Attachment 7

Dietary Modelling Methodologies for Micronutrient 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, with a formulated beverage being a water–based, non-alcoholic flavoured drink with added vitamins and minerals. It was requested that the formulated beverage 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 formulated beverages. 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 formulated beverages. 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 formulated beverages with added vitamins and minerals were identified, nutrient intakes were then compared to the EAR to determine whether the consumption of formulated beverages 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

Formulated beverages are currently sold in New Zealand under Dietary Supplements regulations. These products contain nutrients such as pantothenic acid and vitamin C. Formulated beverages 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 formulated beverages 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 formulated beverage. 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 Formulated Beverages	
		(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 formulated beverages. 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 formulated beverages. 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 formulated beverages. 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 formulated beverages 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 formulated beverages. 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 formulated beverages 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 formulated beverages 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 formulated beverage for Scenario 1 and 2 according to assumptions discussed earlier.

The Applicant provided concentrations of nutrients in formulated beverages 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 percent 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 a formulated beverage. Whilst the Applicant provided some information on the products currently on the market that would be substituted with formulated beverages, there is uncertainty about what consumers will actually do when given the choice between a beverage they may normally consume and a formulated beverage. Additionally, it is not known exactly what volume of formulated beverages 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 formulated beverages in Scenario 1 was rounded to be 5%, and when the maximum claimable concentrations of the nutrients in the formulated beverage 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 a formulated beverage product

- consumers always select the formulated beverage containing nutrient being assessed;
- consumers do not alter their food consumption habits besides to substitute non-formulated beverages with a formulated beverage;
- consumers do not increase/decrease their consumption of foods/food groups upon formulated beverages becoming available;
- all of the nutrients in the formulated beverage 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 formulated beverage 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 formulated beverages 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.

Dietary exposure assessment

Dietary exposure assessments were conducted only on those food additives with a numerical ADI, i.e., those where there was more likely to be 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'

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 the small increase in exposure resulting from their use in formulated beverages.

Food additives, which have a numerical ADI

For the additives with a numerical ADI, 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 not result in an increase in exposure, and therefore would pose no 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 isobutrate, glycerol ester of wood rosin, and dioctyl sodium succinate. The addition of the following food additives to formulated beverages at the requested concentration could result in a small increase in exposure, however it would not pose a public health and safety risk: annatto, benzoates, acesulphame potassium (ace K), saccharin and alitame.

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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, 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.

The Applicant requested that 57 food additives/food additive groups be approved for use in formulated beverages including colourings, intense sweeteners, preservatives, emulsifiers, modifying agents and flavourings. The additives and the maximum concentration levels to be used in formulated beverages 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 formulated beverages (mg/kg)	Schedule 2	Maximum proposed concentration levels to be used in formulated beverages (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 formulated beverages. 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 formulated beverage 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 formulated beverages. 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 'Formulated Beverage' Scenario ('FB'), 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 formulated beverages 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 'Formulated Beverage' scenario.

Table 3: Estimated dietary exposure to 102 – Tartrazine

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	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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing quinoline yellow at that concentration.

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

Table 4: Estimated dietary exposure to 104 – Quinoline 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	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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' scenario.

Table 5: Estimated dietary exposure to 110 – Sunset 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	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 formulated beverages 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 formulated beverages 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 'Formulated Beverages' 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 formulated beverages 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 'Formulated Beverage' scenario.

Table 6: 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 'Formulated Beverages' 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' scenario.

Table 10: Estimated dietary exposure to 132 – Indigotine

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	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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing brilliant blue at that concentration.

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

Table 11: Estimated dietary exposure to 133 – Brilliant blue

				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 (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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing fast green at that concentration.

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

Table 12: Estimated dietary exposure to 143 – Fast green

				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 (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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' scenario.

Table 14: Estimated dietary exposure to 155 – Brown HT

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	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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverage.

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 'Formulated Beverage' scenario.

Table 15: Estimated dietary exposure to 160b – Annatto

				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	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 formulated beverages 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 formulated beverages. 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' scenario.

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

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	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 formulated beverages 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 formulated beverages 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). The ADI of 0-5 mg/kg bodyweight established by JECFA for benzoic acid and its salts is based on a long-term exposure study in rats. The NOEL was established at the highest dose tested (500 mg/kg bodyweight per day) where no adverse effects were observed. Signs of toxicity were observed in more recent short-term studies at higher dose levels. In establishing the ADI, a safety factor of 100 was applied to the NOEL to take into account species differences and individual human variation.

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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' 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 'Formulated Beverage' scenario, and for children aged 2-6 years for Australia at baseline and for the 'Formulated Beverage' scenario.

The addition of benzoates to formulated beverages 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 formulated beverages. 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 formulated beverages 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 formulated beverages 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 studies conducted in rats and pigs, where exposure to sulphites was found to cause gastric lesions in both short- and long-term studies. The no-observed-effect level (NOEL) was 70 mg/kg bodyweight per day. There was little evidence of toxicity in other organs, even at higher dose levels. In establishing the ADI, a safety factor of 100 was applied to the NOEL to take into account species differences and individual human variation. JECFA also noted that the gastric effects arise from local irritation, and therefore the effects would be more dependent on concentration in the stomach than on daily dose.

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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing calcium disodium EDTA at that concentration.

There is no change in exposure to calcium disodium EDTA between the baseline and the 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing sucrose acetate isobutrate at that concentration.

There is little change in exposure to sucrose acetate isobutrate between the baseline and the 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing DSS at that concentration.

There is little change in exposure to DSS between the baseline and the 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing Ace K at that concentration.

There is an increase in exposure to Ace K between the baseline and the 'Formulated Beverage' 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 formulated beverages 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 formulated beverages 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 Ace K was permitted in formulated beverages. This is because of the way the modelling has been conducted and the assumptions made about what beverages were substituted with formulated beverages. It is assumed that people substitute bottled water and sugar sweetened water-based flavoured drinks with a formulated beverage that contains Ace K, therefore increasing estimated exposure.

In conclusion, the addition of Ace K to formulated beverages 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

Two dietary exposure assessments were undertaken; a baseline estimate and a scenario estimate where it was assumed formulated beverages were substituted for other similar type drinks. 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 or fruit and vegetable juice products except for low joule fruit and vegetable juice products.

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, and may therefore overestimate current dietary exposure to saccharin.

FSANZ recently considered 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 uses the new level of 150 mg/kg for this class of drinks. FSANZ has no manufacturer use levels for products produced under this new permission. Therefore, it is likely that the estimated dietary exposure is over-estimated.

When estimating dietary exposures based on the 'Formulated Beverage' Scenario, it was additionally assumed that the requested maximum level of 150 mg/kg of saccharin was present in bottled waters, fruit and vegetable juice products and sugar sweetened water based flavoured drinks, assuming these are replaced with formulated beverages containing saccharin at that concentration.

For the Australian population there is an increase in dietary exposure to saccharin between the baseline and the 'Formulated Beverage' scenario. Where as for the New Zealand population, estimated dietary exposure to saccharin is higher at baseline than when it is assumed formulated beverages are consumed.

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	1.3 (25)	3.6 (70)
		'FB'	7224	1.8 (35)	5.1 (100)
	2-6 yrs	Baseline	84	2.2 (45)	6.4 (130)
		'FB'	707	3.8 (75)	10.3 (210)
New Zealand	15+	Baseline	392	1.9 (35)	6.8 (135)
		'FB'	1880	1.3 (25)	3.8 (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 saccharin to formulated beverages 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 'Formulated Beverage' scenario and at baseline for the New Zealand consumers, have estimated exposures to saccharin below the ADI.

Whilst the estimated dietary exposures in this model exceed the ADI for high consumers of saccharin in the population groups outlined, it is not considered that the actual dietary 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 'Formulated Beverage' scenario. This is because of the way the modelling has been conducted and the assumptions made about what beverages were substituted with formulated beverages. It is assumed that people substitute bottled water and sugar sweetened water based flavoured drinks with a formulated beverage that contains saccharin, therefore increasing potential exposure.

For the New Zealand population, the baseline estimate of exposure is higher than exposure when assuming formulated beverages are consumed ('Formulated Beverage' scenario). The results are an artifact of the way the modeling has been conducted and the assumptions that are made about what beverages were substituted with formulated beverages. At baseline, only a few products contained saccharin where as for the 'Formulated Beverage' scenario it is assumed that people substituted bottled water, fruit and vegetable juice products and sugar sweetened water based flavoured drinks with a formulated beverage that contains saccharin.

Therefore, there are more consumers of saccharin in the 'Formulated Beverage' scenario. This means, the estimated dietary exposures for baseline and 'Formulated Beverages' scenario are derived from different numbers of consumers of saccharin and therefore different distributions of individual dietary exposures. This results in different mean and 95th percentile dietary exposures being derived and the 'apparent' decrease in intakes for the New Zealand population. However, some individuals in the New Zealand population would have had increases in saccharin dietary exposure for the 'Formulated Beverage' scenario.

In conclusion, the addition of saccharin to formulated beverages 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 'Formulated Beverage' 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 formulated beverages containing alitame at that concentration.

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

Table 25: Estimated dietary exposure to 956 – Alitame

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	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 formulated beverages 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 'Formulated Beverage' scenario and 2-6 year olds for the 'Formulated Beverage' 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 'Formulated Beverage' scenario. This is because of the way the modelling has been conducted and the assumptions made about what beverages were substituted with formulated beverages. It is assumed that people substitute bottled water and sugar sweetened water based flavoured drinks with a formulated beverage that contains alitame, therefore increasing exposure.

In conclusion, the addition of alitame to formulated beverages 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 formulated beverages. 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 formulated beverages. 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 formulated beverages 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 formulated beverages 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 formulated beverages have the same concentration. This was based on the assumption made by FSANZ that the additives will have the same technological function in the formulated beverage 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 formulated beverages, the formulated beverage 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 formulated beverage 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 formulated beverages.

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 formulated beverage. The Applicant provided data on the types of beverages that are likely to be replaced by formulated beverages. 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 formulated beverages is included. A '100% substitution' approach was also modelled ('Formulated Beverage' scenario). For this scenario it was assumed that people will take a beverage out of the diet and replace it with a formulated beverage. 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 formulated beverage 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 'Formulated Beverage' scenario, however, it was assumed that the normal counterpart of a beverage (i.e. a sugar sweetened soft drink) could be substituted with a formulated beverage 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 formulated beverages 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 formulated beverage. Whilst the Applicant provided some information on the products currently on the market that would be similar to formulated beverages, 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 formulated beverage.

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 formulated beverages were available, consumers always substitute the 'like' beverages and select the formulated beverage containing the additive;
- consumers substitute all of the 'like' beverages with the formulated beverage, 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-formulated beverage with a formulated beverage;
- the number of serves per day recommended or bottle size of formulated beverages does not influence the amount consumed and therefore, formulated beverages 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 formulated beverage 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 this Application 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. 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 in general 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 formulated beverages is given at the Appendix to 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 were 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 of food additives for formulated beverages.

There have been some changes to the intense sweetener permissions for 14.1.3 – Water based flavoured drinks since the Application was originally submitted. A new intense sweetener, aspartame-acesulphame (called TwinSweet as a trademark) with a maximum permitted level of 6,800 mg/kg has been approved. This sweetener is a combination of two already approved intense sweeteners, being aspartame and acesulphame potassium. The permission for saccharin for category 14.1.3 - Water based flavoured drinks has been increased from 80 mg/kg to 150 mg/kg. These recent amendments to food additive permissions for water based flavoured drinks have implications for comparable formulated beverages and the new permissions need to be assessed. The Applicant has confirmed they are seeking comparable permissions for these food additives in formulated beverages consistent with the current amendments.

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.

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 testing 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.

Formulated beverages have a sugars restriction of not greater than 75 g/L (7.5%). To produce a formulated beverage with comparable sweetness to water based flavoured drinks or fruit juice products the use of intense sweeteners is required. Comparable products have a sweetness of 10 or 11% sugar or greater. Allowing the use of intense sweeteners and the maximum limit of sugars would maintain the limit on sugars for nutritive purposes, but would allow the manufacture of commercially acceptable products with comparable sweetness to be derived from non-nutritive sources.

To achieve this outcome the restrictions of clause 4 of Standard 1.3.1 which limit the use of intense sweeteners 'to replace, either wholly or partially, the sweetness normally provided by sugars' need to be exempted for formulated beverages. This means formulated beverages is a special case comparable to brewed soft drinks and chewing gum where the clause 4 restrictions also do not apply. A qualification statement 'clause 4 limits do not apply' is added against the intense sweetener approvals for formulated beverages in Schedule 1 of Standard 1.3.1.

Acesulphame potassium (INS 950), saccharin (INS 954), alitame (INS 956) and aspartame-acesulphame salt (INS 962) 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 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 formulated beverages comparable to water based flavoured drinks.

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

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 formulated beverages. 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 formulated beverages. 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 formulated beverages.

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).

Emulsifiers

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 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 formulated beverages 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 formulated beverages in this Application.

Carbon dioxide

The Applicant has indicated that formulated beverages will not be carbonated. That is they have confirmed that they have not requested permission for addition of carbon dioxide for formulated beverages. The legal drafting proposed for the composition of formulated beverages states that carbon dioxide is not permitted in formulated beverages.

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 formulated beverages 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.
- Clause 4 limits do not apply for the intense sweeteners.

References

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Appendix

TABLE OF REQUESTED FOOD ADDITIVES

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	Requested approval mg/kg	Comments and qualifications for the 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.
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.

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	Requested approval mg/kg	Comments and qualifications for the requested permissions
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) Clause 4 limits do not apply
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	Clause 4 limits do not apply
954	Saccharin	low joule fruit and vegetable juice products 80	150	150	for water based flavoured drinks 150 mg/kg Clause 4 limits do not apply

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	Requested approval mg/kg	Comments and qualifications for the requested permissions
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	Clause 4 limits do not apply
956	Alitame	40	40	40	Clause 4 limits do not apply
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	Clause 4 limits do not apply
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	Clause 4 limits do not apply
962	Aspartame-acesulphame salt	6800	6800	6800	Clause 4 limits do not apply
	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