.2 Kola soft drinks and some category 4 foods (Fruits and vegetables) do not contain food colours. Sunset yellow is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of sunset yellow was present in bottled waters assuming these are replaced with FBs containing sunset yellow at that concentration. Kola drinks also contained sunset yellow at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to sunset yellow between the baseline and the 'FB' scenario.

Table 5: Estimated dietary exposure to 110 – Sunset yellow

Country	Population sub-group	Scenario	No. of Consumers	Mean consumer exposure mg/kg bw/day (% ADI)	95th %ile consumer exposure mg/kg bw/day (%ADI)
Australia	2+	Baseline	13772	1.4 (55)	4.2 (170)
		"FB"	13782	1.4 (55)	4.2 (170)
	2-6 yrs	Baseline	986	3.0 (120)	7.8 (310)
		"FB"	986	3.0 (120)	7.9 (310)
New Zealand	15+	Baseline	4583	1.1 (45)	3.3 (130)
		"FB"	4587	1.1 (45)	3.4 (140)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation

The addition of sunset yellow to FB would not result in an increase in estimated dietary exposure for any of the population groups assessed.

The ADI is exceeded for mean consumers aged 2-6 yrs for Australia, and for all population groups assessed for 95th percentile consumers of sunset yellow in Australia and New Zealand, for baseline and scenario estimates.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the specified population groups, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of sunset yellow, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured yellow, and alternative yellow colours may be used. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain sunset yellow is 10%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

Whilst the SA food colours survey provided some information on actual concentrations in some food groups, it did not cover all the food groups that could potentially contain sunset yellow, nor did it provide any indication of the exact proportion of each food category to contain the additive.

In conclusion, the addition of sunset yellow to FB would not pose a public health and safety risk.

122 – Azorubine (Schedule 4)

Hazard identification and Characterisation
Azorubine was evaluated by the JECFA in 1983, and an ADI of 0-4 mg/kg bw was allocated (WHO, 1983a). JECFA based the ADI for azorubine on the absence of adverse effects observed at the highest dose in long-term studies in rats, mice and pigs. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Some foods were assigned an analytical concentration from the SA food colours survey (South Australia Department of Health, personal communication). Based on information found in the Food Additive Database and manufacturer use levels used in the food additive review, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 2.2.1.3 Margarine, 7.1.1 Plain breads, 8.2 Processed meat in whole cuts, 8.3 Processed comminuted meat, 11.4 Tabletop sweeteners, 12.1.2 Reduced sodium salt mixture, 12.1.3 Salt substitutes, 14.1.3.2 Kola soft drinks and some category 4 foods (Fruits and vegetables) do not contain food colours. Azorubine is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of azorubine was present in bottled waters assuming these are replaced with FBs containing azorubine at that concentration. Kola drinks also contained azorubine at the mean concentration from the SA survey assuming these were also substituted.

There is no change in exposure to azorubine between the baseline and the 'FB' scenario.

Table 5: Estimated dietary exposure to 122 – Azorubine

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13597	0.5 (15)	2.1 (50)
		"FB"	13646	0.5 (15)	2.1 (50)
	2-6 yrs	Baseline	983	1.3 (30)	4.6 (110)
		"FB"	983	1.3 (30)	4.6 (110)
New Zealand	15+	Baseline	4550	0.4 (10)	1.7 (45)
		"FB"	4562	0.4 (10)	1.7 (45)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of azorubine to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed, with the exception of 2-6 year olds at the 95th percentile exposure, have estimated exposures to azorubine below the ADI. Exposure for high consumers of azorubine for 2-6 year olds is estimated to only marginally exceed the ADI (110%).

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of azorubine, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured red/maroon, and alternative red/maroon colours may be used.

For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain azorubine is 5%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data. Whilst the SA food colours survey provided some information on actual concentrations in some food groups, it did not cover all the food groups that could potentially contain azorubine, nor did it provide any indication of the exact proportion of each food category to contain the additive.

In conclusion, the addition of azorubine to FB would not pose a public health and safety risk.

123 – Amaranth (Schedule 1)

Hazard identification and Characterisation
Amaranth was evaluated by the JECFA in 1984, and an ADI of 0-0.5 mg/kg bw was allocated (WHO, 1984a). JECFA based the ADI for amaranth on adverse effects observed in rats, where high exposures were found to cause increased renal calcification and lesions in long-term studies, which included in utero exposure. A safety factor of 100 was used.

Dietary exposure assessment
Amaranth has restricted permissions for use in specific food groups as it is included in Schedule 1 of Standard 1.3.1 in the Code.

For the baseline dietary exposure estimate for amaranth, analytical concentration data from the SA food colours survey were used for a range of foods (South Australia Department of Health, personal communication). Manufacturers' use data were also used for some food groups. It was assumed that the category 14.1.3.2 Kola soft drinks does not contain amaranth, based on information on the market leaders in this food group, Coca Cola and Pepsi.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 30 mg/L of amaranth was present in bottled waters assuming these are replaced with FBs containing amaranth at that concentration. Kola drinks also contained amaranth at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to amaranth between the baseline and the 'FB' scenario.

Table 7: Estimated dietary exposure to 123 – Amaranth

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	10266	0.08 (15)	0.3 (60)
		"FB"	10964	0.09 (20)	0.3 (65)
	2-6 yrs	Baseline	922	0.2 (45)	0.6 (130)
		"FB"	926	0.2 (50)	0.7 (140)
New Zealand	15+	Baseline	3092	0.04 (8)	0.1 (30)
		"FB"	3278	0.05 (10)	0.2 (40)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of amaranth to FB would not result in a large increase in dietary exposure for any of the population groups assessed.

All population groups assessed, with the exception of high consumers of amaranth aged 2-6 years from Australia, have estimated exposures to amaranth below the ADI. Exposure for high consumers of amaranth for 2-6 year olds is estimated to only marginally exceed the ADI (130-140%).

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the specified age groups, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of amaranth, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured red/purple, and alternative red/purple colours may be used. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain amaranth is 5%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

Whilst the SA food colours survey provided some information on actual concentrations in some food groups, it did not cover all the food groups that could potentially contain amaranth, nor did it provide any indication of the exact proportion of each food category to contain the additive.

In conclusion, the addition of amaranth to FB would not pose a public health and safety risk.

124 – Ponceau 4R (Schedule 4)

Hazard identification and Characterisation
Ponceau 4R was evaluated by the JECFA in 1983, and an ADI of 0-4 mg/kg bw was allocated (WHO, 1983b). JECFA based the ADI for ponceau 4R on adverse effects observed in mice, where high exposures were found to cause foamy reticuloendothelial cells in liver and glomerulonephrosis in long-term studies. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Some foods were assigned an analytical concentration from the SA food colours survey (South Australia Department of Health, personal communication). Based on information found in the Food Additive Database and manufacturer use levels from the food additive review, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 2.2.1.3 Margarine, 4.3 Processed fruits and vegetables, 7.1.1 Plain breads, 8.2 Processed meat in whole cuts, 8.3 Processed comminuted meat, 11.4 Tabletop sweeteners, 12.1.2 Reduced sodium salt mixture, 12.1.3 Salt substitutes and 14.1.3.2 Kola soft drinks do not contain food colours. Ponceau 4R is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of ponceau 4R was present in bottled waters assuming these are replaced with FBs containing ponceau 4R at that concentration.

Kola drinks also contained ponceau 4R at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to ponceau 4R between the baseline and the 'FB' scenario.

Table 8: Estimated dietary exposure to 124 – Ponceau 4R

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13715	1.1 (25)	3.5 (90)
		"FB"	13731	1.1 (25)	3.6 (90)
	2-6 yrs	Baseline	985	2.2 (55)	6.4 (160)
		"FB"	985	2.2 (55)	6.4 (160)
New Zealand	15+	Baseline	4576	1.0 (25)	3.1 (75)
		"FB"	4580	1.0 (25)	3.1 (75)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of ponceau 4R to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed, with the exception of 2-6 year olds at the 95th percentile exposure, have estimated exposures to ponceau 4R below the ADI.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of ponceau 4R, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured red, and alternative red colours may be used. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain ponceau 4R is 5%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

Whilst the SA food colours survey provided some information on actual concentrations in some food groups, it did not cover all the food groups that could potentially contain ponceau 4R, nor did it provide any indication of the exact proportion of each food category to contain the additive.

In conclusion, the addition of ponceau 4R to FB would not pose a public health and safety risk.

129 – Allura Red AC (Schedule 4)

Hazard identification and Characterisation
Allura red was evaluated by the JECFA in 1981, and an ADI of 0-7 mg/kg bw was allocated (WHO, 1980).

JECFA based the ADI for allura red on adverse effects observed in rats, where high exposures were found to decrease body weight in long-term studies. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Some foods were assigned an analytical concentration from the SA food colours survey. Based on information found in the Food Additive Database and manufacturer use levels from the food additive review, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 2.1.1 Olive oil, 7.1.1 Plain breads, 11.4 Table top sweeteners, 12.1.2 Reduces sodium salt mixture, 12.1.3 Salt substitute, 14.1.3.2 Kola soft drinks and some category 4 foods (Fruits and vegetables) do not contain food colours. Allura red is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of allura red was present in bottled waters assuming these are replaced with FBs containing allura red at that concentration. Kola drinks also contained allura red at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to allura red between the baseline and the 'FB' scenario.

Table 9: Estimated dietary exposure to 129 – Allura red

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13800	1.3 (20)	4.0 (55)
		"FB"	13808	1.3 (20)	4.0 (55)
	2-6 yrs	Baseline	987	2.8 (40)	7.1 (100)
		"FB"	987	2.8 (40)	7.1 (100)
New Zealand	15+	Baseline	4608	1.1 (15)	3.2 (45)
		"FB"	4610	1.1 (15)	3.3 (45)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of allura red to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to allura red at or below the ADI.

In conclusion, the addition of allura red to FB would not pose a public health and safety risk.

132 – Indigotine (Schedule 4)

Hazard identification and Characterisation
Indigotine was evaluated by the JECFA in 1975, and an ADI of 0-5 mg/kg bw was allocated (WHO, 1975). JECFA based the ADI for indigotine on adverse effects observed in rats, where high exposures were found to decrease body weight in long-term studies.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Some foods were assigned an analytical concentration from the SA food colours survey (South Australia Department of Health, personal communication). Based on information found in the Food Additive Database and manufacturer use levels from the food additive review, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 2.1.1 Olive oil, 2.2.1.3 Margarine, 4.3 Processed fruits and vegetables, 7.1.1 Plain breads, 8.2 Processed meat in whole cuts, 8.3 Processed comminuted meat, 8.4 Edible casings, 11.4 Table top sweeteners, 12.1.2 Reduced sodium salt mixture, 12.1.3 Salt substitute and 14.1.3.2 Kola soft drinks do not contain food colours. Indigotine is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of indigotine was present in bottled waters assuming these are replaced with FBs containing indigotine at that concentration. Kola drinks also contained indigotine at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to indigotine between the baseline and the 'FB' scenario.

Table 10: Estimated dietary exposure to 132 – Indigotine

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13715	1.1 (20)	3.5 (70)
		"FB"	13731	1.1 (20)	3.6 (70)
	2-6 yrs	Baseline	985	2.2 (45)	6.4 (130)
		"FB"	985	2.2 (45)	6.4 (130)
New Zealand	15+	Baseline	4576	1.0 (20)	3.1 (60)
		"FB"	4580	1.0 (20)	3.1 (60)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of indigotine to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed, with the exception of 2-6 year olds, have estimated exposures to indigotine below the ADI. Exposure for high consumers of indigotine for 2-6 year olds is estimated to only marginally exceed the ADI (130%).

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of indigotine, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured blue/purple/mauve, and alternative blue/purple/mauve colours may be used. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain indigotine is 5%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

Whilst the SA food colours survey provided some information on actual concentrations in some food groups, it did not cover all the food groups that could potentially contain indigotine, nor did it provide any indication of the exact proportion of each food category to contain the additive.

In conclusion, the addition of indigotine to FB would not pose a public health and safety risk.

133 – Brilliant Blue (Schedule 4)

Hazard identification and Characterisation
Brilliant Blue was evaluated by the JECFA in 1969, and an ADI of 0-12.5 mg/kg bw was allocated (WHO, 1970). JECFA based the ADI for brilliant blue on the absence of adverse effects observed at the highest dose in long-term studies in rats. A safety factor of 250 was used.

Dietary exposure assessment
For the baseline estimate of exposure, all food groups were assumed to have concentrations at the MPLs. Based on information found in the Food Additive Database, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 7.1.1 Plain breads and some category 4 foods (Fruits and vegetables) do not contain food colours. Brilliant blue is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of brilliant blue was present in bottled waters assuming these are replaced with FBs containing brilliant blue at that concentration.

There is no change in exposure to brilliant blue between the baseline and the 'FB' scenario.

Table 11: Estimated dietary exposure to 133 – Brilliant blue

Country	Population sub-group	Scenario	No. of Consumers	Mean consumer exposure mg/kg bw/day (% ADI)	95th %ile consumer exposure mg/kg bw/day (%ADI)
Australia	2+	Baseline	13809	2.4 (20)	6.8 (55)
		"FB"	13810	2.4 (20)	6.8 (55)
	2-6 yrs	Baseline	987	6.2 (50)	12.8 (100)
		"FB"	987	6.2 (50)	12.8 (100)
New Zealand	15+	Baseline	4610	1.8 (15)	4.6 (35)
		"FB"	4610	1.8 (15)	4.6 (35)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of brilliant blue to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to brilliant blue at or below the ADI.

In conclusion, the addition of brilliant blue to FB would not pose a public health and safety risk.

143 – Fast Green FCF (Schedule 4)

Hazard identification and Characterisation
Fast green was evaluated by the JECFA in 1986, and an ADI of 0-25 mg/kg bw was allocated (WHO, 1987b). JECFA based the ADI for fast green on the absence of adverse effects observed at the highest dose in long-term studies in rats. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, all food groups were assumed to have concentrations at the MPLs. Based on information found in the Food Additive Database, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 7.1.1 Plain breads and some category 4 foods (Fruits and vegetables) do not contain food colours. Fast green is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of fast green was present in bottled waters assuming these are replaced with FBs containing fast green at that concentration.

There is no change in exposure to fast green between the baseline and the 'FB' scenario.

Table 12: Estimated dietary exposure to 143 – Fast green

Country	Population sub-group	Scenario	No. of Consumers	Mean consumer exposure mg/kg bw/day (% ADI)	95th %ile consumer exposure mg/kg bw/day (%ADI)
Australia	2+	Baseline	13809	2.4 (10)	6.8 (25)
		"FB"	13810	2.4 (10)	6.8 (25)
	2-6 yrs	Baseline	987	6.2 (25)	12.8 (50)
		"FB"	987	6.2 (25)	12.8 (50)
New Zealand	15+	Baseline	4610	1.8 (7)	4.6 (20)
		"FB"	4610	1.8 (7)	4.6 (20)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of fast green to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to fast green below the ADI.

In conclusion, the addition of fast green FCF to FB would not pose a public health and safety risk.

151 – Brilliant Black (Schedule 4)

Hazard identification and Characterisation
Brilliant black was evaluated by the JECFA in 1981, and an ADI of 0-1 mg/kg bw was allocated (WHO, 1981). JECFA based the ADI for brilliant black on adverse effects observed in pigs, where high exposures were found to cause cysts containing mucus and fibrin in the mucosa of the ileum in short-term studies. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Some foods were assigned an analytical concentration from the SA food colours survey (South Australia Department of Health, personal communication). Based on information found in the Food Additive Database and manufacturer use levels used in the food additive review, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 2.2.1.2 Butter products, 4.3 Processed fruits and vegetables, 7.1.1 Plain breads, 8.2 Processed meat in whole cuts, 8.3 Processed comminuted meat, 8.4 Edible casings, 11.4 Table top sweeteners, 12 Salts and condiments and 14.1.3.2 Kola soft drinks do not contain food colours. Brilliant black is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of brilliant black was present in bottled waters assuming these are replaced with FBs containing brilliant black at that concentration. Kola drinks also contained brilliant black at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to brilliant black between the baseline and the 'FB' scenario.

Table 13: Estimated dietary exposure to 151 – Brilliant black

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13782	1.1 (110)	3.6 (360)
		"FB"	13791	1.1 (110)	3.6 (360)
	2-6 yrs	Baseline	987	2.2 (220)	6.5 (650)
		"FB"	987	2.3 (230)	6.5 (650)
New Zealand	15+	Baseline	4598	1.0 (100)	3.1 (310)
		"FB"	4600	1.0 (100)	3.1 (310)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of brilliant black to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to brilliant black above the ADI, except for consumers of brilliant black at the mean exposure for New Zealand.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of brilliant black, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured black, and there are very few 'black' or very darkly coloured foods in the food supply. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain brilliant black is <1%, which is extremely small in comparison to some of the other food colourings and also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

Whilst the SA food colours survey provided some information on actual concentrations in some food groups, it did not cover all the food groups that could potentially contain brilliant black, nor did it provide any indication of the exact proportion of each food category to contain the additive.

In conclusion, the addition of Brilliant Black to FB would not pose a public health and safety risk.

155 – Brown HT (Schedule 4)

Hazard identification and Characterisation
Brown HT was evaluated by the JECFA in 1984, and an ADI of 0-1.5 mg/kg bw was allocated (WHO, 1984b). JECFA based the ADI for brown HT on adverse effects observed in mice, where high exposures were found to cause reduced body weight gain and heart weight, increased incidence of leucocyte infiltration and an increased incidence of cystic ovaries in long-term studies. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Some foods were assigned an analytical concentration from the SA food colours survey (South Australia Department of Health, personal communication). Based on information found in the Food Additive Database and manufacturer use levels used in the food additive review, it was assumed foods in classification codes 1.3 Condensed and evaporated milk, 1.4.2 Cream products, 1.5 Dried milk, 2.2.1.2 Butter products, 2.2.1.3 Margarine, 4.3 Processed fruits and vegetables, 7.1.1 Plain breads, 8.2 Processed meat in whole cuts, 8.3 Processed comminuted meat, 11.4 Table top sweeteners, 12.1.2 Reduced sodium salt mixture, 12.1.3 Salt substitutes and 14.1.3.2 Kola soft drinks do not contain food colours. Brown HT is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 70 mg/L of brown HT was present in bottled waters assuming these are replaced with FBs containing brown HT at that concentration. Kola drinks also contained brown HT at the mean concentration from the SA survey assuming these were also substituted.

There is little change in exposure to brown HT between the baseline and the 'FB' scenario.

Table 14: Estimated dietary exposure to 155 – Brown HT

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13715	1.1 (70)	3.5 (240)
		"FB"	13731	1.1 (70)	3.5 (240)
	2-6 yrs	Baseline	985	2.2 (140)	6.4 (430)
		"FB"	985	2.2 (150)	6.4 (430)
New Zealand	15+	Baseline	4576	1.0 (65)	3.1 (200)
		"FB"	4580	1.0 (65)	3.1 (210)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation

The addition of brown HT to FB would not result in an increase in dietary exposure for any of the population groups assessed.

The ADI for brown HT is exceeded for mean consumers aged 2-6 yrs for Australia, and for all population groups assessed for 95th percentile consumers in Australia and New Zealand.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the specified population groups, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of brown HT, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured brown, and alternative brown colours could have been used. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain brown HT is 5%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

Whilst the SA food colours survey provided some information on actual concentrations in some food groups, it did not cover all the food groups that could potentially contain tartrazine, nor did it provide any indication of the exact proportion of each food category to contain the additive.

In conclusion, the addition of Brown HT to FB would not pose a public health and safety risk.

160b – Annatto Extracts (Schedule 1)

Hazard identification and Characterisation
Annatto extracts were most recently evaluated by the JECFA in 2003 (WHO, 2004). JECFA could not establish a generic ADI for the various annatto extracts on the basis of the data submitted and therefore established a temporary ADI for each of the individual preparations tested. With the application of a 200-fold safety factor to the NOEL for each of the annatto preparations, the following ADIs were allocated:

Annatto B: 0-7.0 mg/kg bw, based on adverse effects observed in rats, where high exposures were found to cause urinary effects (elevated concentrations of protein in urine and crystals in urine sediment).

Annatto C: 0-0.4 mg/kg bw, based on adverse effects observed in rats, where high exposures were found to cause increases in liver weight accompanied by hepatocellular hypertrophy and necrosis.

Annatto E: 0-4.0 mg/kg bw, based on adverse effects observed in rats, where high exposures were found to cause increases in thyroid and kidney weights and decreased spleen weights.

Annatto F: 0-0.4 mg/kg bw, based on adverse effects observed in rats, where high exposures were found to cause increases in kidney weights, haematological changes and alterations in serum proteins.

No data on the potential toxicity of Annatto D or Annatto G were available, and no ADI could be established. An additional safety factor of 2 was applied to the NOELs, because of deficiencies in the database.

JECFA adopted tentative specifications for the four annatto extracts tested, with the following minimum essay values:

Annatto extract (solvent-extracted bixin) – Annatto B: not less than 85% pigment (as bixin, of which not more than 2.5% is norbixin).

Annatto extract (solvent-extracted norbixin) – Annatto C: not less than 85% pigment (as norbixin).

Annatto extract (aqueous processed bixin) – Annatto E: not less than 25% pigment (as bixin, of which not more than 7% is norbixin).

Annatto extract (alkali-processed norbixin) – Annatto F: not less than 35% pigment (as norbixin).

JECFA also adopted tentative specifications with minimum assay values as proposed for the commercial products annatto D and G, which has not been tested biologically.

For the purpose of this assessment, the ADI for 2 norbixin extracts at a level of 0.4 mg/kg bw was used, which was at a lower level than the ADI for the bixin extracts.

Dietary exposure assessment
Annatto extracts have restricted permissions for use in specific food groups, given in Schedule 1 of Standard 1.3.1 in the Code.

For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Most foods were assigned manufacturer use levels from the food additive review (ANZFA, 1998; ANZFA, 1999). It was also assumed that 40% of yoghurts and 10% of ice cream and edible ice products contained Annatto. Annatto is only currently permitted in fruit juice based beverages. At baseline, annatto was not permitted in water based flavoured drinks or bottled waters as per Standard 1.3.1.

For the 'FB' Scenario the requested maximum level of 10 mg/kg of annatto has been assigned to water based flavoured drinks and bottled waters assuming that a person will replace these beverages with a fruit juice based FB.

The MPLs in the Code do not specify to which annatto extract they apply. FSANZ has some manufacturers use data for annatto extracts specified as being either 'bixin' or 'norbixin' for some foods. However, it is unknown as to what bixin or norbixin extract they apply to. With a lack of any other relevant data on the concentrations of annatto extracts in foods, all manufacturers' use data on annatto extracts available to FSANZ were used in the exposure assessment, without making a distinction between bixin and norbixin. Therefore, there are some significant limitations with the exposure estimates for annatto extracts.

There is an increase in exposure to annatto between the baseline and the 'FB' scenario.

Table 15: Estimated dietary exposure to 160b – Annatto

Country	Population sub-group	Scenario	No. of Consumers	Mean consumer exposure mg/kg bw/day (% ADI)	95th %ile consumer exposure mg/kg bw/day (%ADI)
Australia	2+	Baseline	13515	0.07 (20)	0.2 (60)
		"FB"	13621	0.1 (30)	0.4 (100)
	2-6 yrs	Baseline	981	0.2 (55)	0.6 (150)
		"FB"	983	0.4 (95)	0.9 (230)
New Zealand	15+	Baseline	4570	0.05 (10)	0.1 (35)
		"FB"	4582	0.07 (20)	0.2 (55)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of annatto to FB would result in an increase in dietary exposure for all the population groups assessed.

All population groups assessed, with the exception of 2-6 year olds, have estimated exposures to annatto at or below the ADI.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that for every food category that was assigned a numerical concentration of annatto, every product in that category contained the colour, which in reality is not the case. Only a small proportion of the category would be coloured yellow, and alternative yellow colours may be used. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain annatto is 10%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

For annatto there was a difference in estimated exposures between baseline, representing current permissions, and the scenario model assuming annatto was permitted in FBs. This is because at baseline, neither the bottled water or water based flavoured drinks (e.g. cordial, soft drink) contain annatto. Whereas, when it is assumed that water based flavoured drinks are replaced with FBs that do contain annatto, exposure goes up significantly since beverages are consumed in larger quantities in comparison to solid foods, and if a food additive is in a beverage, the exposure to that additive is likely to be higher.

For annatto a conservative approach was taken with the hazard identification and characterisation, i.e. the lowest available ADI, as established by JECFA, for the various annatto extracts was used. Whether this form of annatto is representative for annatto used in Australia and New Zealand is currently unknown.

In conclusion, the addition of annatto FB would not pose a public health and safety risk.

200 – Sorbic Acid and Sorbates (Schedule 1)

Hazard identification and Characterisation
Sorbates were evaluated by JECFA in 1985, where a group ADI of 0-25 mg/kg bw for sorbic acid and its calcium, potassium and sodium salts was allocated (WHO, 1986). JECFA based the ADI for sorbates on the absence of adverse effects observed at the highest dose in long-term studies in rats. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Most foods were assigned an analytical concentration from the unpublished 21st ATDS results (FSANZ, unpublished). Kola drinks were assumed not to contain sorbates based on information from manufacturers'. This was confirmed by assessing the labels of the two market leaders of kola drinks, Coca Cola and Pepsi, neither of which use sorbates in their products. Sorbates are not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 400 mg/kg of sorbates was present in bottled waters assuming these are replaced with FBs containing sorbates at that concentration. Kola drinks also then contained sorbates at the mean concentration from the ATDS.

There is little change in exposure to sorbates between the baseline and the 'FB' scenario.

Table 16: Estimated dietary exposure to 200-203 – Sorbic acid and sorbates

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	13802	3.6 (15)	10.6 (40)
		"FB"	13808	3.6 (15)	10.7 (45)
	2-6 yrs	Baseline	988	9.1 (35)	22.8 (90)
		"FB"	988	9.2 (35)	22.9 (90)
New Zealand	15+	Baseline	4604	2.8 (10)	8.8 (35)
		"FB"	4607	2.9 (10)	8.9 (35)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of sorbates to FB would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to sorbates below the ADI.

In conclusion, the addition of sorbic acid and sorbates to FB would not pose a public health and safety risk.

210 – Benzoic Acid and Benzoates (Schedule 1)

Hazard identification and Characterisation
Benzoates were most recently evaluated by JECFA in 1996, and an ADI for benzoic acid and sodium benzoate of 0-5 mg/kg bw was allocated (WHO, 1996b). JECFA based the ADI for benzoic acid and its salts on short-term (90 days) and long-term (lifetime) exposure in rats where the adverse effect observed at a low dose level was testicular tubular atrophy. Other adverse effects such as decreased body weight and neurological changes occurred at higher dose levels. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Most foods were assigned an analytical concentration from the unpublished 21st ATDS results (FSANZ, unpublished). Based on market leaders, Coca Cola and Pepsi, it was assumed that regular sugar sweetened kola drinks do not contain benzoates, however artificially sweetened kola drinks do. Benzoates are not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 400 mg/kg of benzoates was present in bottled waters assuming these are replaced with FBs containing benzoates at that concentration. Kola drinks also then contained benzoates at the mean concentration from the ATDS.

There is an increase in exposure to benzoates between the baseline and the 'FB' scenario.

Table 17: Estimated dietary exposure to 210-213 – Benzoic acid and benzoates

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	12807	1.3 (25)	5.2 (100)
		"FB"	12912	1.7 (35)	6.5 (130)
	2-6 yrs	Baseline	966	4.3 (85)	12.0 (240)
		"FB"	967	4.8 (95)	13.5 (270)
New Zealand	15+	Baseline	4177	0.6 (10)	2.4 (45)
		"FB"	4214	0.8 (15)	3.4 (70)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The ADI is exceeded for 95th percentile consumers aged 2 years and above for the FB scenario, and for children aged 2-6 years for Australia at baseline and for the FB scenario.

The addition of benzoates to FB would result in an increase in dietary exposure for all the population groups assessed.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons.

Firstly, it was assumed that where benzoates are used in a food category, all foods within that category contained benzoates at the specified level, which in reality is not the case. Only a small proportion of the category would contain benzoates. For example, the Food Additive Database indicates the maximum proportion of the products in the database that contain benzoates is 5%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

For benzoates there was a difference in estimated exposures between baseline, representing current permissions, and the scenario model assuming benzoates was permitted in FBs. This is because at baseline, neither the bottled water or sugar-sweetened kola drinks contain benzoates. Whereas, when it is assumed that these drinks are replaced with FBs that do contain benzoates, exposure goes up significantly since beverages are consumed in larger quantities in comparison to solid foods, and if a food additive is in a beverage, the exposure to that additive is likely to be higher.

Benzoates were identified during the Review (ANZFA, 1998; ANZFA, 1999) as a cause for concern and placed on the list for future monitoring, which is why benzoates are currently being assessed in the 21st ATDS (FSANZ, unpublished).

In conclusion, the addition of benzoic acid and benzoates to FB would not pose a public health and safety risk.

220 – Sulphur Dioxide and Sulphites (Schedule 1)

Hazard identification and Characterisation
Sulphur dioxide and sulphites were most recently re-evaluated by JECFA in 1998, where the previously allocated group ADI of 0.7 mg/kg bw was maintained (WHO, 1999). JECFA based the ADI for sulphites on adverse effects observed in rats and pigs, where high exposures were found to cause gastric lesions in long-term studies. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, some food groups were assumed to have concentrations at the MPLs. Most foods were assigned an analytical concentration from the unpublished 21st ATDS results (FSANZ, unpublished). Based on market leaders, Coca Cola and Pepsi, it was assumed all kola drinks do not contain sulphites. Sulphites are not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 115 mg/kg of sulphites was present in bottled waters assuming these are replaced with FBs containing sulphites at that concentration. Kola drinks also then contained sulphites at the mean concentration from the ATDS.

There is little change in exposure to sulphites between the baseline and the 'FB' scenario.

Table 18: Estimated dietary exposure to 220-225 – Sulphur dioxide and sulphites

Country	Population sub-group	Scenario	No. of Consumers	Mean consumer exposure mg/kg bw/day (% ADI)	95th %ile consumer exposure mg/kg bw/day (%ADI)
Australia	2+	Baseline	13365	0.5 (75)	1.9 (270)
		"FB"	13445	0.6 (80)	2.0 (280)
	2-6 yrs	Baseline	981	1.2 (180)	4.0 (570)
		"FB"	981	1.3 (180)	4.0 (570)
New Zealand	15+	Baseline	4453	0.3 (45)	1.1 (160)
		"FB"	4464	0.3 (50)	1.2 (170)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation

The addition of sulphites to FB would not result in a large increase in dietary exposure for all the population groups assessed.

The ADI is exceeded for mean consumers of sulphites aged 2-6 yrs for Australia, and for all population groups assessed for 95th percentile consumers for Australia and New Zealand.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was assumed that where sulphites are used in a food category, all foods within that category contained sulphites at the specified level, which in reality is not the case. Only a small proportion of the category would contain sulphites. For example, the Food Additive Database indicates the maximum proportion of the products in that database that contain sulphites is 10%, which also suggests that the above model is highly conservative. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

Sulphites were identified during the Review (ANZFA, 1998; ANZFA, 1999) as a cause for concern and placed on the list for future monitoring, which is why they are currently being assessed in the 21st ATDS (FSANZ, unpublished).

JECFA based the ADI for sulphites on adverse effects observed in rats and pigs, where high exposures were found to cause gastric lesions in long-term studies. As the occurrence of gastric lesions is more likely related to sulphite concentrations in foods than total dietary exposure, potential adverse effects are more likely to be associated with those foods with high concentrations of sulphites. The proposed concentration for sulphite in FB is at a maximum level of 115 mg/kg. This concentration is considerably lower, than that permitted in some other foods (e.g. dried fruits).

In conclusion, the addition of sulphur dioxide and sulphites to FB would not pose a public health and safety risk.

385 – Calcium Disodium EDTA (Schedule 1)

Hazard identification and Characterisation
Calcium disodium EDTA was evaluated by the JECFA in 1973, and an ADI of 0-2.5 mg/kg bw was allocated, calculated as calcium disodium EDTA, no excess of disodium EDTA should remain in foods (WHO, 1974). JECFA based the ADI for calcium disodium EDTA on the absence of adverse effects observed at the highest dose in long-term studies in rats. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, all food groups were assumed to have concentrations at the MPLs. No survey or manufacturers' use data were available to use in the exposure assessment. Calcium disodium EDTA is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 33 mg/L of calcium disodium EDTA was present in bottled waters assuming these are replaced with FBs containing calcium disodium EDTA at that concentration.

There is no change in exposure to calcium disodium EDTA between the baseline and the 'FB' scenario.

Table 19: Estimated dietary exposure to 385 – Calcium disodium EDTA

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	10444	0.3 (10)	1.0 (40)
		"FB"	10548	0.3 (10)	1.0 (40)
	2-6 yrs	Baseline	826	0.8 (30)	2.3 (90)
		"FB"	828	0.8 (30)	2.3 (90)
New Zealand	15+	Baseline	3590	0.2 (7)	0.6 (25)
		"FB"	3603	0.2 (7)	0.6 (25)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of calcium disodium EDTA to FBs would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to calcium disodium EDTA below the ADI.

In conclusion, the addition of calcium disodium EDTA to FB would not pose a public health and safety risk.

444 – Sucrose Acetate Isobutrate (Schedule 1)

Hazard identification and Characterisation
Sucrose acetate isobutrate was most recently evaluated by the JECFA in 1996, and an ADI of 0-20 mg/kg bw was allocated (WHO, 1997). JECFA based the ADI for sucrose acetate isobutrate on the absence of adverse effects observed at the highest dose in long-term studies in rats and dogs. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, all food groups were assumed to have concentrations at the MPLs. No survey or manufacturers use data were available to use in the exposure assessment. Sucrose acetate isobutrate is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 200 mg/L of sucrose acetate isobutrate was present in bottled waters assuming these are replaced with FBs containing sucrose acetate isobutrate at that concentration.

There is little change in exposure to sucrose acetate isobutrate between the baseline and the 'FB' scenario.

Table 20: Estimated dietary exposure to 444 – Sucrose acetate isobutrate

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	10229	1.6 (8)	5.4 (25)
		"FB"	10340	1.6 (8)	5.5 (25)
	2-6 yrs	Baseline	822	4.4 (20)	13.0 (65)
		"FB"	824	4.5 (20)	13.1 (65)
New Zealand	15+	Baseline	3452	0.8 (4)	3.2 (15)
		"FB"	3470	0.8 (4)	3.3 (15)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of sucrose acetate isobutrate to FBs would not result in a large increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to sucrose acetate isobutrate below the ADI.

In conclusion, the addition of sucrose acetate isobutrate to FB would not pose a public health and safety risk.

445 – Glycerol Ester of Wood Rosin (Schedule 1)

Hazard identification and Characterisation
Glycerol ester of wood rosin was most recently evaluated by the JECFA in 1996, and an ADI of 0-25 mg/kg bw was allocated (WHO, 1996c). JECFA based the ADI for glycerol ester of wood rosin on the absence of adverse effects observed at the highest dose in a 13-week study in rats. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, all food groups were assumed to have concentrations at the MPLs. No survey or manufacturers use data were available to use in the exposure assessment. Glycerol ester of wood rosin is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 100 mg/L of glycerol ester of wood rosin was present in bottled waters assuming these are replaced with FBs containing glycerol ester of wood rosin at that concentration.

There is little change in exposure to glycerol ester of wood rosin between the baseline and the 'FB' scenario.

Table 21: Estimated dietary exposure to 445 – Glycerol ester of wood rosin

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	10229	0.8 (3)	2.7 (10)
		"FB"	10340	0.8 (3)	2.7 (10)
	2-6 yrs	Baseline	822	2.2 (9)	6.5 (25)
		"FB"	824	2.2 (9)	6.5 (25)
New Zealand	15+	Baseline	3452	0.4 (2)	1.6 (6)
		"FB"	3470	0.4 (2)	1.6 (7)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of glycerol ester of wood rosin to FBs would not result in an increase in dietary exposure for any of the population groups assessed.

All population groups assessed have estimated exposures to glycerol ester of wood rosin well below the ADI.

In conclusion, the addition of glycerol ester of wood rosin to FB would not pose a public health and safety risk.

480 – Dioctyl Sodium Sulphosuccinate (DSS) (Schedule 1)

Hazard identification and Characterisation
DSS was most recently evaluated by the JECFA in 1995, and an ADI of 0-0.1 mg/kg bw was allocated (WHO, 1995). JECFA based the ADI for DSS on adverse effects observed in rats, where high exposures were found to cause reduction in parental body weight as well as weanling pup weight in reproduction studies. A safety factor of 500 was used, because of the limited toxicological database on DSS.

Dietary exposure assessment
For the baseline estimate of exposure, all food groups were assumed to have concentrations at the MPLs apart from one. A manufacturers' use level obtained during the food additives review was assigned to water based flavoured drinks (ANZFA, 1998; ANZFA, 1999). No other survey or manufacturers use data were available to use in the exposure assessment. DDS is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 10 mg/L of DSS was present in bottled waters assuming these are replaced with FBs containing DSS at that concentration.

There is little change in exposure to DSS between the baseline and the 'FB' scenario.

Table 22: Estimated dietary exposure to 480 – Dioctyl sodium sulphosuccinate (DSS)

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	10229	0.1(95)	0.3 (320)
		"FB"	10340	0.1(100)	0.3 (320)
	2-6 yrs	Baseline	822	0.2 (250)	0.7 (690)
		"FB"	824	0.3 (250)	0.7 (690)
New Zealand	15+	Baseline	3452	0.06 (60)	0.2 (200)
		"FB"	3470	0.06 (60)	0.2 (200)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of DDS to FB would not result in a large increase in dietary exposure for any of the population groups assessed.

All population groups assessed, with the exception of mean consumers of DSS aged 2-6 years from Australia, have estimated exposures to DSS below the ADI. All population groups have estimated exposures that exceed the ADI at the 95th percentile exposure.

Whilst, in this conservative model, the estimated exposures exceeded the ADI for the consumers in the 2-6 year groups at the 95th percentile, this is highly unlikely to occur in reality for two reasons. Firstly, it was it was assumed that for every food category that was assigned a numerical concentration of DSS, every product in that category contained DSS, which in reality is not the case.

For example the Food Additive Database did not contain any food products where DSS was used, which also suggests that the model above is highly conservative. This may also indicate that there is very little use of the additive in the food supply, suggesting the actual exposure to DSS would be much lower than predicted. Secondly, the 95th percentile is an overestimate of exposure over a long period of time as it is based on 24-hour food consumption data.

In conclusion, the addition of DSS to FB would not pose a public health and safety risk.

ESTIMATED EXPOSURES FOR INTENSE SWEETENERS

The *Consumption of Intense Sweeteners in Australia and New Zealand: Benchmark Survey 2003* ('The Sweetener Survey')(FSANZ, 2003) was used to obtain concentrations of sweeteners used in food groups. At the time of the survey, concentrations of the sweeteners added to the products (by brand and flavour) were obtained from manufacturers for almost all products on the market that contained intense sweeteners at the time. The mean concentration of each sweetener in each food group was calculated from the compiled database of manufacturers concentrations for use in the dietary modelling for the sweeteners being assessed in this application. The concentrations were assigned to the relevant food groups in DIAMOND for dietary modelling purposes.

It was not possible to use the sweetener survey data directly to undertake predictive modelling for the proposed use of intense sweeteners in FBs for a number of reasons. The sweetener survey collected consumption data using a 7-day diary of intense sweetened foods consumed by brand and flavour. These consumption data are not in a format (e.g. in DIAMOND) to allow dietary exposure assessments to be conducted. Also, other food products (such as the bottled water and fruit juice based products) needed to be included in the scenario modelling, for which consumption data were not collected as a part of the sweetener survey. The sweetener survey only included respondents 12 years of age and above. The dietary modelling for this application needed to include children younger than 12 years of age, therefore, this had to be done using the 1995 NNS consumption data and DIAMOND.

950 – Acesulphame Potassium (Ace K) (Schedule 1)

Hazard identification and Characterisation
Ace K was most recently evaluated by the JECFA in 1990, and an ADI of 0-15 mg/kg bw was allocated (WHO, 1991). JECFA based the ADI for Ace K on the absence of adverse effects observed at the highest dose in long-term studies in rats. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, only food groups that were identified in the 2003 sweetener survey as containing Ace K were included in the exposure assessment (FSANZ, 2003). The concentration data collected for the sweetener survey were for almost all of the products on the market at the time that contained intense sweeteners. Therefore, where there may have been a permission in the Code to allow Ace K in a food group, if there were no data from the sweetener survey on these food groups, a zero concentration was assigned in the modelling. Ace K is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 300 mg/L of Ace K was present in bottled waters and sugar sweetened water based flavoured drinks assuming these are replaced with FBs containing Ace K at that concentration.

There is an increase in exposure to Ace K between the baseline and the 'FB' scenario.

Table 23: Estimated dietary exposure to 950 – Acesulphame potassium (Ace K)

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	4877	1.1 (7)	3.6 (25)
		"FB"	8596	3.1 (20)	9.8 (65)
	2-6 yrs	Baseline	494	2.2 (15)	6.8 (45)
		"FB"	817	7.6 (50)	20.3 (140)
New Zealand	15+	Baseline	1230	0.7 (5)	2.0 (15)
		"FB"	2376	1.9 (15)	5.9 (40)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of Ace K would result in an increase in dietary exposure for all population groups assessed.

All population groups assessed have estimated exposures for consumers of Ace K below the ADI, except for children aged 2-6 years at the 95th percentile exposure when FBs are consumed, where exposures only marginally exceed the ADI (140%).

Whilst the estimated exposures in this model exceed the ADI for high consumers of Ace K in the 2-6 year age group at the 95th percentile when FBs are consumed, it is not considered that the actual exposure to Ace K would exceed the ADI. It was concluded from the sweetener survey (FSANZ 2003) that there are no public health and safety risk associated with exposures to Ace K. This was determined for people identified in the survey as 'high consumers' of intense sweetened foods. For the sweetener survey respondents recorded, for seven days, all foods they consumed that contained intense sweeteners. The concentration of the intense sweetener by brand and flavour was then matched to the consumption in order to estimate exposure for each respondent. For this Application, 24-hour recall consumption data were used, and combined with a mean concentration of the sweetener for each food group. The dietary modelling for this Application therefore is not as realistic as the modelling conducted for the sweetener survey.

For the sweetener survey, exposures were estimated for high consumers of foods containing intense sweeteners aged 12 years and above. Mean exposures for consumers of Ace K were 4% of the ADI for Australia and 3% of the ADI for New Zealand. Estimated 95th percentile exposures for consumers of Ace K were 9% of the ADI for Australia and 11% of the ADI for New Zealand. These estimates are lower than those estimated for this Application.

In addition, it was assumed for this Application, that for every food category that was assigned a numerical concentration of Ace K, every product in that category contained the sweetener, which in reality is not the case. Only a small proportion of the category would contain intense sweeteners and Ace K in particular. Of the 531 products in the sweetener survey database, 33% contained Ace K.

For Ace K there was a difference in estimated exposures between baseline, representing current permissions, and the scenario model assuming annatto was permitted in FBs. This is because of the way the modelling has been conducted and the assumptions made about what beverages were substituted with FBs. It is assumed that people substitute bottled water and sugar sweetened water-based flavoured drinks with an FB that contains Ace K, therefore increasing estimated exposure.

In conclusion, the addition of Ace K to FB would not pose a public health and safety risk.

954 – Saccharin (Schedule 1)

Hazard identification and Characterisation
Saccharin and its salts was most recently evaluated by the JECFA in 1993, and a group ADI of 0-7.5 mg/kg bw was allocated for saccharin and its calcium, potassium, and sodium salts (WHO, 1993). JECFA based the ADI for saccharin on adverse effects observed in rats in a two-generation study, where high exposures were found to cause decreased body weight gain in the presence of increased food consumption, which were probably related to inhibitory effects of saccharin on carbohydrate and protein digestion. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, only food groups that were identified in the 2003 sweetener survey as containing saccharin were included in the exposure assessment (FSANZ, 2003). The concentration data collected for the sweetener survey were for almost all of the products on the market at the time that contained intense sweeteners. Therefore, where there may have been a permission in the Code to allow saccharin in a food group, if there were no data from the sweetener survey on these food groups, a zero concentration was assigned in the modelling. Saccharin is not permitted in bottled waters.

The data for concentrations of sweeteners in foods from the sweetener survey was collected during the 2 year 'transition period' between the old Australian Food Standards Code and the current Code. This meant that during that period, manufacturers could manufacture their products to meet the regulations in either Code (not a mixture of both). As a consequence of the review, the MPLs for saccharin were reduced in some food groups. Therefore, some of the concentration data collected from manufacturers at the time, would now exceed the MPL in the new Code. Therefore, mean concentrations derived for these foods from the manufacturers' data, if they exceeded the current MPL, were 'capped' at the MPL for dietary modelling purposes.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 80 mg/L of saccharin was present in bottled waters and sugar sweetened water based flavoured drinks, assuming these are replaced with FBs containing saccharin at that concentration.

FSANZ is currently considering another application (A469 – Saccharin in water-based flavoured drinks) requesting the concentration of saccharin permitted to be added to water based flavoured drinks be raised from 80 mg/kg to 150 mg/kg. The dietary modelling for this Application used the current maximum permitted level in the Code of 80 mg/kg as A469 had not been approved at final assessment at the time the modelling for this application was conducted.

There is an increase in exposure to saccharin between the baseline and the 'FB' scenario.

For the New Zealand population, the baseline estimate of exposure is higher than exposure when assuming FBs are consumed (FB scenario).

Table 24: Estimated dietary exposure to 954 – Saccharin

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	2020	1.0 (20)	2.8 (55)
		"FB"	7224	1.0 (20)	3.0 (60)
	2-6 yrs	Baseline	84	1.3 (25)	2.8 (55)
		"FB"	707	2.1 (40)	5.5 (110)
New Zealand	15+	Baseline	392	1.7 (35)	6.5 (130)
		"FB"	1880	0.9 (15)	2.6 (50)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of saccharin to FB would result in an increase in dietary exposure for the population groups assessed, except for the New Zealand population, which saw a decrease in saccharin exposure.

All population groups assessed, with the exception of 2-6 year olds for the FB scenario and at baseline for the New Zealand consumers, have estimated exposures to saccharin below the ADI. Exposure for high consumers of saccharin for the FB scenario for 2-6 year olds is estimated to only marginally exceed the ADI (110%).

Whilst the estimated exposures in this model exceed the ADI for high consumers of saccharin in the population groups outlined, it is not considered that the actual exposure to saccharin would exceed the ADI. It was concluded from the sweetener survey (FSANZ, 2003) that there are no public health and safety risks associated with exposures to saccharin. This was determined for people identified in the survey as 'high consumers' of intense sweetened foods. For the sweetener survey respondents recorded, for seven days, all foods they consumed that contained intense sweeteners. The concentration of the intense sweetener by brand and flavour was then matched to the consumption in order to estimate exposure for each respondent. For this Application, 24-hour recall consumption data were used, and combined with a mean concentration of the sweetener for each food group. The dietary modelling for this Application therefore is not as realistic as the modelling conducted for the sweetener survey.

For the sweetener survey, exposures were estimated for high consumers of foods containing intense sweeteners aged 12 years and above. Mean exposures for consumers of saccharin were 10% of the ADI for Australia and 6% of the ADI for New Zealand. Estimated 95th percentile exposures for consumers of saccharin were 51% of the ADI for Australia and 24% of the ADI for New Zealand. These estimates are lower than those estimated for this Application.

In addition, it was assumed that for every food category that was assigned a numerical concentration of saccharin, every product in that category contained the sweetener, which in reality is not the case. Only a small proportion of the category would contain intense sweeteners and saccharin in particular. Of the 531 products in the sweetener survey database, 20% contained saccharin.

There is an increase in exposure to saccharin between the baseline and the 'FB' scenario. This is because of the way the modelling has been conducted and the assumptions made about what beverages were substituted with FBs. It is assumed that people substitute bottled water and sugar sweetened water based flavoured drinks with an FB that contains saccharin, therefore increasing potential exposure.

For the New Zealand population, the baseline estimate of exposure is higher than exposure when assuming FBs are consumed (FB scenario). This is because of the way DIAMOND is programmed, and how consumers of specific food chemicals are counted. At baseline, only a few food products contained saccharin, and therefore only a part of the population is considered to be a consumer at baseline. However, for modelling it was assumed that all of the following beverages wee replaced: cordials, carbonated drinks, fruit juices, fruit juice drinks, sport drinks and bottled water. This would increase the number of saccharin consumers. The exposure estimates based on the baseline exposures and FB scenario exposures are derived from different numbers of consumers of saccharin and therefore, different distributions of individual exposures. This results in different mean and 95th percentile exposures being derived, and in some cases higher exposures for the baseline model.

In conclusion, the addition of saccharin to FB would not pose a public health and safety risk.

956 – Alitame (Schedule 1)

Hazard identification and Characterisation
Alitame was most recently evaluated by the JECFA in 1996, and an ADI of 0-1 mg/kg bw was allocated (WHO, 1996a). JECFA based the ADI for alitame on adverse effects observed in dogs, where high exposures were found to cause decreased body weight gain and increased liver weight in long-term studies. A safety factor of 100 was used.

Dietary exposure assessment
For the baseline estimate of exposure, only food groups that were identified in the 2003 sweetener survey as containing alitame were included in the exposure assessment (FSANZ, 2003). Only two products in the sweetener survey contained alitame. The concentration data collected for the sweetener survey were for almost all of the products on the market at the time that contained intense sweeteners. Therefore, where there may have been a permission in the Code to allow alitame in a food group, if there were no data from the sweetener survey on these food groups, a zero concentration was assigned in the modelling. Alitame is not permitted in bottled waters.

When estimating exposures based on the 'FB' Scenario, it was additionally assumed that the requested maximum level of 40 mg/L of alitame was present in bottled waters and sugar sweetened water based flavoured drinks, assuming these are replaced with FBs containing alitame at that concentration.

There is an increase in exposure to alitame between the baseline and the 'FB' scenario.

Table 25: Estimated dietary exposure to 956 – Alitame

				Mean consumer exposure	95th %ile consumer exposure
Country	**Population sub-group**	**Scenario**	**No. of Consumers**	**mg/kg bw/day (% ADI)**	**mg/kg bw/day (%ADI)**
Australia	2+	Baseline	3653	0.1 (10)	0.3 (30)
		"FB"	8667	0.4 (40)	1.2 (120)
	2-6 yrs	Baseline	360	0.2 (20)	0.5 (50)
		"FB"	797	1.0 (100)	2.6 (260)
New Zealand	15+	Baseline	1449	0.1 (9)	0.2 (20)
		"FB"	2670	0.2 (25)	0.7 (75)

NB: Total number of respondents: Australia 2+ = 13858; Australia 2-6 years = 989; New Zealand 15+ = 4636.
Mean body weight: Australia 2+ = 67 kg; Australia 2-6 years = 19 kg; New Zealand 15+ = 71 kg.

Risk characterisation
The addition of alitame to FB would result in an increase in dietary exposure for all the population groups assessed.

All population groups assessed, with the exception of the 95th percentile consumers aged 2 years and above for the FB scenario and 2-6 year olds for the FB scenario only, have estimated exposures to alitame below the ADI.

Whilst the estimated exposures in this model exceed the population groups mentioned, it is not considered that the actual exposure to alitame would exceed the ADI. It was concluded from the sweetener survey (FSANZ, 2003) that there are no public health and safety risks associated with exposures to alitame. This was determined for people identified in the survey as 'high consumers' of intense sweetened foods. For the sweetener survey respondents recorded, for seven days, all foods they consumed that contained intense sweeteners. The concentration of the intense sweetener by brand and flavour was then matched to the consumption in order to estimate exposure for each respondent. For this Application, 24-hour recall consumption data were used, and combined with a mean concentration of the sweetener for each food group. The dietary modelling for this Application therefore is not as realistic as the modelling conducted for the sweetener survey.

For the sweetener survey, exposures were estimated for high consumers of foods containing intense sweeteners aged 12 years and above. Mean exposures for consumers of alitame were 2% of the ADI for both Australia and New Zealand. A 95th percentile exposure for consumers of alitame was not presented. It could not be calculated due to the small number of consumers of alitame. These estimates are lower than those estimated for this Application.

In addition, it was assumed that for every food category that was assigned a numerical concentration of alitame, every product in that category contained the sweetener, which in reality is not the case. Only a small proportion of the category would contain intense sweeteners and alitame in particular. From the sweetener survey, there were only 3 products (in 2 food groups) that contained alitame. There were 531 products in total in the sweetener survey database.

There is an increase in exposure to alitame between the baseline and the 'FB' scenario. This is because of the way the modelling has been conducted and the assumptions made about what beverages were substituted with FBs. It is assumed that people substitute bottled water and sugar sweetened water based flavoured drinks with an FB that contains alitame, therefore increasing exposure.

In conclusion, the addition of alitame to FB would not pose a public health and safety risk.

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Appendix 1

Details of how the dietary modelling for food additives was conducted

Dietary exposure assessment provided by the Applicant

The Applicant did not provide any estimates of exposure to the food additives that could result from the consumption of FBs. Therefore, FSANZ conducted dietary exposure assessments for the food additives.

What food additives were assessed?

There were 57 additives/additive groups requested by the Applicant to be added to FBs. Of these, dietary modelling was conducted for 23 additives/additive groups. 'Selection criteria' were developed in order to determine when a dietary exposure estimate was required. Dietary modelling was not conducted in cases where:

1. additives had no numerical ADI (see hazard identification/characterisation);
2. additives had no numerical permissions in the Food Standards Code, such as those that have GMP permissions, and no numerical concentration data were available on actual use levels by manufacturers to be used for modelling (e.g. those in Schedule 2 and Schedule 3 of Standard 1.3.1,);
3. if the Applicant requested a GMP permission for the additive, and a numerical concentration was not available to be used for dietary modelling.

Dietary survey data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

Estimated exposures to food additives were based on a single 24-hour recall for all survey respondents.

The NNS data used for the exposure assessments were from 1995 and 1997, which are the best, most comprehensive data available for dietary modelling purposes. Therefore, conducting dietary modelling based on these data provides the best estimate of actual consumption of a food and the resulting estimated exposure to a food chemical. However, it should be noted that limitations exist within the NNS data. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since the NNSs were conducted (Cook *et al*., 2001). However, there is an increasing level of uncertainty associated with the consumption of other foods where these may have changed in consumption since 1995 or 1997, or where new foods are now available on the market that were not available in 1995 or 1997.

Despite FBs currently being permitted to be manufactured in New Zealand under the Dietary Supplement regulations, there was no reported consumption of the products in the 1997 New Zealand NNS.

Population groups assessed

The dietary exposure assessments for food additives were conducted for both the Australian and New Zealand populations. An assessment was conducted for the whole population, as well as for children aged 2-6 years for Australia only. Dietary exposure assessments were conducted for the whole population as a proxy for lifetime exposure. An exposure assessment was conducted on children as they tend to have higher exposures per kilogram of body weight due to their smaller body weight, and they consume more food per kilogram of body weight compared to adults. It is important to note that, while children aged 2-6 years have been assessed as a separate group, this group has also been included in the dietary exposure assessment for the whole population estimate for Australia.

Food additive concentration levels

The concentrations of the food additives in foods that were used in the dietary exposure assessments were derived from a range of sources, including the MPLs in the Code, manufacturers use data and analytical concentrations from surveys. Proposed concentrations of additives in FBs were provided by the Applicant (see Table 1). The concentrations requested by the Applicant were in most cases the same for equivalent beverage products in the Code. For example, if fruit drinks are permitted to contain additive X at 200 mg/kg, it was requested by the Applicant that the fruit drink based FBs have the same concentration. This was based on the assumption made by FSANZ that the additives will have the same technological function in the FB and therefore will need to be used at the same concentration to achieve the desired effect.

Concentrations of food additives were assigned to food groups using DIAMOND food classification codes. These codes are based on the Australian New Zealand Food Classification System (ANZFCS) used in Standard 1.3.1 Food Additives (for example 14.1.3 represents Water-based flavoured drinks).

Additives in Schedule 1 of Standard 1.3.1 of the Code have specific permissions in a restricted range of foods.

Many of the colourings being assessed were in Schedule 4 of Standard 1.3.1, meaning they are permitted to be used in a broad range of processed foods and beverages at 70 mg/kg in beverages and 290 mg/kg in foods other than beverages. It is unrealistic to assume that all foods in every classification code will contain a colour at the MPL, or that every food within each classification contains the colouring. However, there are limited data available that reflect more accurate uses that can be used to refine the exposure estimates. Where more specific data were available, these were used to refine the estimates.

For example, where concentrations from an analytical survey were available, these were used for the relevant food classification. If there were no analytical data, manufacturers' use data were used, if available. If manufacturers' use data were not available, the MPL from food standards (Standard 1.3.1 of the Code) was used.

Where an analytical level or manufacturers' use level was available for a drink being substituted by FBs, the FB was assumed to contain the specific use level and not the maximum requested level, as it was assumed that the additive would have the same technological function in the FB and therefore would be used at the same level.

Two recent surveys were available that had analytical data for foods. The first, the 21st Australian Total Diet Survey (ATDS) (FSANZ, unpublished), and the South Australian Food Colouring Survey (South Australia Department of Health, personal communication).

Analytical concentration data for the preservatives (sorbates, benzoates and sulphites) were obtained from the 21nd Australian Total Diet Survey, which is currently being undertaken by FSANZ (FSANZ, unpublished). Multiple analytical results were available for each food analysed. The mean concentration derived from the analysed composite samples was derived and assigned to the most relevant classification code in DIAMOND for dietary modelling purposes. Where there were analytical samples whose result was 'not detected', an 'upper bound' mean concentration was derived for the food. This was calculated assuming that not detected results were at the limit of reporting (LOR) for the analytical method. The LOR is the lowest concentration of a chemical that can be detected and quantified, with an acceptable degree of certainty, using a specified laboratory method and/or item of laboratory equipment. An upper bound mean is a worst case scenario, as it concentration could be anywhere between the LOR and zero.

In 2004, the South Australian (SA) Department of Health conducted a compliance survey for food colourings. The results from this survey were provided to FSANZ for dietary modelling purposes (South Australia Department of Health, personal communication). The colours that were assessed included tartrazine, allura red, indigotine, sunset yellow, azorubine, amaranth, ponceau 4R, brown HT and brilliant black. The food groups analysed included fruit drinks, ice cream, cordials, soft drinks, flavoured milk, cheese, confectionery, breakfast cereals, biscuits, jams, meat pies, cakes, toppings and sauces, snack foods, alcoholic beverages, jelly, yoghurt and dairy snacks, table spreads and margarine. There were 255 individual samples analysed in total. The mean concentration from individual samples for a food group was derived and assigned to the most appropriate classification code in DIAMOND for dietary modelling purposes. Where there were analytical samples whose result was 'not detected', an 'upper bound' mean concentration was derived for the food and used for the exposure assessments.

Manufacturers' use data had previously been obtained from certain manufacturers' in 1998-1999, when dietary exposure assessments were being conducted by FSANZ for the Review of the Code, for proposal P150 – Food Additives (ANZFA, 1998; ANZFA, 1999). This information was provided by a number of major food manufacturers through personal communication via meetings and other correspondence. A smaller amount of data for other additives were obtained from manufacturers following the review when it was required for other projects, such as amaranth.

The *Consumption of Intense Sweeteners in Australia and New Zealand: Benchmark Survey 2003* ('The Sweetener Survey') (FSANZ, 2003) was used to obtain concentrations of sweeteners used in food groups. More information on how these survey data were used for the dietary modelling for this Application can be found in the main report.

Additional food consumption data or other relevant data

The 1995 Australian NNS did not include any consumption information for formulated beverages. The New Zealand 1997 NNS did not report any consumers of FBs.

For the purposes of the dietary modelling for food additives, it was necessary to determine what beverages a person may take out of their diet and substitute with an FB. The Applicant provided data on the types of beverages that are likely to be replaced by FBs. These data were used in the assessment exposure to food additives. The food groups assumed to be substituted were cordials (excluding those made up from powder), carbonated drinks, fruit juice drinks, sports drinks and bottled water.

Over the past few years, FSANZ has compiled a Food Additive Database, recording the food additives used in over 2200 food products, primarily processed foods and beverages. The database itself is by no means complete or considered representative of the whole food supply, however, it does provide a guide to likely proportions of each food category in the food supply that may contain certain additives. Each product entered into the database is given a code relevant to the classification numbering system used in Standard 1.3.1 of the Code. From the database, FSANZ was able to determine how the proportion of products within a classification code, that contained the food additive of interest. In the absence of other specific data on the proportion of each food category that contains the additive, the information from this database was used qualitatively to put into context the estimated exposures. The data from the database were of most use for the assessments for food colourings.

Scenarios for dietary modelling

A baseline estimate of exposure was calculated, in order to determine current food additive exposures before any additional level of exposure from the additives in FBs is included. A '100% substitution' approach was also modelled ('FB scenario'). For this scenario it was assumed that people will take a beverage out of the diet and replace it with a FB. It was assumed that all of the following beverages were replaced: cordials, carbonated drinks, fruit juices, fruit juice drinks, sports drinks and bottled water. The consumption amount of the FB remained the same as the beverage it replaced.

How were the estimated dietary exposures calculated?

The DIAMOND program allows food additive concentrations to be assigned to food groups. For intense sweetened foods, the food chemical level is only normally assigned to intense sweetened food groups, where these were reported separately. For the 'FB' scenario, however, it was assumed that the normal counterpart of a beverage (i.e. a sugar sweetened soft drink) could be substituted with an FB that contains the intense sweetener being assessed.

Exposure to the food additives was calculated for each individual person in the NNSs using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of the food additive by the amount of food that an individual consumed in order to estimate the exposure to the additive from each food. Once this has been completed for all of the foods specified to contain the additive, the total amount of the additive consumed from all foods is summed for each individual.

Population statistics (mean and high percentile exposures) are then derived from the individuals' ranked exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individuals' total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived. A small number of NNS respondents did not provide a body weight. These respondents are not included in calculations of estimated dietary exposures that are expressed per kilogram of body weight.

Where estimated exposures are expressed as a percentage of the reference health standard (ADI), each individual's total exposure is calculated as a percentage of the reference health standard (using the total exposures in units per kilogram of body weight per day), the results are then ranked, and population statistics derived.

Food consumption amounts for each individual take into account where each food in a classification code is consumed alone and as an ingredient in mixed foods. For example, ice cream eaten 'as is' or in a thickshake are all included in the consumption of ice cream. Where a higher-level food classification code (e.g. 14.1.3 Water based flavoured drinks) is given an additive concentration, as well as a sub-category (e.g. 14.1.3.2 Kola soft drinks), the consumption of the foods in the sub-classification is not included in the higher level classification code.

In DIAMOND, all mixed foods in classification codes 20 and 21 have a recipe. Recipes are used to break down mixed foods into component ingredients that are in classification codes 1-14. The data for consumption of the ingredients from the recipe are then used in models and multiplied by the additive concentrations for each of the raw ingredients. This only occurs if the *Mixed food* classification code (classification code 20) is not assigned its own additive permission. If the *Mixed foods* classification is assigned an additive concentration, the total consumption of the mixed food is multiplied by the specified level, and the recipes are not used for that food group.

When a food that does not have a recipe is classified in two food groups in classification codes 1-14, and these food groups are assigned different permissions, DIAMOND will assume the food is in the food group with the highest assigned additive level (worst-case scenario). If the food groups have the same permitted additive concentration, DIAMOND will assume the food is in the food group that appears first, based numerically on the ANZFCS.

In DIAMOND, hydration factors are applied to some foods to convert the amount of food consumed in the dietary survey to the equivalent amount of the food in the form to which a food chemical permission is given. For example, consumption figures for cordial concentrate are converted into the equivalent quantities of cordial beverage as consumed.

Uncertainty associated with the exposure assessment

Where there are uncertainties in the data used for dietary exposure assessments, assumptions normally have to be made. Some of the uncertainly associated with the exposure estimates for food additives are outlined below.

It is not known what the current consumption pattern and volume of FBs is by consumers, as there are no data in the NNSs and no survey data available.

It is not known what beverages consumers will substitute with a FB. Whilst the Applicant provided some information on the products currently on the market that would be similar to FBs, and these were assumed to be substituted, there is uncertainty about what consumers will actually do when given the choice between a beverage they may normally consume and a FB.

Whilst additives are used at specific concentrations in order to perform a specific technological function, there is uncertainly around the range of concentrations manufacturers use.

In relation to the exposure assessments for food colourings, there is uncertainly around the food groups that actually contain colours. There may be a broad range of food groups permitted to contain a colour, however, some of these food groups may never contain the colour. Also, the percent of each category that actually contains the colour is unknown.

Assumptions in the dietary modelling

The aim of the dietary exposure assessment was to make as realistic an estimate of dietary exposure as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary exposure assessments did not underestimate exposure.

Assumptions made in the dietary modelling include:

where a permission is given to a food classification code, all foods in that group contain the additive;

all the foods within the group contain the additive at the levels specified in DIAMOND. Unless otherwise specified, the maximum permitted level of the additive in each food category has been used;

where a food has a specified additive concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient;

where the concentration of the additives used were from analytical data and the concentration was reported as being less than the LOR, then the additive concentration in the food was equal to the LOR value;

where Australian foods were analysed for certain additives (sorbates, benzoates and sulphites), it was assumed that New Zealand foods had the same concentrations, which is a realistic assumption, as Australia and New Zealand have the same additive permissions, food manufacturers common to both countries and a similar food supply;

where a food was not included in the exposure assessment, it was assumed to contain a zero concentration of the additive being assessed;

where a food or food group has a GMP concentration of the additive, it was assumed to have a zero concentration of the additive, unless manufactures use data or survey data were available;

for food colourings, it was assumed that for certain food groups, there was no colour added. These food groups are outlined in the discussion for each individual colour in the main part of this report;

consumption of foods as recorded in the NNS represent current food consumption patterns;
if FBs were available, consumers always substitute the 'like' beverages and select the FB containing the additive;
consumers substitute all of the 'like' beverages with the FB, even if they have had more than one of them on the day of the NNS;
consumers do not alter their food consumption amount besides to substitute a non-FB with an FB;
the number of serves per day recommended or bottle size of FBs does not influence the amount consumed and therefore, FBs are consumed in the same volume as the beverage that the person replaces; and
for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. milk, yoghurt).

These assumptions are likely to lead overall, to a conservative estimate for food additive dietary exposures, in particular the assumption that all beverages in the specified types of beverages will be substituted by a FB and that all foods within a food groups will contain the additive being assessed.

Limitations of the dietary modelling

A limitation of estimating dietary exposure over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime.

Daily food consumption amounts for occasionally consumed foods based on 24 hour food consumption data would be higher than daily food consumption amounts for those foods averaged over a longer period of time.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry. As a consequence, another limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser I, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic exposure estimate. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand National Nutrition Survey so that statistically valid assessments could be made for these population groups.

As a result, there may be bias towards these sub-population groups in the dietary exposure assessment because population weights were not used.

The DIAMOND computer program only contains food consumption data from the NNSs. Therefore, the predicted exposure estimates for sweeteners for A470 were not able to utilise the more detailed 7-day consumption data obtained in the sweetener survey. Therefore, the modelling for this Application for the requested sweeteners using DIAMOND will be different to the results obtained in the Sweetener Survey.

There is a lack of actual concentration data for the use of additives across all food groups, as well as a lack of data on the proportion of each category each additive is used in. This is mostly an issue for colourings and means the exposure estimates are for colours are worst case. For preservatives and sweeteners there are extensive concentration data available that were used to calculate refined estimates of exposure.

Attachment 9

Food Technology Report
Application A470 – Formulated Beverages

The use of food additives is regulated by Standard 1.3.1 – Food Additives, with permissions provided by Schedules 1 to 4. Schedule 1 of this Standard permits the use of food additives at specified levels in specific foods. Maximum permitted levels are prescribed for additives where risk assessment indicates a need to restrict usage levels to protect public health and safety. Schedule 2 lists food additives that may be used to levels determined by Good Manufacturing Practice (GMP) where permitted by Schedule 1. Schedule 3 lists colours that are permitted to GMP levels where permitted in Schedule 1. Schedule 4 lists colours that are restricted to 70 mg/kg for liquids and to 290 mg/kg for solid foods and which may be further restricted by Schedule 1. Schedule 5 lists the permitted technological functions to be performed by food additives as distinct from processing aids (Standard 1.3.3) and vitamins and minerals (Standard 1.3.2).

The Applicant has requested permission for use of a wide range of food additives in Formulated Beverages (FB). Some of these requests are covered by the general permissions in Schedule 2 of Standard 1.3.1 and colours have been requested for use in accordance with Schedules 3 and 4. The levels requested for other additives are compliant with the permissions currently available for non-alcoholic beverages in Schedule 1 under the categories of 14.1.2.2 – Fruit and vegetable juice products and of 14.1.3 – Water based flavoured drinks.

A table containing a list of the requested food additives and their maximum requested levels for FB is given at the Appendix at the back of this report, compared to the current permissions in the two existing categories 14.1.2.2 – Fruit and vegetable juice products and 14.1.3 – Water based flavoured drinks. The requested permissions have been amended from the original Application to correct some errors and inconsistencies which had been resolved after communications between FSANZ and the Applicant. The Applicant confirmed they wished the food additive permissions to be consistent with the current permissions for these comparable beverages. The Applicant is not requesting any increase in maximum permitted levels or new permissions.

Schedule 1 of Standard 1.3.1 is currently under review to address complaints and to provide clarification of permissions in Proposal P279 – Review of Schedule 1 and Related Clauses – Standard 1.3.1 – Food Additives. Any changes arising from P279 will need to be incorporated into the assessment for this Application, A470.

Technological justification for the requested food additives

Intense sweeteners

The Applicant has requested approval for a variety of intense sweeteners.

An intense sweetener is a food additive defined by Schedule 5 of Standard 1.3.1 as:

'replaces the sweetness normally provided by sugars in foods without contributing significantly to their available energy'.

The Applicant has requested approvals for the intense sweeteners currently permitted in categories 14.1.2.2 – Fruit and vegetable juice products and 14.1.3 – Water based flavoured drinks in Schedule 1 of Standard 1.3.1.

The different intense sweeteners have different properties including advantages and disadvantages compared to each other and to sucrose (Smith, 1991). These different properties include comparable sweetness to sucrose, cost, flavour profile to replicate that of sucrose in the drink matrix and stability in the drink (including different pH, temperatures and storage times). Manufacturers of commercial products will make decisions on which individual intense sweetener or combination of sweeteners to use taking these considerations into account and the results of trial products. Examples of disadvantages that some intense sweeteners have are that cyclamate has accelerated decomposition in the presence of water soluble vitamins at elevated temperature, while thaumatin's taste is reduced by mono- and divalent salts (Smith, 1991).

Aspartame (INS 951), sucralose (INS 955), thaumatin (INS 957) and neotame (INS 961) are intense sweeteners which are currently listed in Schedule 2 of Standard 1.3.1, which allows their use in accordance with GMP. These intense sweeteners are only approved with the limitation 'technological use consistent with clause 4 only'. This means that such intense sweeteners may only be added to food in an amount necessary to replace the sweetness normally provided by sugars or as a flavour enhancer. This limitation would apply to any approvals if this Application is successful.

Acesulphame potassium (INS 950), saccharin (INS 954) and alitame (INS 956) have also been requested as intense sweeteners at the same permitted levels as is currently permitted in comparable drinks in Schedule 1.

The current permissions for acesulphame potassium (INS 950) in the Code are 500 mg/kg for fruit and vegetable juice products, and 3,000 mg/kg for both low joule fruit and vegetable juice products, and water based flavoured drinks. The Applicant has confirmed that they are seeking permission for acesulphame potassium at 3,000 mg/kg for FB comparable to water based flavoured drinks.

The Applicant has not requested approval for cyclamate (INS 952) as an intense sweetener for FB.

Preservatives

A variety of preservatives are currently approved in categories 14.1.2 – Fruit and vegetable juices and fruit and vegetable juice products and 14.1.3 – Water based flavoured drinks in Schedule 1 of Standard 1.3.1. These preservatives are sorbic acid and sorbates (INS 200, 201, 202 and 203), benzoic acid and benzoates (INS 210, 211, 212 and 213), sulphur dioxide and sulphites (INS 220, 221, 222, 223, 224, 225 and 228) and dimethyl dicarbonate (INS 242). Sodium and calcium propionate (INS 281 and 282 respectively) are approved at GMP for category 14.1.2 - Fruit and vegetable juices and fruit and vegetable juice products.

The different preservatives have different properties and antimicrobial activity (Smith 1991) relevant to their use in currently produced drinks and proposed use in FB. Sorbic acid and sorbates have broad spectrum activity against fungi, with less activity against bacteria. Benzoic acid and benzoates have activity against yeasts and moulds, food poisoning bacteria, and spore-forming bacteria. Sulphur dioxide and sulphites has activity against most bacteria and less activity against yeast and moulds. Propionic acid and propionates have activity against moulds but not yeasts. Dimethyl dicarbonate is used as a yeast inhibitor for beverages (Ash and Ash, 2002).

A combination of sulphites with another preservative, e.g., sorbates or benzoates, is frequently used for fruit juices where the sulphite acts to control chemical spoilage reactions, and lactic and acetic acid fermentations, whilst the second preservative acts as a longer lasting agent against yeasts and moulds (Encyclopedia, 2003, p 4778).

A qualification listed in the Code for fruit and vegetable juice products, which will need to be considered if this Application is successful is that the 'GMP principle precludes the use of preservatives in juices represented as not preserved by chemical or heat treatment'.

Sequestrants

Calcium disodium EDTA (INS 385) is a sequestrant (also called a metal chelating agent) which is used for beverages which contain fruit flavouring, juice or pulp or orange peel extract. Calcium disodium EDTA is approved within the Code for carbonated fruit drink products under category 14.1.2.2 – Fruit and vegetable juice products and category 14.1.3 - Water based flavoured drinks for products containing fruit flavouring, juice or pulp or orange peel extract only.

Sequestrants are used to ensure flavour retention (Smith, 1991). Free metal ions which naturally occur at low levels in beverages can readily form inactive complexes with flavour compounds so reducing the active flavour concentration and hence reduced perceptible flavour. Calcium disodium EDTA acts to selectively bind up metal ions preventing them from reacting with flavourings.

The current restrictions for EDTA will need to be considered if the Application is successful.

Colourings

The Applicant has requested that the colours permitted in Schedule 3 and Schedule 4 be approved for FB. These colours are currently permitted in categories 14.1.2.2 – Fruit and vegetable juice products and 14.1.3 – Water based flavoured drinks in the Code.

Annatto extracts (INS 160b) are currently approved for category 14.1.2.2 – Fruit and vegetable juice products. Annatto is available in a water soluble form. It is a well established food colour (producing yellow to red colour) due to its superior technical properties compared to other colours (Watson, 2002). Permission to use annatto extracts has only been sought by the Applicant for fruit and vegetable juice FB.

The situation with the colouring annatto extracts is complicated by the fact that there are a number of different types of extracts that can be produced and used commercially.

The FAO/WHO Joint Expert Committee on Food Additives (JECFA) recently re-evaluated the toxicology of the various annatto extracts in 2003, and assigned different temporary Acceptable Daily Intakes (ADI) for a number of different annatto extracts, while others have no ADI established (discussed in Attachment 8 – Safety Assessment – Food Additives).

Annatto extracts are obtained from the annatto seed, using a number of different extraction methods including water, vegetable oil, solvent and alkaline extraction. Bixin is the principle pigment of oil-soluble annatto extracts, while norbixin is the principle pigment of alkaline water-soluble annatto extracts.

JECFA designated six different types of annatto extracts in their 2003 evaluation:

Annatto B	Annatto extract (solvent-extracted bixin)
Annatto C	Annatto extract (solvent-extracted norbixin)
Annatto D	Annatto extract (oil-processed bixin suspension)
Annatto E	Annatto extract (aqueous-processed norbixin)
Annatto F	Annatto extract (alkali-processed norbixin)
Annatto G	Annatto extract (alkali-processed norbixin, not acid-precipitated)

The specific type of annatto extract used by Australian and New Zealand food manufacturers, specifically for fruit and vegetable juice products is important to ensure that the correct ADI is used for dietary modelling work.

Clause 5 – Maximum permitted levels of additives of Standard 1.3.1 may require amendment, due to consideration of the 2003 JECFA report, where it refers to annatto, *viz*

> **annatto** and annatto extracts shall be calculated as bixin

in Proposal P279 – Review of Schedule 1 and related clauses – Standard 1.3.1 – Food Additives.

FSANZ will seek advice from food manufacturers and the Applicant on which of the six forms of annatto extracts (for example, alkali-processed norbixin) is used in food manufactured in Australia and New Zealand, specifically category 14.1.2.2 – Fruit and vegetable juice products in Schedule 1 of Standard 1.3.1.

Amaranth (INS 123) is currently approved in categories 14.1.2.2 – Fruit and vegetable juice products and 14.1.3 – Water based flavoured drinks in the Code. Amaranth is a water soluble colour which produces a dark red to purple colour (Ash and Ash, 2002).

<u>Emulsifiers</u>

An emulsifier as defined in Schedule 5 of Standard 1.3.1 of the Code:

'facilitates the formation or maintenance of an emulsion between two or more immiscible phases'.

In general this means a food additive that improves the solubility or mixing of an aqueous phase and an oil phase. To achieve this emulsifiers usually have a hydrophilic group (aqueous loving) and a lipophilic group (oil loving) within the molecule.

For beverages this can mean compounds that improve the solubilisation and dispersion of flavours and colours which normally have poor solubilities in aqueous solutions or would form cloudy emulsions. Emulsifiers can help to produce clear solutions of the resultant beverage mixture (Smith, 1991).

Sucrose acetate isobutyrate (INS 444), glycerol esters of wood rosins (INS 445) and dioctyl sodium sulphosuccinate (INS 480) are currently approved as emulsifiers (or stabilisers) in fruit drinks under category 14.1.2.2 – Fruit and vegetable juice products and category 14.1.3 – Water based flavoured drinks within Schedule 1 of Standard 1.3.1.

Sucrose acetate isobutyrate is used as an emulsion stabiliser for flavouring oils in non-alcoholic beverages (Ash and Ash, 2002). Glycerol esters of wood rosins are listed as having functional use as emulsifiers and stabilisers/density adjustment agents for flavouring oils in beverages (Food and Agriculture Organisation, 1992). Dioctyl sodium sulphosuccinate use includes being an emulsifier, a wetting agent, dispersant and diluent in food colourants (Ash and Ash, 2002).

Flavourings

Flavourings (excluding quinine and caffeine) are included in Schedule 2 of Standard 1.3.1 so are permitted in both categories 14.1.2.2 – Fruit and vegetable juice products and category 14.1.3 – Water based flavoured drinks at GMP. Permitted flavourings are regulated by clause 11 of Standard 1.3.1.

Permitted flavourings currently approved in such beverages as above should also be allowed in FB if this Application is approved.

Quinine is permitted in Schedule 1 to 100 mg/kg in category 14.1.3 for tonic, bitter and quinine drinks only. However quinine is not requested for addition in FB in this Application.

Carbon dioxide

The Applicant has indicated that FB will not be carbonated. That is they have confirmed that they have not requested permission for addition of carbon dioxide for FB. This needs to be included in any permissions within Schedule 1 of Standard 1.3.1 if this Application is successful. The complication is that carbon dioxide (INS 290) is listed in Schedule 2 of Standard 1.3.1 so any products that allow additives in Schedule 2 do have permissions for carbon dioxide addition.

Conclusion

The requested food additives are technologically justified for their proposed use in formulated beverages in the same way as they are technologically justified for their current use in comparable fruit and vegetable juice products and water based flavoured drinks.

Consideration of the current restrictions in Schedule 1, and any changes resulting from P279, for a number of food additives will need to be considered if the Application is successful. The Application has also not sought permissions for some additives which need to be addressed. The important areas of difference between current permissions in the Code and requested permissions for FB for this Application are listed below.

No permissions sought for quinine.
No permissions sought for cyclamate.
No permissions sought for carbon dioxide.
Permissions for acesulphame potassium at 3,000 mg/kg comparable to water based flavoured drinks.
Permissions for sodium and calcium propionate for fruit and vegetable juices and fruit and vegetable juice products only at GMP.
Permission for calcium disodium EDTA for products containing fruit flavouring, juice or pulp or orange peel extract only.
Permission for annatto extracts for fruit and vegetable products only.

References

Ash, M. and Ash I. (2002) *Handbook of food additives second edition*, Synnapse Information Resources. Inc., New York, U.S.A.

Encyclopedia of Food Sciences and Nutrition, second edition (2003), Elsevier Science Ltd., Oxford, UK.

Food and Nutrition Paper 52, Compendium of Food Additive Specifications Volumes 1 and 2 (1992), Food and Agriculture Organisation of the United Nations, Rome

Smith, J. (1991) *Food additive user's handbook*, Blackie Academic & Professional, Glasgow, UK.

Watson, D.H. (Editor) (2002) *Food chemical safety Volume 2: Additives*, Woodhead Publishing Limited, Cambridge, England.

Appendix

TABLE OF REQUESTED FOOD ADDITIVES
A470 – FORMULATED BEVERAGES

INS	Food additive name	Current approval in 14.1.2.2- Fruit and vegetable juice products mg/kg	Current approval in 14.1.3- Water based flavoured drinks mg/kg	A470 requested approval mg/kg	Comments and qualifications for A470 requested permissions
123	Amaranth	30	30	30	
160b	Annatto extracts	10	-	10	for fruit and vegetable products only
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	400	400	400	for fruit and vegetable juice products the GMP principle precludes use of preservatives in products not treated by chemicals or heat.
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	400	400	400	for fruit and vegetable juice products the GMP principle precludes use of preservatives in products not treated by chemicals or heat.
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	115	115	115	for fruit and vegetable juice products the GMP principle precludes use of preservatives in products not treated by chemicals or heat.
242	Dimethyl dicarbonate	250	250	250	for fruit and vegetable juice products the GMP principle precludes use of preservatives in products not treated by chemicals or heat.

INS	Food additive name	Current approval in 14.1.2.2- Fruit and vegetable juice products mg/kg	Current approval in 14.1.3- Water based flavoured drinks mg/kg	A470 requested approval mg/kg	Comments and qualifications for A470 requested permissions
281	Sodium propionate	GMP	-	GMP	for fruit and vegetable juice products only, GMP principle precludes use of preservatives in products not treated by chemicals or heat.
282	Calcium propionate	GMP	-	GMP	for fruit and vegetable juice products only, GMP principle precludes use of preservatives in products not treated by chemicals or heat.
385	Calcium disodium EDTA	fruit drink 33 (carbonated products only)	33 (products containing fruit flavouring, juice or pulp or orange peel extract only)	33	for products containing fruit flavouring, juice or pulp or orange peel extract only
444	Sucrose acetate isobutyrate	fruit drink 200	200	200	for fruit drink and water based flavoured drinks only
445	Glycerol esters of wood rosins	fruit drink 100	100	100	for fruit drink and water based flavoured drinks only
480	Dioctyl sodium sulphosuccinate	fruit drink 10	10	10	for fruit drink and water based flavoured drinks only
950	Acesulphame potassium	fruit and vegetable juice products (500), low joule fruit and vegetable juice products (3,000)	3,000	3,000	for water based flavoured drinks (3,000 mg/kg)

INS	Food additive name	Current approval in 14.1.2.2- Fruit and vegetable juice products mg/kg	Current approval in 14.1.3- Water based flavoured drinks mg/kg	A470 requested approval mg/kg	Comments and qualifications for A470 requested permissions
951	Aspartame	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, schedule 2	use consistent with clause 4 of Standard 1.3.1 only
954	Saccharin	low joule fruit and vegetable juice products 80	80	80	for water based flavoured drinks and low joule fruit and vegetable juice products only
955	Sucralose	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, schedule 2	use consistent with clause 4 of Standard 1.3.1 only
956	Alitame	40	40	40	
957	Thaumatin	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, schedule 2	use consistent with clause 4 of Standard 1.3.1 only
961	Neotame	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, Schedule 2 use consistent with clause 4 of Standard 1.3.1 only	GMP, schedule 2	use consistent with clause 4 of Standard 1.3.1 only
	Schedule 3 colours	permitted at GMP	permitted at GMP	requested	covered by the use of the asterisk, Schedule 3 colours are approved for use at GMP
	Schedule 4 colours	permitted to prescribed limits in Schedule 4	permitted to prescribed limits in Schedule 4	requested	covered by the use of the asterisk, Schedule 4 colours are approved for use to specified limits
	flavourings	permitted, Schedule 2	permitted, Schedule 2	requested	covered by the use of the asterisk, flavourings (excluding quinine and caffeine) are permitted in Schedule 2

Attachment 10

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

FSANZ received 19 submissions in response to the Initial Assessment Report on Application A470 – Formulated Beverages, during the six-week public consultation period of 15 January to 26 February 2003. A summary of submitter comments is provided in the table below.

Two regulatory options were presented in the Initial Assessment Report:

Option 1 – Maintain *status quo*; and
Option 2 – Include regulations specific to formulated beverages in the Code.

No.	Submitter	Submission Comments
1	**Australian Food and Grocery Council**	**Supports Option 2** **Characteristics** • Should be considered as general purpose foods. • Policy guidance required from the ANZFRMC to guide FSANZ in considering fortification of foods. • Recommends that all non-alcoholic water-based beverages, including formulated caffeinated beverages, be included in the definition of FBs. **Consumption** • Estimated New Zealand consumption for the year to June 2001 was 0.14 litres per capita, and 0.39 litres per capita for the year to June 2002. **Composition** • Considers there is adequate risk management for the addition of medicinal herbs to FBs, through the control of restricted botanicals and in consideration of Proposal P260 – Medicinal Herbs. • The beverage vehicle should be considered a mere carrier of the added micronutrients such that the composition of the beverage is incidental and therefore of no regulatory issue. • Recommends that rather than constraining the use of terms such as 'daily dose', 'daily quantity' or 'one-day quantity', Standard 1.3.2 be reviewed to permit a more rational approach to FBs.

No.	Submitter	Submission Comments
		• Does not consider the use of FBs as ingredients in other foods a concern. **Food Additives** • Considers food additives raise no additional safety concerns for their intended use. • Considers the list of additives requested to be appropriate as they are present for a technological purpose. **Labelling** • Supports that FBs be permitted to carry claims, based on the principle that if they are present in the FB then consumers have a right to know. • Consumer's rights to useful information would be denied if per cent of RDI were not permitted. • Does not consider mandatory statements are necessary. • Label statements that advise against regarding a product as a substitute for a healthy diet could apply to all foods, and the AFGC does not support the use of such label statements on FBs. **Impact Analysis** Option 1: • Likely to cost consumers more than if local manufacturer of FBs were permitted. • No information to suggest any possible harm to consumers outside the target market. • Will continue to disadvantage Australian industry. • Potential cost of enforcing food standards in Australia. Option 2: • Likely price benefit to Australian consumers. • Unlikely that an increase in availability of FBs would result in unintended consumption and thus result in excessive intake of certain nutrients. Believes substitution for unfortified drinks tends to be the pattern of consumption rather than increased consumption. • Will benefit Australian industry. • Would contribute significantly to Australian exports of FBs, through the use of concentrates with overseas bottling plants. • Considers it possible that FBs and non-beverage products such as dietary supplements could be substituted. • Initial reduction in New Zealand exports of FBs to Australia. • Potential competitive advantage to New Zealand industry while the *New Zealand Dietary Supplements Regulations 1985* is still in place.

2	**Australian Beverages Council** *(formerly the Australasian Soft Drink Association Ltd) - The Applicant* Ms Melanie McPherson	**Supports Option 2** *Note: the following comments have been provided by the Applicant* **General Comments** • Concerned with the emphasis placed on the issue of botanical extracts, as ASDA is <u>not</u> seeking approval for the addition of herbal extracts. **Characteristics** • Should be considered as general purpose foods, as consumers purchase them as part of their normal diet. • Composition is their defining feature, and they fit as a subset of water-based non-alcoholic beverages. • Suggests the definition 'a water-based product, that may be sweetened and/or flavoured; may or may not contain juice; and that contains a mix of added vitamins and/or minerals'. **Consumption** • Provided consumption data as part of their Application. • Target groups are those consumers who are looking for these types of beverages, rather than consumers who are purchasing these products imported from or through New Zealand. **Composition** • ASDA has sought levels of vitamins and minerals that are currently permitted in a range of other beverages. • All vitamins and minerals are listed at levels established as safe. • Vitamin K has been excluded in consideration of health and technological issues. **Food Additives** • All levels of food additives are consistent with current approvals for additives, taking into consideration safety and technological need. **Labelling** • Seek permission to use the current provisions of 'a source' and 'a good source' in order to provide consumers with adequate information on the content of the beverage. • Consider using a statement regarding maximum daily consumption is appropriate to manage the risk associated with the use of one-day quantities. • Vitamin and mineral information displayed in quantitative terms only will not give consumers meaningful information.

		• No need for FBs to have a prescribed name. • Should not be labelled with statements that advise against regarding FBs as substitutes for a healthy diet. **Impact Analysis** • Not aware of any credible data showing substitution of other beverage products with water-based beverages • Consumer's use of these products is more likely to be as an addition to their current diet. • No evidence of progressive replacement resulting in a lowering of other nutrients. • No issues for enforcement agencies. • Labelling will provide consumers with information that can be expected to all but eliminate unintended consumption. • The 20% rate of growth is based on a small base. Hence, a small volume growth will initially appear to be a larger percentage growth, than for a product sold in a mature market. From estimations of overseas markets this growth is sustainable. • Refer to the Allen Consulting Report, regarding likely economic expansion. • Expect there to be some substitution of other water-based beverages only, however there is no data available. • Overseas experience shows the predominant growth of these products appears to be consumption additional to current diets. • Reduction in the volume of product imported from New Zealand. • Significant market is available to manufacturers in exporting product to Singapore and other Asian countries. This market can be expected to develop in the medium to longer term.
3	**Australian Self-Medication Industry** Mr Jonathan Breach	**Supports Option 1** **Characteristics** • Should be treated as supplementary foods, and as such remain within the scope of the FTDS discussions. • Lack of clarity between those FBs that will be used for general-purpose verses those that are supplementary. • The primary purpose of some FBs is likely to be 'hydration', and others 'functional' or health benefit related. • Appears lack of insight as to who is currently buying FBs, for what purpose and how the composition and presentation influences their decision. • Regulatory controls should be based on both a compositional and functional approach. • Consider FBs are the same in function as multivitamin pills, where the medicines manufacturing industry must comply with strict manufacturing practice standards, none of which is applicable to the foods manufacturing industry.

		Consumption • Refers to a submission by the Australasian Soft Drink Association Ltd to the Productivity Commission Citrus Growing and Processing Inquiry in 2001 which comments on market growth and sales for still water and energy drinks – provided as an attachment to their submission. • Refers to other market trend data over the past two years for mineral water, still water and energy drinks – provided as an attachment to their submission. • The level of consumption potentially becomes a public health and safety concern in context to the proposed composition of the FB covered by this application. **Composition** • Level of selenium is inappropriate for a food. If a TTDS were to contain the proposed level of selenium it would be scheduled as a Pharmacist Only Medicine due to safety risk. • The level of vitamin A proposed would require a mandatory warning if used as an ingredient in a Complementary Medicine. The vitamin A limit is a potential public health risk as these products could be used in a manner other than supplementary to the diet. • Reasonable expectation of the consumer that any vitamins and minerals formulated within these products would remain at the label stated amounts at the end of shelf life. • Lack of clarity over the identity of the role of the carrier. • One-day quantity may be an appropriate basis for regulation in context to supplementary use. However, products presented in context to the still water market may be consumed in larger quantities, and doubt exists as to the effectiveness of consumer labelling recommending restricted intake. • Should not be used as an ingredient in other foods, due to concern regarding the stability and therefore nutritive value of the vitamins and minerals if further altered. **Food Additives** • Need for safety assessments of the requested maximum limits, taking into account the potential for some products to be consumed in greater quantities than may occur for 'supplementary use'. **Labelling** • Potential for false and misleading labelling to occur in vitamin, mineral and herbal content claims (and the implied health benefits). • Use of the terms 'source' and 'good source' are only applicable if the formulation ensures adequate bioavailability and stability of the vitamins and minerals, including at the end of shelf life. • Content and nutrition based claims for FTDS should only be acceptable where there is sufficient quantity i.e. 25% of the RDI. However, quantification should still be mandated at levels below this amount.

		• Maximum consumption limits are only useful when the total presentation of a product is considered, and whether the product is viewed for supplementary or general use. • Refers to 'Performance Based Labelling' that is gaining interest in the medicines arena, as a means to ensure correct consumer interpretation of a label and appropriate use of product from the label. **Impact Analysis** • Retail World (Vol 55, No 24, December 2002) – Still waters (including FBs such as Mizone) experienced a 20% growth in market value and 14% growth in market volume from 2001. • Public health concern is whether an increase in water based beverage consumption will result in unreasonably widespread consumption of formulated waters not containing the same nutritional complexity as may be found in fruit based drinks. • Children will be a potential target market of some manufacturers. • To create a separate standard for FBs would prematurely create another interface between foods and medicines that needs to be interpreted and enforced, without suitable resolution to other similar functional FTDS products. • The claim regarding market potential is not reasonable because of the regulatory environments of Australia and the US differ significantly. • Concern that the formulation of vitamins, minerals, amino acids and medicinal herbs at levels comparable to that found in Complementary Medicines may increase the incidence of adverse reactions to particular substances and increase the potential for food-medicine interactions, especially if used as part of the general food supply rather than strictly for supplemental purposes. • Questions whether the market growth is due to greater numbers of the population consuming FBs or that individual consumers are increasing their levels of consumption, and whether this poses health risks based on maximum daily intake. • Any increase in the capacity to manufacture FBs may be offset by a corresponding decline in manufacture of other beverages. • Any shift in consumers using FBs as a source of supplementary intake of vitamins and minerals may result in a decline in manufacture, sales and thus employment in the local medicines manufacturing industry. • Australia has always had the capacity to supply FBs and other FTDS products to export market, even though not approved for sale in Australia. • Difficult to postulate a 20% growth without a firm identification of who the target consumer is, the purchase motivation and in what quantities it will be consumed. • Unclear how these products are perceived by consumers with regard to their total diet and how this may affect dietary education. • Suggests that currently available multivitamin and mineral products sold as effervescent tablets and powders in sachets, which are added to water to produce as liquid beverage to be consumed for supplementary purposes, are comparable products to FBs. • Herb containing FBs imported from NZ will still have a promotional advantage over Australian manufactured products unless Australian manufacturers include herbal ingredients under the pre-text of being 'flavours'.

4	**Australian Dairy Corporation** Dr Anita Wells	**Supports Option 1** **Regulatory Principles** • Considers this Application not compatible with nationally endorsed guidelines on healthy eating, and therefore does not meet the Regulatory Principles for Addition of Vitamins and Minerals to Food. • Not consistent with the national guidelines of 'encourage water as a drink' and 'eat only a moderate amount of sugars and foods containing added sugars'. **Consumption** • The Australian Dairy Corporation commissioned a Newspoll survey among a nationally representative cohort of 1,200 adults aged 18 years and over (Beanham et al, 2003). In light of survey results the Australian Dairy Corporation believes that approval of Application A470 is likely to lead to (evidence provided): - an increase in consumption of fruit drinks/soft drinks; and - a decline in the consumption of milk. **Health Impact** • In light of previous research (references provided) and the Newspoll survey, the Australian Dairy Corporation believes the approval of Application A470 would not be in the interest of public health as: - dental caries and dental erosion would be likely to increase; - it is likely to adversely affect bone health; and - it may have a detrimental effect on Australia's growing obesity problem. **Composition** • Does not consider soft drinks and fruit drinks to be suitable vehicles for voluntary fortification. **Cited References** • Beanham S et al. Australian dairy Corporation Issues Research: Calcium-Fortified Drinks Executive Summary, February 2003. • Other references provided throughout the submission.
5	**Blackmores Ltd** Ms Lynda McFarlane	**Supports Option 2** **General Comments** • Supports a specific standard to ensure there are adequate controls in place to characterise and regulate FBs. • It is not in the interests of either consumers or industry to extend permissions without adequate consideration to the public health and safety consequences, particularly for children and teenagers who are currently high demand consumers for other water-based beverages.

		Characteristics • Should be considered 'supplemental foods', have a separate standard, and their purpose could be 'formulated supplemental beverages'. • Should be defined using parameters of both composition and purpose, to avoid confusion with other food products and medicines. • The definition could encompass both carbonated and non-carbonated water based premade drinks. These drinks could include flavours and fruit additives. **Consumption** • Not aware of any additional consumption data. • Potential target groups are any groups that currently consume soft-drinks and other dietary supplement beverages (New Zealand made or imported), and includes all age groups. Composition • Identifies safety concerns regarding current restrictions on selenium and chromium contained within the Therapeutic Goods Regulations. • A safety assessment needs to be made to establish the appropriate range and content of vitamins and minerals. • The quality of the base beverages should be considered, given that there is potential for large quantities to be consumed. • Likely to be used by consumers as thirst quenchers, energy boosters and in social situations as an alternative to alcohol or other beverages. • One-day quantity is appropriate. • Seems reasonable to limit the use of FBs in other foods unless there is data available on their usage and consumption in order to make an appropriate safety assessment. • The level of claimed vitamin and mineral content should be maintained during the shelf life of the product, so that consumers are not mislead. **Labelling** • Explicit or implied health or therapeutic claims should not be made, however should be free to state the presence of vitamins and minerals in the beverage. • The vitamin and mineral content should be displayed on the packaging and be consistent with the current requirements for other foods. They should be disclosed as a mandatory requirement to inform consumers. • Considers the one-day quantity statement to be reasonable, but that it needs to be examined further. • Suggested some alternative/additional statements used for traditional vitamin and mineral supplement products. • Supports use of a prescribed name for identification and enforcement purposes. • Labelling with statements that advise against regarding FBs as substitutes for a healthy diet or as providing health benefits is appropriate and consistent with complementary medicines and other food categories.

		• Where products contain substances that have been evaluated by other government agencies and require safety warnings, then those same warnings should be required on FBs to ensure consumers are aware of any risks. **Impact Analysis** Option 2: • Known documented risks on excess consumption of specific vitamins and minerals - selenium, vitamin A, zinc, vitamin B6, iodine and iron. • Consumers may substitute more traditional vitamin and mineral supplement products such as complementary medicines for FBs, particularly if they perceive they have some health benefit. **Advertising** • Strongly support a co-regulatory system of advertising controls to ensure that FBs are responsibly promoted, especially to children and teenagers.
6	**Community Nutrition Team, Central Sydney Area Health Service** Ms Ruth Kharis	**Supports Option 1** **General Comments** • To maintain public health, a sustainable food supply and help address the increasing incidence of obesity and overweight, they request that A470 is not progressed further. • Appears this is a vitamin/mineral tablet in a liquid form posing as a beverage. • Proposal P235 is yet to be determined and the decisions made regarding how to distinguish a FTDS from TTDS. • The high kilojoule content contributes further to the increasing incidence of overweight and obesity. Consumers do not need more choices of high kilojoule drinks, there are ample already. • There must be a demonstrated need for the product, including that the nutritional requirements cannot be met by existing supplements. • It is important to keep the roles and intake of tablets and food separate, to avoid nutritional harm through displacement of foods and excessive consumption of vitamins and minerals. • A470 is premature, as New Zealand is currently reviewing and may rescind the law that allows FBs to be imported and exported from New Zealand. **Characteristics** • No suitable purpose category. Meeting consumer demand is not a purpose category the warrants the development of additional food standards. • Do not meet several criteria of the FSANZ regulatory principles including, adequate nutritional rationale, they are not a 'food category' and the carrier product is devoid of naturally occurring vitamins and minerals. • Are not general purpose foods. They naturally lack nutrients in sufficient quantities, contain high levels of vitamins and minerals like a tablet, and some population groups would be at risk if they consumed FBs. • Are not special purpose foods or a food type dietary supplement (reasons provided). • Possibility to use the Therapeutic Goods Act to assess these products.

		• FSANZ should not regulate to allow a liquid vitamin and mineral tablet to pose as a food. • Are not functional foods, as they do not provide health benefits beyond simple nutrition. • Do not sufficiently differ from a vitamin and mineral tablet to warrant defining. • If accepted, the definition must at least include a nutritional purpose of the product that relates to the composition of the product alleviating a disease. Both composition and purpose would be defining features. **Consumption** • Possible that current supplement users may consume FBs instead. • No appropriate target consumer groups as people's diets are adequate with respect to fluid intake and for most vitamins and minerals. • Concern that the excessive level of kilojoules in the proposed product is likely to contribute further to the increasing incidence of obesity. • Concern regarding the expected average consumption of 500 ml per day, and the subsequent high kilojoule content of this product. **Composition** • FBs would not be an effective method to address dietary gaps. The high kilojoule content and presence of sugars and food acids would harm the consumer's health. • Likely to be marketed as a 'healthy soft drink'. • Need to limit the percentage of juice, sugar, kilojoules and volume size. • Regulatory control over the nutritional quality of the beverage vehicle is needed, given that the Applicant has sought permission to make claims. • Safety concerns regarding the lack of controls to protect the public from consuming and over consuming the product. • Particular concern for children, pregnant and lactating women who are at risk of over consumption of nutrients. For children the requested amounts exceed the RDI for vitamin A, thiamin, riboflavin, B6, folate, vitamin C and magnesium. For pregnant and lactating women the RDI is exceeded for thiamine, riboflavin, B6 and vitamin C. • Concerns regarding kilojoule content, where 500 ml soft drink provides 8-18% of the RDI for adult and 1-2 year olds respectively. Also concern regarding links with diet and obesity and type-2 diabetes. • The range of vitamins and minerals proposed is not appropriate and is unnecessary. • The nutritional quality of the base beverage must be considered, as it has a much more significant role in the diet than just being a carrier for added vitamins and minerals. • The suggested one-day quantities are in excess of the RDI and people will also be obtaining these nutrients from other foods. • The use of FBs as ingredients in other foods should be prohibited. **Food Additives** • Some safety concerns regarding the type and amounts of proposed food additives. • Sensitive individuals with asthma, hyperactivity and chronic allergy are known to react with benzoic acid, sulphur dioxide and annatto (Briggs et al 1985, Hanssen et al 1989). • Sulphur dioxide is known to destroy thiamin in food.

		Labelling • Should restrict labelling of vitamin and mineral claims, as the base product is nutritionally poor, they are high kilojoule products, and the nutrients are not naturally present. • If the proposal goes ahead mandatory warning statements are essential to ensure informed consumer choice. Suggested warning statements: 'a healthy diet provides other essential components as well as vitamins and minerals', 'this product is not a meal or food replacement', 'to meet your nutritional needs you will still need to eat a healthy diet on the same day as drinking this beverage', 'not to be consumed by children, pregnant women and lactating women'. • People with poor maths skills will not understand the percentage daily intake information, and it is open to abuse in terms of marketing. • If the percentage daily intake is made mandatory then warning statements should also be mandatory, explaining that more of a vitamin/mineral is not always better and that a healthy diet is sufficient. • Prescribed name is needed to distinguish them from soft drinks given that they are more like a tablet. • Should be labelled with statements that advise against regarding them has substitutes for a healthy diet or as providing health benefits. **Advertising** • Should not be promoted on television, and if it is then equal time must be given to the health warnings. • Access to the product should be restricted to avoid unintended over consumption of the vitamins and minerals in the product, e.g. not sold in vending machines or school canteens. **Impact Analysis** • Disagree that consumers automatically 'benefit substantially from exercising choice', as there are many barriers to people exercising choice, e.g. language, literacy, how to read food labels. **Cited Research** • Briggs D, Wahlqvist M. Eating matters food additives – facts for consumers. Methuen Haynes North Ryde 1985, pages 122, 124 and 161. • Hanseen M, Marsden J. The new additive code breaker. Lothian Publishing Company Melbourne 1989, pages 22, 42, 46, 62-64, 78-79 and 92-83. • Other references provided throughout submission.

7	**Complementary Healthcare Council of Australia**	**Supports Option 1** **General Comments** • Currently no equivalent standard for such beverages in any other country. • Such a standard would only facilitate the provision of sugar water as a carrier of supplemental vitamin and minerals. • Understands that there is no fundamental nutritional value in the proposed FBs. **Characteristics** • Strongly opposes incorporation into general purpose foods on the grounds that: daily intake will be firmly influenced by marketing companies; the possible mass dosing of consumers; lack of controls over claims/safety/quality; and poor enforcement of standards. • Appear to be of a supplementary composition and could more appropriately meet the proposed standard for FTDS. • Neither composition nor purpose are defining features. **Consumption** • Normally sold in New Zealand as sports waters and consumption levels appear high. • Likely target group is 14-35 years old, as they are more susceptible to advertising of perceived health type foods and supplements. **Composition** • Concern about the toxicity of selenium at the level proposed. • Iron limit appears high and is likely to be a safety issue, particularly for children. • Vitamin A at the proposed level may pose a risk to pregnant women when included in addition to the normal diet. • There are many minerals that are not appropriate to be included in FBs including phosphorus. • The combination of phosphorus, magnesium and iron makes little sense as phosphorus acts to bind to magnesium and iron making them unavailable for absorption. • The nutritional quality of the base beverage must be addressed as the proposed food vehicle has no basic nutritional role. The request to contain sugar at unspecified amounts is contrary to the principles of a healthy diet. The request to contain fruit juice etc appears to be there principally as a flavouring agent. • Consumers perceive FBs as 'pick-me up', 'feel-good' and 'contains vitamins and minerals, therefore must be good for me' products. Perceive them as a way to meet the recommended 1-2 litres of water per day. Doubtful that they would consider them as part of a nutrition plan. • Strongly opposes use of FBs as an ingredient in other foods. **Labelling** • Should not permit products to be labelled with 'source of' or 'good source' or any other claims, as with potentially high sugar content they are of an unhealthy composition.

		• Prescribed name is appropriate to allow identification of the product. **Impact Analysis** Option 2 • Potential economic loses for the Complementary Medicines sector, and the economic impact would be cost neutral. • Difficult for government to monitor the safety aspects associated with FBs (e.g. stability, quality) • High risk of excess consumption, especially by teenagers, which could result in adverse health outcomes. • Difficult to formulate a stable vitamin-mineral preparation. • Less costly to produce under a food standard compared with the Therapeutic Goods Regulations.
8	**Dietitians Association of Australia**	**Supports Option 1** **Characteristics** • Recommends regulation as general purpose foods, to restrict the ability of manufacturers to add vitamins and minerals to these beverages. • No definition required. **Consumption** • Not aware of any data on per capita consumption of FBs. • Concern that FBs may promote consumption of excess kilojoule intake, and therefore further contributing to Australia and New Zealand's escalating rate of obesity and overweight in children and adults. • Cited research (Ludwig et al, 2001) showing an association between sugar-sweetened drinks and the development of obesity in children in the United States. • Poppitt et al, 1996 showed that energy from drinks adds to total energy intake and does not displace energy from other foods. • Mattes, 1996 showed that compensation at subsequent meals for energy consumed in the form of a liquid is less complete than for energy consumed from foods. • Based on advertising and popularity, the target groups are likely to be children and teenagers. • Concerned about the potential for FBs to replace more nutritious beverages, such as milk and water, in these groups. **Composition** • Not aware of any safety concerns. However, consider the level of iron proposed of potential concern for haemochromatosis sufferers, and the proposed levels could also present a risk for children and pregnant and lactating women. • Does not support the application to add more than recommended dietary intake levels for vitamin B12, vitamin C, folate, thiamin, riboflavin, niacin and vitamin B6. • Believes it unnecessary to add any of the proposed vitamins and minerals, as the base of the beverages is likely to be nutritionally poor. • Considers the nutritional quality of the base beverage is important should the application proceed. • Concerned about further increasing the range and consumption of sugar sweetened beverages.

		• Considers a 'one-day' quantity more appropriate than a 'daily dose', and a need to state the target group for whom this one-day quantity was established (if the application proceeds). • Use of FBs as ingredients in other foods should be prohibited. If not, they could be used inappropriately to circumvent the current food standards for the addition of vitamins and minerals to foods. **Food Additives** • Although not in support of this application, they consider the proposed maximum levels appropriate considering they are allowed for other non-alcoholic beverages in the Food Standards Code. • Not aware of any safety concerns, however recommend FSANZ seek comment from food technology experts. **Labelling** **(if the Application proceeds)** • Believes all claims for vitamins and minerals should be prohibited. • Believes labelling with percentage daily intake information will provide consumers with a misleading perception that FBs are a healthy addition to the diet. • Information should be listed in quantitative terms only. • Considers the warning statement provided to be appropriate. • Supports the use of a prescribed name on the label of FBs. • Consider statements on product labels that advise against regarding FBs as a substitute for a healthy diet or as providing health benefits should be mandatory. **Cited Research** • Ludwig DS, Peterson KE, Gortmaker SL. Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective observational analysis. Lancet 2001;357:505-508. • 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. Physiol Behav 1996;59:179-187.

9	**FORK** Ms Diane Temple	**Support Option 1** **Characteristics** • No additional supplemental food categories are needed. • Are not general purpose foods because of the high level of vitamin and mineral supplementation, use of a high kilojoule carrier, and due to the nutritional concerns associated with an increase in intake of sugar and the increase in incidence of overweight and obesity. • However, if FSANZ proceeds to put FBs into a purpose category then they best fit with general purpose foods, as this would require them to comply with Standard 1.3.2. • Do not fit the food type dietary supplements category because of the poor nutritional quality of the carrier product, the product is not designed for a specific nutritional deficiency, the product is likely to be used as a fancy expensive soft drink, and they do not fit the category for formulated caffeinated beverages. • FBs do not belong in the Code as they are a water based carrier of a mineral/vitamin tablet and are not a food. • If FBs are approved, then both composition and purpose should be defining features. **Consumption** • No evidence of consumer demand. • As there is no demonstrated nutritional need for this product there is no target consumer group. • Likely consumer groups are the worried well with disposable cash who the marketing companies reach by trading on people's fear of ill health and people who drink soft drinks. **Composition** • Safety concerns regarding the presence of trace elements (copper, chromium, iodine, manganese, selenium), vitamin D and some vitamins well in excess of the RDI (thiamin, riboflavin, B6, folate, B12 and vitamin C). • No demonstrated need for such an excessive level of so many vitamins and minerals to fortify food. • At risk groups include high intake consumers, children and adolescents, and pregnant and lactating women. • Do not need vitamin D supplemented, due to the sunny climate. • Nutritional quality of base beverage is important given the increasing incidence of obesity. If people need to take vitamins and minerals it is better that it does not come with extra kilojoules. The presence of food acids and sugar are a concern for dental health. • Should not be used as ingredients in other foods. **Labelling** • All claims for vitamins and minerals should be prohibited, as the carrier does not naturally contain these nutrients and any claim is likely to persuade the misinformed to consume this product unnecessarily. • A safety warning should be present, for example, 'This product is not a substitute for a healthy diet/healthy foods. More vitamins and minerals are not always good for health. Excessive vitamins and minerals can harm your health'.

		• People may have difficulty understanding and interpreting a percentage daily intake label. For those who can understand percentage labelling, it will assist them to make an informed choice. Stating levels of nutrients alone would be meaningless, as people do not know what the RDI is for a particular nutrient. • The vitamin and mineral content should be stated within the context of the RDI and a healthy diet. • Suggests limiting package size and purchase quantity to 100-200 ml and only 10% of the RDI for the various nutrients as an alternative means of managing the risk associated with the use of one-day quantities. • If approved, FBs would need a prescribed name. **Impact Analysis** Option 2 • Government enforcement agencies would have a significant responsibility to ensure FB advertising, food labelling and composition laws are not breached. In addition, these agencies would need to provide consumer education. • Having a greater choice of 'dubious nutritional quality' is not a benefit to consumers and is not a benefit in the long-term sustainability of our food supply. • The product itself is unsustainable. • No export opportunities when ethical and sustainability issues are considered.
10	**Food Technology Association of Victoria Inc** Mr David Gill	**Supports Option 2** • Questioned if the calcium levels per reference quantity requested in the current Application and those proposed in the draft variation to Standard 1.3.2 for Application A424 are consistent.
11	**Heyhoe & Associates on behalf of Johnson & Johnson Pacific Pty Ltd** Mr Tom Heyhoe	**Supports Option 2** **General Comments** • Supports Option 2 as a means of addressing and partially rectifying the regulatory contradiction that the *New Zealand Dietary Supplements Regulations 1985* provide. **Composition** • Permission to use all currently permitted intense sweeteners in combination with sugars would allow management of product sugar content without loss of taste quality, as per ASDA's request. **Food Additives** • Considers the proposed additives and their maximum permitted use levels are both responsible and appropriate.

12	**Nestlé Australia Ltd** Ms Robyn Banks	**Supports Option 2** **General Comments** • Supports the AFGC submission, where Nestle is a member. Additional comments are: **Composition** • Should be permitted to contain other foods and not restricted to a certain few ingredients. • Permission to add 'medicinal herbs' should be provided, if they are permitted in the Code to be added to other foods. Those botanicals that are prohibited under the Code should not be permitted. **Food Additives** • The additives permitted for non-alcoholic water-based beverages should be applicable to FBs. **Labelling** • Claims for vitamins and mineral content should be permitted. • No need for a prescribed name.
13	**New South Wales Health, Food Branch** Mr Michael Apollonov	**Supports Option 1** **General Comments** • Strongly opposes the Application. • Opposes the Applicant's reason for the request, stating 'this is not a valid argument for the creation of yet another standard in a product area that is already crowed with standards and the wrong way to address what amounts to an exploitation of a blatant loophole in the Dietary Supplement Regulations'. • Need to remove the loophole that permits the manufacture of foods as 'dietary supplements'. • The addition a 'formulated beverage' to the already existing formulated caffeinated beverages, formulated supplementary sports foods etc would add to the confusion of regulators and consumers.

14	**New Zealand Food Safety Authority**	**Supports Option 1** **General Comments** • Does not support proceeding with A470 at this stage, until policy guidance for the fortification of foods and for food type dietary supplements are developed by FRSC. • Recommends FSANZ consider data on the contribution of sweetened drinks to the overall energy intakes of New Zealand children that will be available in late 2003. • By recognising high energy/high sugar foods as potential sources of a range of nutrients and hence promoting possible health benefits, we are possibly increasing the potential risk of overweight and obesity. • Not clear if these products would replace consumption of other sweetened beverages or increase current levels of consumption of sweetened beverages due to the potential benefits of added nutrients. • Need to consider dental health if there is a potential for increased consumption of sweetened beverages. • Suggests use of dietary modelling, particularly for children.
15	**New Zealand Juice Association** Mr John Robertson	**Supports Option 2** **Characteristics** • Should not be considered general purpose foods. • Should include all non-alcoholic beverages excluding white milk but including juices, fruit drinks non-fruit drinks and sports water type products. **Composition** • Is aware of safety concerns regarding the proposed maximum levels, and consequently support the use of a maximum daily consumption statement. • No need to address the nutritional quality of the base beverage as nutrition panels remove the possibility of deceiving the consumer. • Use of one-day quantity is appropriate. • Should not be ingredients in other foods. **Food Additives** • The same additives allowed in other non-alcoholic beverages should be permitted. **Labelling** • Should not be restricted in making nutrition claims. • Use of percentage RDI more appropriate than quantitative amounts, to assist with consumer understanding.

		• Should not have a prescribed name as this would have no meaning to the consumer. • The proposed warning statements are only required if all other foods also require this labelling. **Impact Analysis** • No history of problems of unintended consumption based on data from the last 4-5 years of consumption of similar products. • Export markets have already been established by New Zealand manufacturers.
16	**PB Foods Ltd** Ms Monica Witsch	**Supports Option 2** *General Comments* • Strongly recommends that FSANZ review the overall principles for adding vitamins, minerals and other bioactive ingredients to general purpose, special purpose, medical foods and dietary supplements to simplify the standards instead of developing a new standard in isolation. • Understands that FBs were allowed as part of R9 before ANZFA incorporated minimum macronutrient criteria as part of Standard 2.9.3 and changed the definition of formulated supplementary foods. PB Foods consider that it was not the intention of ANZFA to prohibit liquid formulated supplementary foods. • Comments that the policy frameworks for fortification and functional foods have not been finalised, and until this time they cannot adequately comment on this proposal. • Recommends removing the minimum macronutrient criteria for formulated supplementary foods, which will then allow for FBs as part of Standard 2.9.3 until the policy guidelines are finalised. • Recommends that the formulated supplementary foods standard be reviewed to allow the development of liquid formulated supplementary foods.
17	**Public Health Services, Queensland Health** Mr Gary Bielby	**Supports Option 1** *General Comments* • Strongly opposes the manufacture and sale of formulated beverages. • Opposes Application A470 as FRSC has established a working group to develop a policy on the fortification of food, and progressing this application may compromise any future decision made by this group. • FBs have significant potential to mislead or deceive consumers. *Characteristics* • Should not be considered general purpose foods, as they have a supplemental purpose. • Composition and purpose are defining features, where non-alcoholic water-based beverages should only encompass those of an appropriate nutritional profile (e.g. low sugar, low saturated fat).

		Consumption • Data on consumption of flavoured mineral water and electrolyte drinks from the 1995 National Nutrition Survey showed largest intake by males across all age groups, with largest volume intake by those aged between 16 and 24 years. • The Queensland Health Youth Oral Health Survey (2002) found that of the 2203 13-15 year old children surveyed, 34% consumed soft drinks, 29% juice, 10% cordial and 7% sports drinks while at school. • Likely target groups are children and youth, as well as other vulnerable groups such as women of child-bearing age. **Composition** • Opposes all additions of vitamins and minerals to the proposed beverages. • Concerned that the proposed addition of niacin, folate, magnesium, copper and manganese are at or above the upper limit for some at risk groups, notably children. • Concern of toxicity with excess consumption of fat soluble vitamins. • Excess vitamin D, C and E can have adverse health outcomes and/or affects on medications. • Without estimated consumption data it is difficult to estimate the impact of their consumption on total vitamin/mineral intake. • The nutritional quality of the base beverage is important, with major concern that the proposed products are likely to be very high in sugar. • One-day quantity is only appropriate if it is adequately labelled and policed. Serving size is a vital consideration in the potential impact of such beverages on calorie consumption. • Use of FBs as ingredients in other foods should be prohibited. **Labelling** • All vitamin and mineral claims should be prohibited, particularly given the doubtful nutritional quality of the beverages in question. • Percentage labelling enables the consumer to make a more informed choice, as few consumers would be aware of the quantitative RDIs and be able to interpret them. • Require a prescribed name so that they could be distinguished from other beverages. • Should be labelled with statements that advise against using them as substitutes for a healthy diet or as providing health benefits. **Impact Analysis** Option 1 • Most likely that consumers would consume FBs for their vitamin and mineral content.

		• Notes that just because there is no information to suggest any possible harm from unintended consumption by consumers outside the target market, does not mean that there is no harm. • Concern regarding the potential impact on rates of overweight and obesity. Option 2 • Consumers are currently overawed by the number of food products on supermarket shelves which have increased from around 6000-40000 from 1960 to 2000. As such the addition of FBs is hardly a benefit. • Risks of unintended consumption relate to concerns regarding overweight and obesity and excess consumption of vitamins and minerals. • The potential market for FBs is likely to be huge. • The addition of vitamins and minerals and the promotion of this may encourage some groups to consume even more of these high sugar drinks. • Need to consider the impact on nutrition and oral health education regarding the appropriate use of FBs, where government and non-government resources are already stretched to their limit.
18	**Sanitarium Health Food Company** Dr Sidney Cole, Ms Trish Guy and Ms Ruth Truswell	**Supports Option 2** *General Comments* • Sanitarium currently markets a range of vitamin and mineral fortified beverages that are produced under the New Zealand Dietary Supplements Regulations. • Sanitarium generally supports the proposal, but would like to prevent poor nutritional quality beverages from qualifying as FBs. **Characteristics** • Should be designated as Special Purpose Foods, as per formulated sports drinks and formulated caffeinated beverages. • Notes that the FBs Sanitarium are interested in do have a 'supplemental' function, and therefore may best fit under food type dietary supplements. • Their purpose is to provide an enhanced water based product that will improve consumer nutrition by encouraging the consumption of greater quantities of water as part of the daily food intake. In addition they will provide consumers with vitamin and minerals required for replacement of lost nutrients e.g. after exercise. They will provide a water product that will simultaneously provide a well balanced mineral and vitamin supplementation. • Should be defined using a combination of composition and purpose features, with purpose the most important aspect. • To define composition they suggest, 'a water product which supplies a good balance of vitamins and minerals'. **Composition** • Not aware of any safety issues with the levels of vitamins and minerals proposed.

		• Levels of biotin, pantothenic acid, calcium, iron, magnesium, phosphorous and zinc are all higher in the current supplementary sports foods, and know of no evidence why the higher levels should not be permitted for FBs. • The regulations need to address the possibility that a manufacturer may have an agenda encouraging the consumption of amounts of vitamins and minerals which may be excessive, for example through use of artificially low serving sizes. If manufacturers base the vitamin and mineral composition on reasonable maximum daily consumption there is not danger of excessive intake of these nutrients. • Serving size should be regulated to prohibit the use of artificially low volumes, as this would increase the maximum amount consumed in a day. Suggest a cut-off point of 700-800 ml may be suitable. • The range of vitamins and minerals requested is satisfactory. • The range of vitamins and minerals allowed should be the same as that allowed in formulated supplementary sports foods, as the types of consumers and the purpose of FBs in relation to vitamin and mineral supplementation is very similar. • Prefers that a maximum claimed amount is specified for those vitamins and minerals where there is evidence that high intakes may have negative impact. • The nutritional quality of the base beverage should be addressed. • If the energy content of a food is low, even large intakes will not have a significant dilution effect on other nutrients. • Concerned about the energy content that may be allowed in FBs to which vitamins and minerals are added, particularly if this misleads consumers that the food has been made 'healthy' by the addition of vitamins and minerals. This should be addressed by limiting FBs to those with low energy content, and perhaps using prescribed maximum sugar and fat levels. • Used by consumers as a thirst quenching drink that they believe will also supply reasonable levels of a broad range of vitamins and minerals. Many consumers of Sanitarium water products are using them to replace vitamin and mineral supplement pills. • One-day quantity is appropriate, however the quantity supplied per normal serve is a more important regulatory principle. • The use of FBs as ingredients in other foods should be prohibited. **Food Additive** • The proposed maximum levels are appropriate. • Would like the permissions to allow for the addition of new additives that may be approved in the future, and that these be automatically allowed for use in FBs, for example artificial sweeteners. • All permitted natural colouring, including food caramel, should be permitted. • Not aware of any need to do further safety assessments. **Labelling** • Some restrictions to labelling of vitamin and mineral claims should be in place. The principles established for the vitamin and mineral regulation should be the basis for this restriction (Standard 1.3.2).

		• Some restriction for beverages that are not classified as low energy drinks may be appropriate. • Claims should be permitted only on the basis of per serve quantities of nutrients. Claims on the basis of maximum daily consumption should not be allowed. • Does not support limiting claims to an expression of content only, e.g. 'good source'. • Supports use of percentage RDI claims, as these are readily understood and used by consumers to interpret the nutritional information. • Information on the quantity of vitamins and mineral present in a normal serve should be made mandatory and the percent RDI information could be optional. • If no RDI is established, then the claim should be limited to claims of content only. • Possibility of distortion of nutritional information by inappropriate values assigned to the serving size. A normal serve could be defined as the total contents of the package which the beverage is contained up to a bottle size of 750 ml. For larger size packages their label should define the size of a normal serve, for example 300 ml. • Use of the statement 'consume no more than….per day' is not appropriate, as it is too strong a statement and will tend to give the consumer a false assessment of the type of risk. Instead suggest 'recommended maximum daily intake no more than (amount of 1 day quantity)' • Ingredient and nutrition panel information are sufficient to identify FBs. • Unreasonable for FBs to be required to carry a warning or statements that advise against using them as substitutes for a healthy diet.
19	**Unilever Australasia** Ms Julie Newlands	**Supports Option 2** *General Comments* • Fully supports the AFGC submission. • Supports consideration of all Standards within the Food Standards Code relevant to this submission, including Standards 1.3.1, 1.3.2, 2.6.2, 2.6.4, 2.9.4 and the reviews of P235 and P260. • Supports Option 2 to include regulations specific to FBs in the Code, however opposes developing a specific prescribed standard. **Characteristics** • Should be considered as general purpose foods, as this is how these beverages are being consumed. • Does not agree with Table 1 of the Initial Assessment Report. • Should be defined to include the existing more specific standards for Formulated Caffeinated Beverages and Formulated Supplementary Sports Foods.

		• Should be established under Standard 2.6 – Non-alcoholic Beverages, with the relevant additive and vitamins and mineral permissions in Standards 1.3.1 and 1.3.2. **Composition** • A similar allowance made for medicinal herbs in the Formulated Caffeinated Beverages standard should be made for FBs, even though this is outside the scope of the Application. • Supports the use of a one-day quantity. • Questions the appropriateness of the range and levels of vitamins and minerals. Suggest that the range and levels appropriate for caffeinated beverages and sports foods be reviewed to determine levels appropriate for FBs. **Food Additives** • Supports use of the same food additive permissions for FBs as permitted for non-alcoholic beverages. **Labelling** • Labelling should be consistent with other product labelling requirements to promote consumer understanding and prevent complexity and potential confusion. • If vitamins and minerals are permitted to be added then a claim should also be permitted. The same rationale applies to percentage daily intake information. • Generic naming provisions are adequate, particularly where additional information such as claims, mandatory nutrition information panel and an ingredient list will all be present. • Unnecessary to include a statement to advise against regarding FBs as substitutes for a healthy diet or as providing health benefits, as the label will provide complete product information.