FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Application A603 Supporting Document 2

DIETARY EXPOSURE ASSESSMENT REPORT

Executive Summary

The purpose of this dietary exposure assessment is to estimate dietary exposure to the food colouring erythrosine for the Australian and New Zealand populations if the permitted use of erythrosine is extended as proposed in Application 603 – Red 3 Erythrosine in Food Colouring Preparations. Dietary exposure was estimated for the addition of erythrosine according to existing and proposed permissions, at levels not exceeding the maximum use level and also assuming that poorly controlled conditions in home cooking result in using ten times the proposed maximum amount of erythrosine in icing.

The exposure assessment shows that:

- at a concentration of 2 mg of erythrosine per kg of food, only foods that are consumed every day and in large amounts could notably contribute to exposure.
- if the use of erythrosine is extended to foods with icing, consumers including children are highly unlikely to exceed the Acceptable Daily Intake (ADI) for erythrosine of 0.1 mg/kg bodyweight/day
- all estimated dietary exposures for the population groups assessed are below 50% of the ADI, even when highly protective assumptions are made
- consumption of iced foods coloured with erythrosine would increase erythrosine exposure only marginally, because the vast majority of exposure rests with the existing permissions
- home use of erythrosine is unlikely to lead to exposure of concern even if erythrosine is used at ten times the proposed maximum level in all iced home cooked foods.
  foods that might conceivably be coloured at home, are typically eaten occasionally and only in low or moderate amounts. Therefore, exposure to erythrosine from such foods is unlikely to pose a significant health risk.

Contributors to dietary erythrosine exposure are canned fruit with cherries, preserved cherries, commercial food with icing, home cooked food with icing, and coloured icing that consumers reported consuming as a stand alone food item. Canned fruit salads containing cherries are the most important contributor to erythrosine dietary exposures, even if the use of the colouring is extended to iced foods. This reflects the much higher permitted concentration of erythrosine in preserved cherries.

Should the requested uses of erythrosine be approved, mean consumer dietary exposures are estimated at no more than 0.3 mg/day or up to 0.02 mg/kg bw/day. Dietary exposures for consumers at the 90th percentile would be less than 1 mg/day or 0.05 mg/kg bw/day.

1 Introduction

FSANZ received an Application from Golding Handcrafts on 20 March 2007 seeking to amend Standard 1.3.1 – Food Additives. The Applicant is seeking to extend the use of erythrosine from a single food that is consumed in low amounts (i.e. preserved cherries) to a food additive preparation that would be added to products such as icing and frostings used in other foods that are more widely consumed (e.g. cakes, biscuits, fancy breads). This dietary exposure assessment was carried out to estimate dietary exposure to erythrosine for the Australian and New Zealand populations if the permitted use of erythrosine was extended as proposed. The maximum permitted level for icing and frosting proposed in the current Application is 1/100th of the maximum permitted level in preserved cherries.

2. Dietary exposure assessment provided by the Applicant

The Applicant provided some dietary exposure information, stating that there are no anticipated dietary implications caused by the extension of use of erythrosine as proposed in the Application.

3. Dietary exposure assessments in previous Applications

In the Full Assessment report prepared in 1993 for Proposal P22 – Restriction of the Permitted Uses of Erythrosine, estimates of dietary exposure to erythrosine indicated that the permitted uses at that time would lead to a dietary exposure in excess of the Acceptable Daily Intake (ADI) of 0.1 mg/kg. This led to a withdrawal of use of erythrosine for all foods except preserved cherries.

In 2000, the dietary exposure assessment in relation to Application A396 – Erythrosine in Preserved Cherries concluded that the withdrawal of permission for erythrosine use from all major processed foods had reduced the level of exposure considerably, and that remaining uses of erythrosine would lead to low levels of dietary exposure without any significant public health and safety concerns.

It should be noted that at that time calculations were based on the average body weight of the respondents to the Australian and New Zealand National Nutrition Surveys (67 kg and 71 kg for Australia and New Zealand respectively), and the proposed level of erythrosine in preserved cherries (200 mg/kg) These quantities were compared to the 95th percentile consumption of preserved cherries as derived from the NNS data. Dietary exposure estimates for children were not calculated.

4. Dietary modelling

As an indicative estimate of potential dietary exposure the amount and number of serves of a range of foods that may be consumed before exposure exceeds the ADI was calculated for a range of body weights. This was followed by a refined dietary exposure assessment 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:

Dietary exposure = food chemical concentration x food consumption

Dietary exposure was estimated using FSANZ's dietary modelling computer program DIAMOND by combining usual patterns of food consumption derived from NNS data with proposed levels of use of erythrosine in foods.

4.1. Food consumption data

Conducting dietary modelling based on food consumption data from national nutrition surveys provides the best available estimate of actual consumption of a food and the resulting estimated exposure to a food chemical. DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 Australia National Nutrition Survey (1995 NNS; see McLennan & Podger 1997) that surveyed 13,858 people aged 2 years and above, the 2007 Australian Children's Nutrition & Physical Activity Survey (NCNPAS; see Commonwealth of Australia 2008a&b) that collected data on nutrition and physical activity for 4,487 children aged 2-16 years and the 1997 New Zealand National Nutrition Survey (1997 NNS; see Russel *et al.* 1999) that surveyed 4,636 people aged 15 years and above. All surveys used a 24-hour food recall methodology.

All results reported here based on the 2007 NCNPAS were weighted two day averages to represent the overall population of Australian children because stratified sampling with non-proportional samples was used in the survey methodology.

It should be noted that, as with any nutrition survey, limitations exist within the national nutrition survey data. These limitations relate to the currency of the data and the changes in eating patterns that may have occurred since the data were collected and the survey methodology.

4.2 Additional food consumption data or other relevant data

To estimate dietary exposure to erythrosine from consumption of iced foods, the amount of icing in each relevant food had to be estimated. This was achieved by drawing on a variety of data sources, including commercial and domestic recipes, food composition data and food label data bases.

To estimate dietary exposure to erythrosine from consumption of cherries in canned fruit salad, a number of canned fruit salads were purchased and the amount of cherries by weight determined. The amount of cherries in canned fruit salad varied from 1-3%. The maximum amount measured (i.e. 3% of the drained weight) was used as an estimate of the concentration of erythrosine in canned fruit salads. The estimated dietary exposure to erythrosine from canned fruit salad is therefore highly protective of consumers.

4.3 Population groups assessed

The dietary exposure assessment was conducted for both Australian and New Zealand populations. An assessment was conducted for the whole population, as well as for Australian children aged 2 to 6 years. Dietary exposure assessments for the whole population are a proxy for lifetime exposure. An exposure assessment was conducted on Australian children aged 2 to 6 years (1995 NNS and 2007 NCNPAS) because children generally have higher exposures due to their smaller body weight as they consume more food per kilogram of body weight compared to adults. It is important to note that, while children aged 2 to 6 years have been assessed as a separate group, this group has also been assessed in the whole population's dietary exposure assessment based on the 1995 NNS.

4.4 Erythrosine concentration levels

The levels of erythrosine in foods that were used in the dietary exposure assessment were derived from the Application and from Schedule 1 of Standard 1.3.1. The foods and levels of use used in the dietary modelling are shown in Table 1.

4.5 Scenarios for dietary modelling

Two scenarios were modelled for the purpose of this Application:

Scenario One (existing plus proposed use level) assumes that erythrosine is present in foods at the Maximum Permitted Level MPL currently permitted in the Code and in all foods prepared using icing at the proposed maximum use level of 2 mg/kg in the icing.

Scenario Two ('existing plus high use level') assumes that erythrosine is present in foods at the MPL currently set out in the Code, and in any commercially produced foods that use icing, at the proposed maximum use level of 2 mg/kg. To account for the variability that can occur in home cooking any homemade foods prepared using icing were assigned concentrations at ten times the proposed maximum use level (20 mg/kg).

4.6 How were the estimated dietary exposures calculated?

The DIAMOND program allows erythrosine concentrations to be assigned to food groups using DIAMOND food classification codes. These codes are based on the Code. For example, Schedule 1 of Standard 1.3.1 contains a section *4.3 Processed fruits and vegetables* with an entry for preserved cherries known as maraschino, cocktail or glacé cherries.

The foods proposed by the Applicant to contain erythrosine were matched to the most appropriate processed and home prepared food in Schedule 1 of Standard 1.3.1 for modelling purposes. Each individual's exposure to erythrosine was calculated using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of erythrosine by the amount of food that an individual consumed from that group in order to estimate the exposure to erythrosine from each food. Once this has been completed for all of the foods specified to contain erythrosine, the total amount of erythrosine consumed from all foods is summed for each individual. Population statistics (mean for all respondents, mean and 90th percentile dietary exposures for consumers) are then derived from the individuals' ranked exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individual's total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived. A small number of 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 dietary exposures are expressed as a percentage of the reference health standard, each individual's total exposure (in units per kilogram of body weight per day) is calculated as a percentage of the reference health standard, the results are then ranked, and population statistics derived.

Percentage contributions of each food group to total estimated exposures are calculated by summing the exposures for a food group from each individual in the population group who consumed a food from that group and dividing this by the sum of the exposures of all individuals from all food groups containing erythrosine and multiplying this by 100.

Table 1 Concentrations of erythrosine used in the dietary modelling

Food category used in model	Concentration (mg/kg)		Icing (% by weight)	Examples
	*Scenario 1**	*Scenario 2*#		
Preserved cherries	200	200	N/A	Glace cherry
Canned fruit with cherries	6.0	6.0	N/A	Fruit salad, canned in natural juice$
Coloured Icings	2.0	20.0	100	Icing, fruit-flavoured
Iced Biscuits	0.6	0.6	30	Biscuit, fruit, iced, commercial
Iced Cakes 10%	0.2	0.2	10	Doughnut, iced
Iced Cakes 15%	0.3	0.3	15	Cake, plain, iced, butter, commercial
Iced Cakes 20%	0.4	0.4	20	Cake, layer, rich, iced, commercial
Iced Cakes 30%	0.6	0.6	30	Cake, sponge, commercial
Iced Fancy Breads	0.3	0.3	15	Bun sweet, with nuts, iced
Iced Pastries	0.3	0.3	15	Choux pastry, custard-filled, iced
Iced Prepared dishes (commercial)	0.3	0.3	15	Pie, pecan & custard, Danish pastry top, iced
Iced Slices	0.2	0.2	10	Slice, with nuts, iced, commercial
Mixed Foods, iced (homecooked), 10%	0.2	2.0	10	Slice, muesli, iced, homemade
Mixed foods, iced (homecooked), 15%	0.3	3.0	15	Cake, sultana, iced, homemade
Mixed foods, iced (homecooked), 20%	0.4	4.0	20	Cake, chocolate, rich, iced, homemade
Mixed foods, iced (homecooked), 30%	0.6	6.0	30	Cake, sponge, flavoured, iced, homemade

*existing plus proposed use level #existing plus high use level in home prepared products
$on average, cherries make up 3% by weight in canned fruit salad

4.7 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, protective assumptions were used to ensure that the dietary exposure assessment did not underestimate exposure.

Assumptions made in the dietary modelling include:

- where a permission is given to a food classification, all foods in that group contain erythrosine at the level given in Table 1
- wherever icing is coloured this is done using erythrosine
- erythrosine is not used to colour any food other than icing
- consumption of foods as recorded in the NNS and the NCNPAS represent current food consumption patterns
- consumers do not alter their food consumption habits as a consequence of erythrosine being added to a wider range of foods containing icing
- non-dietary sources of erythrosine are expected to contribute little to the estimated exposure and have not been included in the dietary exposure assessment
- where a food has a specified erythrosine concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient
- there are no reductions in erythrosine concentrations from food preparation or due to cooking.

Overall, the assumptions are likely to lead to a highly protective estimate of dietary exposure to erythrosine. While there is a possibility that home prepared foods other than icing may be coloured with erythrosine this is offset by the highly protective assumption that all icing is coloured with erythrosine. In addition, home prepared foods other than icing that may typically be coloured with erythrosine, such as toffees and coconut ice, were not reported as being consumed in the 1995 NNS or 2007 NCNPAS.

4.8 Limitations of the dietary modelling

Dietary exposure based on single 24-hour dietary survey data tend to over-estimate habitual food consumption amounts for high consumers. Therefore, the predicted high percentile exposures for the 1995 and 1997 NNSs reported are likely to be higher than actual high percentile exposures over a lifetime. However, the 2007 NCNPAS exposure were based on two day averages of food consumption and therefore are less likely to overestimate dietary exposure for high consumers.

Currently, FSANZ does not apply statistical population weights to each individual in the 1995 and 1997 NNSs in order to make the data representative of the population. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand NNS 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 exposure assessment for New Zealand because population weights were not used.

5. Results

5.1 Indicative estimates of dietary exposure in a range of foods

Currently, the maximum permitted level for erythrosine in preserved cherries is 200 mg/kg. Under the existing permissions, an adult weighing 75 kg would have to consume 38 g of these cherries every day of his or her life to reach the ADI of 0.1 mg per kg body weight. Individuals with lower body weight would have to consume a smaller amount of cherries daily to reach the ADI. However, it is highly unlikely that any individual would follow such an unusual consumption pattern, and the national nutrition surveys show that the consumption of preserved cherries is considerably lower (see below).

At the MPL of 2 mg/kg for icing proposed by the Applicant an adult would have to consume close to 4 kg of this food every day to reach the ADI. As was noted in the Food Technology Report (Attachment 4) addition of erythrosine is self-limiting as overuse of this colour leads to less appealing shades. Furthermore, depending on the colour and shade required, it is likely that some colouring applications will require the use of erythrosine at levels below 2 mg/kg. At such low concentration, even individuals with a body weight of 15 kg (i.e. children) would have to consume 800 g of a food every day to reach the ADI (Table 2).

It is conceivable that foods other than icing could be coloured with red food colouring at home on an occasional basis. Table 3 shows the number of serves for a selection of foods that would have to be consumed before the ADI is reached for people of different body weights. Serving sizes of beverages, such as milk and cordials, are comparatively large and therefore are the most likely type of food that might lead to exposures close to the ADI. However, at a concentration of 2 mg/kg even small children would have to consume three 300 mL serves of a beverage that has been coloured with erythrosine at home daily over a lifetime to exceed the ADI. It should be noted that there is no evidence that such behaviour is likely to occur and the Applicant does not seek permission to add erythrosine to food colouring preparations that are intended for colouring beverages. Although included in this table, children are highly unlikely to consume homemade playdough made with food colouring on a daily basis.

It should be emphasised that these estimates contains a high level of uncertainty and that models based on actual consumption of the foods which have permissions, or for which permission have been proposed, have a higher level of certainty and therefore provide a better estimate of dietary exposure.

Table 2: Amount of food at three concentrations of erythrosine that would have to be consumed everyday for a lifetime by individuals of different body weight to exceed the ADI of erythrosine

Erythrosine in the food (mg/kg)	Amount of food consumed daily (g) to exceed ADI			
	BW =75 kg	BW = 50 kg	BW = 30 kg	BW = 15 kg
200	38	25	15	8
20	375	250	150	80
2	3750	2500	1500	800

Table 3: Numbers of servings of home prepared food that might occasionally be coloured with erythrosine that would have to be consumed everyday for a lifetime to exceed the ADI. Concentration of erythrosine is 2 mg/kg.

Food	Average Serving size (g)	Serves of food required to be consumed daily to exceed the ADI			
		BW =75 kg	BW = 50 kg	BW = 30 kg	BW = 15 kg
Coloured icing	30	125	83	50	25
Coloured cake	50	75	50	30	15
Coloured Biscuits	25	150	100	60	30
Coloured cordial	300	13	8	5	3
Coloured Milk	300	13	8	5	3
Coloured jam	20	188	125	75	38
Coloured Jelly	125	30	20	12	6
Chinese roast pork	250	15	10	6	3
Playdough	20	188	125	75	38

5.2 Estimated dietary exposures to erythrosine based on survey data

The number of Australians and New Zealanders that reported consuming foods that may contain erythrosine under Scenarios 1 and 2 are listed in Table 4. In summary, approximately 10-12% of Australians and New Zealanders in the 1995 and 1997 NNSs ate foods that might contain erythrosine under Scenarios 1 and 2 on the survey day. However, 32% of children that responded to the 2007 NCNPAS reported consuming foods that might contain erythrosine under the proposed permissions and assuming that all iced foods are coloured with erythrosine. The higher proportion of consumers reported in the 2007 NCNPAS is most likley due to the fact that a child could be a consumer on day 1 and/or day 2 of the survey.

Table 4: Number of consumers that reported consuming foods that may contain erythrosine under Scenarios 1 and 2 and consumers as a proportion of respondents to the surveys

Country	Survey	Population group	Number of consumers	Consumers as a % of respondents
Australia	1995 NNS	Whole population	1365	10
		2-6 years	113	11
	2007 NCNPAS[a]	2-6 years	566	32
New Zealand	1997 NNS	Whole population	478	10

Total number of respondents for 1995 NNS: whole population 2 years and above= 13 858, 2-6 years = 989; 2007 NCNPAS: 2-6 years 1791; New Zealand 1997 NNS: whole population 15 years and above = 4 636.
[a] number of consumers over 2 days of survey.

The estimated dietary exposures for each scenario for erythrosine for Australia and New Zealand are shown in Tables 5 and 6. Based on the 1995 NNS, 2 to 6 year old consumers had the highest estimated dietary exposure to erythrosine based on a bodyweight basis for both Scenarios, followed by New Zealanders 15 years and above and Australians 2 years and above. However, dietary exposure to erythrosine in 2-6 year olds based on the 2007 NCPAS was lower than that for that age group from the 1995 NNS and was similar to whole population dietary exposure calculated from the consumption amounts reported in the 1995 NNS (Figures 1 and 2). The fact that there was a higher proportion of consumers of foods containing erythrosine in the 2007 survey tends to lower the mean and 90th percentile dietary exposure for consumers of erythrosine compared to the 1995 NNS.

The estimated mean dietary exposures of consumers for Scenario 1 (existing plus proposed use level) varied from 0.2 to 0.3 mg/day or >0.01 to 0.01 mg/kg bw/day (Table 5). The estimated mean dietary exposures for Scenario 2 (existing plus high use level) were 0.01 to 0.02 mg/kg bw/day (Table 6).

The 90th percentile dietary exposures for consumers for Scenario 1 for Australia and New Zealand were 0.3 to 0.8 mg/day (0.01 to 0.04 mg/kg bw/day). Scenario 2 exposure to erythrosine at the 90th percentile for Australian and New Zealand consumers was slightly higher than Scenario: 0.4 to 0.9 mg/day (0.01 to 0.05 mg/kg bw/day).

Under existing permissions erythrosine is restricted to foods containing preserved cherries. Only 1.4% of respondents to the 1995 NNS reported consuming these foods, rather than the wider range of foods included in Scenarios 1 and 2. For the whole Australian population, consumers of preserved cherries had a mean erythrosine exposure of 1.0 mg/day, or less than 0.1 mg/kg bw/day. At the 90th percentile erythrosine exposure was 1.7 mg/day, less than 0.1 mg/kg bw/day (1995 NNS).

Dietary exposure to erythrosine for consumers of preserved cherry are higher than those shown in tables 5 and 6 because the calculations are based on the low numbers of consumers that eat preserved cherries alone, compared to the number of consumers that eat preserved cherries and/or foods with icing. Preserved cherries are permitted to contain up to 100 times more erythrosine than the amount being sought for icing in this Application.

For the 20 children aged 2-6 years that reported eating preserved cherries in the 1995 NNS, the mean erythrosine exposure was the same as for consumers of cherries in the whole population. At the 90th percentile erythrosine exposure was 2.3 mg a day, or 0.1 mg/kg bw/day. Although this dietary exposure is at the ADI, it is considered unlikely that preserved cherries are consumed daily by individual young children over a long period of time.

5.3 Major contributing foods to total estimated dietary exposures

Contributors to erythrosine exposure were canned fruit with cherries, preserved cherries, commercial food with icing (cakes, buns, biscuits, slices et cetera), home cooked food with icing (cakes, biscuits, slices et cetera) and coloured icing reported as a stand alone food item.

The contributors (>1%) to total erythrosine dietary exposures for both Scenarios are shown in Figures 3-5. For all population groups assessed in all the surveys the main contributor was canned fruit with cherries (51%-85%). Preserved cherries were also an important contributor for the whole Australian and New Zealand populations (Figures 3 and 5) but were less important for Australian children in the 1995 NNS. However, they were important contributors to exposure estimates based on the 2007 NCNPAS (Figure 4).

Commercial food with icing was an important contributor to erythrosine dietary exposure in Scenario 1 for the whole population, but less so for 2-6 year olds. As expected, under Scenario 2 home cooked food with icing became a more important contributor to exposure.

Coloured icing *per se* was the least important contributor to dietary exposure under Scenario 1. Under Scenario 2, as would be expected, the contribution of coloured icing to exposure increased markedly for all populations. Under existing permissions, the main contributor to erythrosine dietary exposure for all population groups assessed was canned fruit with cherries and foods containing canned fruit with cherries as an ingredient: 83% for the whole Australian population and 96% for 2-6 year old children in the 1995 NNS. Other foods that contributed to exposure were trifles and cakes with preserved cherries as an ingredient, and preserved cherries *per se*.

Table 5: Estimated mean and 90th percentile exposures to erythrosine under Scenario 1

SCENARIO 1 existing plus proposed use level:

Country	Survey	Population	Mean all respondents	Mean consumers	90th percentile consumers
			mg/day (mg/kg bw/day)	*mg/day (mg/kg bw/day)*	*mg/day (mg/kg bw/day)*
Australia	1995 NNS	Whole population	<0.1 (<0.01)	0.2 (<0.01)	0.6 (0.01)
		2-6 years	<0.1 (<0.01)	0.2 (0.01)	0.8 (0.04)
	2007 NCNPAS[a]	2-6 years	<0.1 (<0.01)	0.1 (0.01)	0.3 (0.02)
New Zealand	1997 NNS	Whole population	<0.1 (<0.01)	0.3 (<0.01)	0.8 (0.01)

[a] weighted 2 day averages
Consumers include the people who have consumed a food that contains erythrosine.
Respondents include all members of the survey population whether or not they consumed a food that contains erythrosine

Table 6: Estimated mean and 90th percentile exposures to erythrosine under Scenario 2

SCENARIO 2 existing plus high use level

Country	Survey	Population	Mean all respondents	Mean consumers	90th percentile consumers
			mg/day (mg/kg bw/day)	*mg/day (mg/kg bw/day)*	*mg/day (mg/kg bw/day)*
Australia	1995 NNS	Whole population	<0.1 (<0.01)	0.2 (0.01)	0.8 (0.01)
		2-6 years	<0.1 (<0.01)	0.3 (0.02)	0.8 (0.05)
	2007 NCNPAS[a]	2-6 years	<0.1 (<0.01)	0.1 (0.01)	0.4 (0.02)
New Zealand	1997 NNS	Whole population	<0.1 (<0.01)	0.3 (0.01)	0.9 (0.01)

[a] weighted 2 day averages
Consumers include the people who have consumed a food that contains erythrosine.
Respondents include all members of the survey population whether or not they consumed a food that contains erythrosine

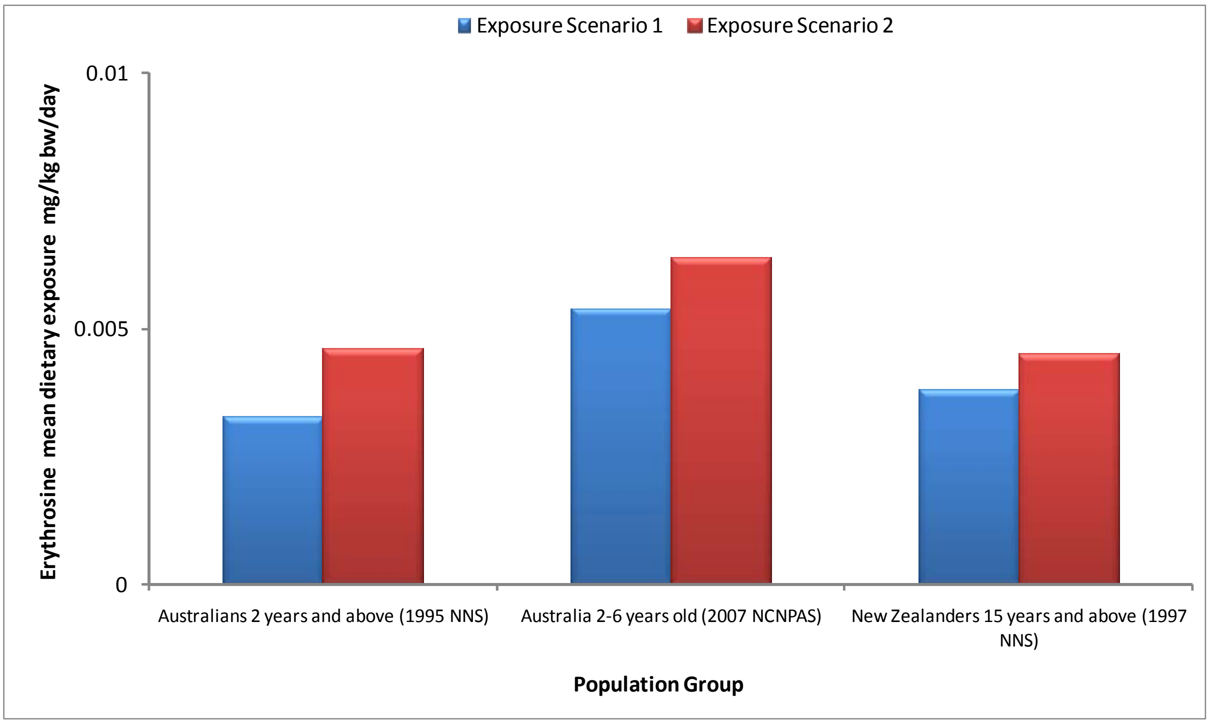


Figure 1: Estimated mean dietary exposures to erythrosine on a bodyweight basis (consumers)

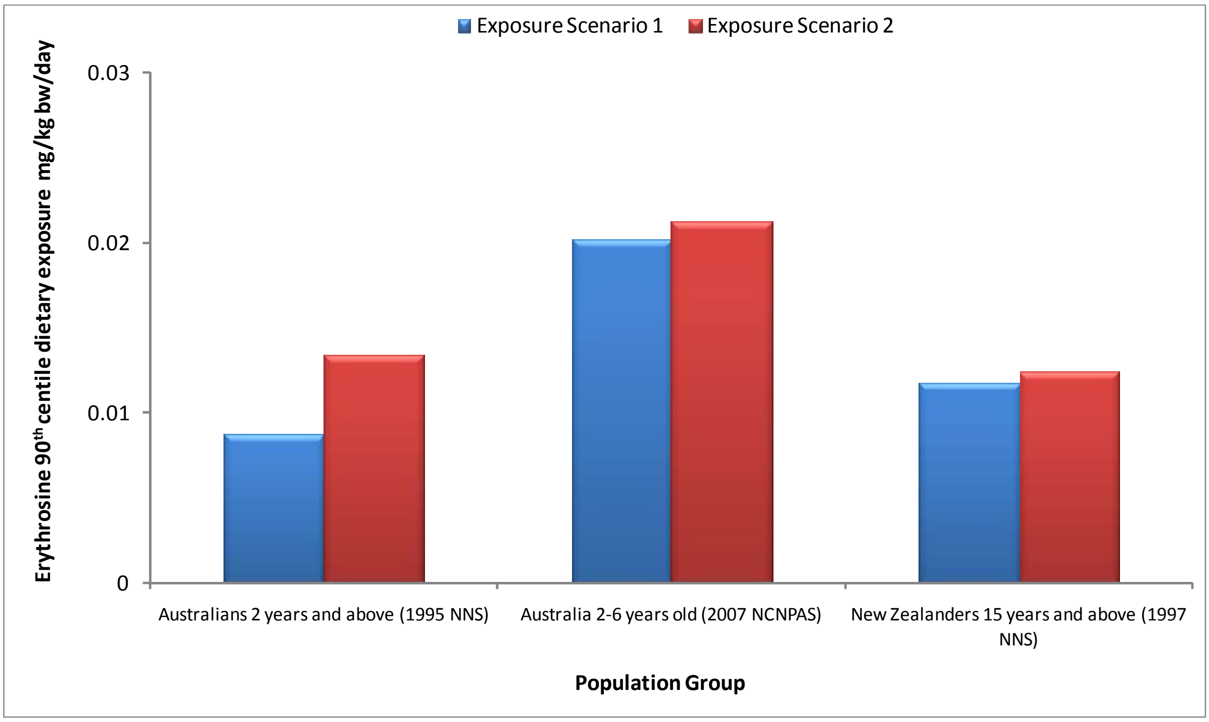
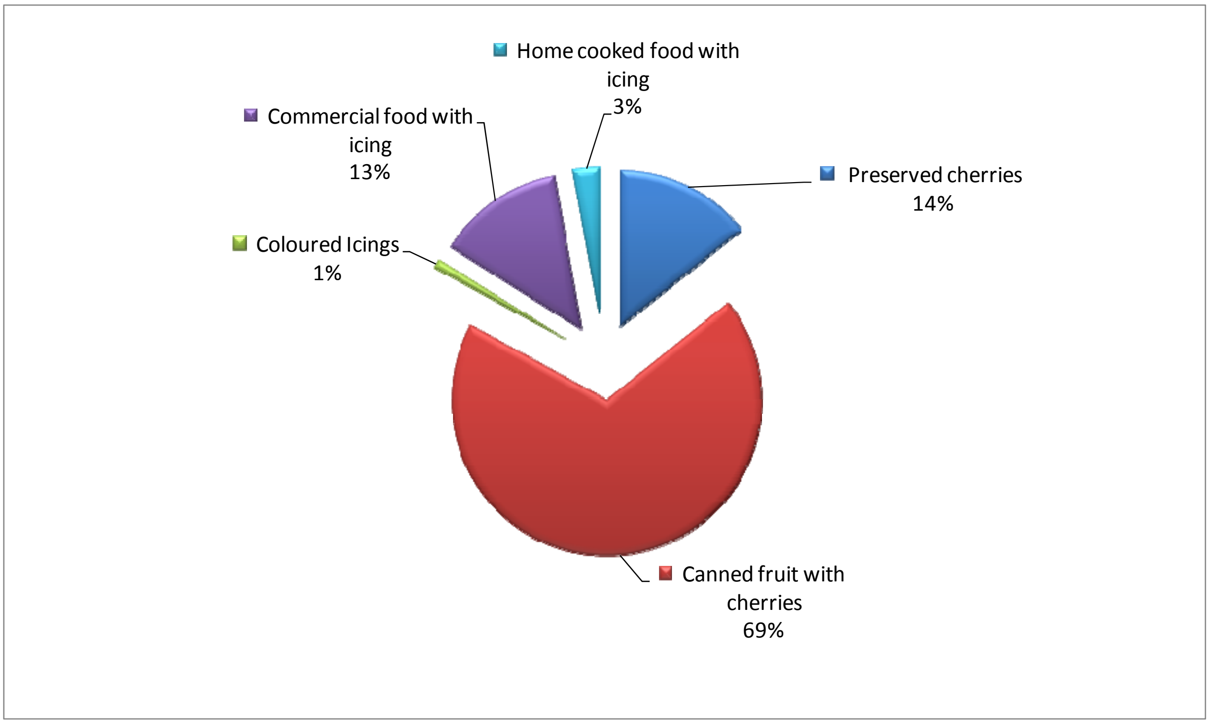


Figure 2: Estimated 90th percentile dietary exposures to erythrosine on a bodyweight basis (consumers)

(a) Scenario 1 existing plus proposed use level in icing



(b) Scenario 2 existing plus high use level in icing

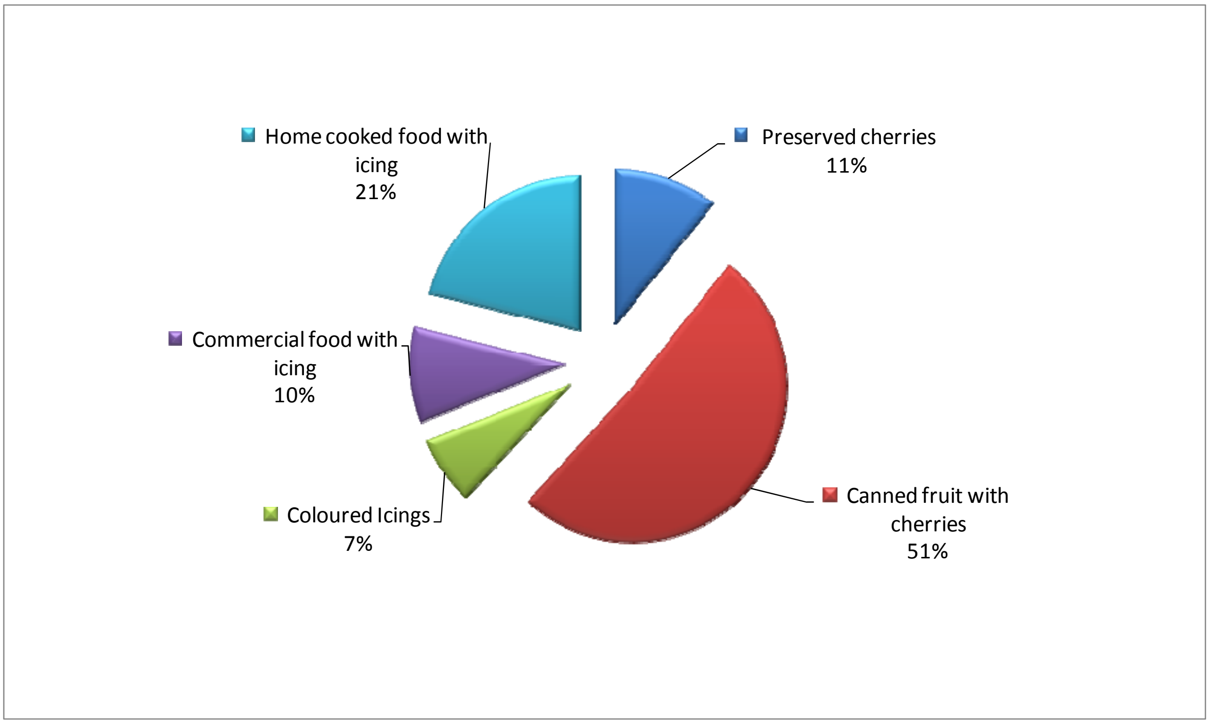


Figure 3: Major contributors to erythrosine dietary exposure for the whole Australian Population (1995 NNS)

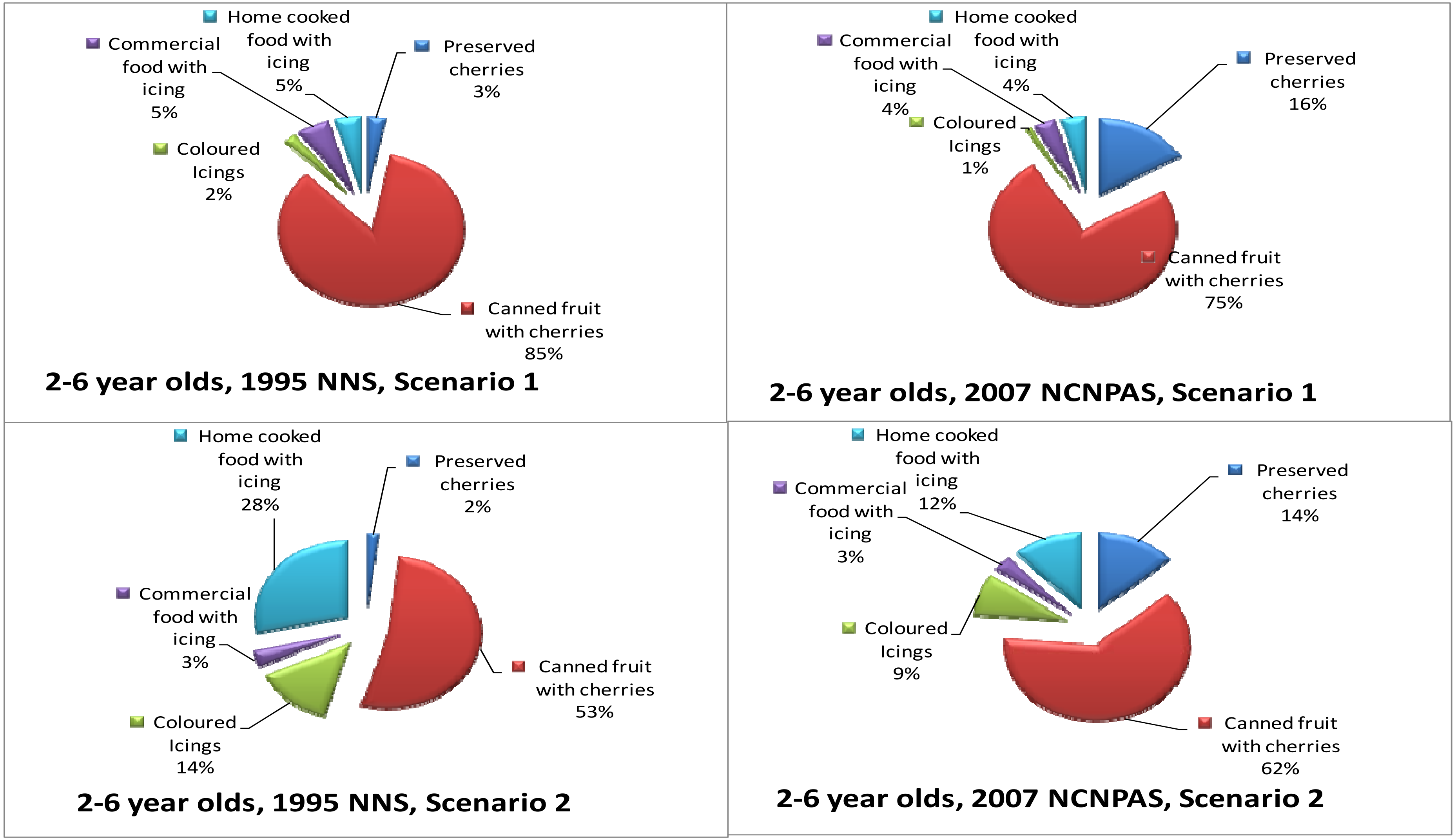
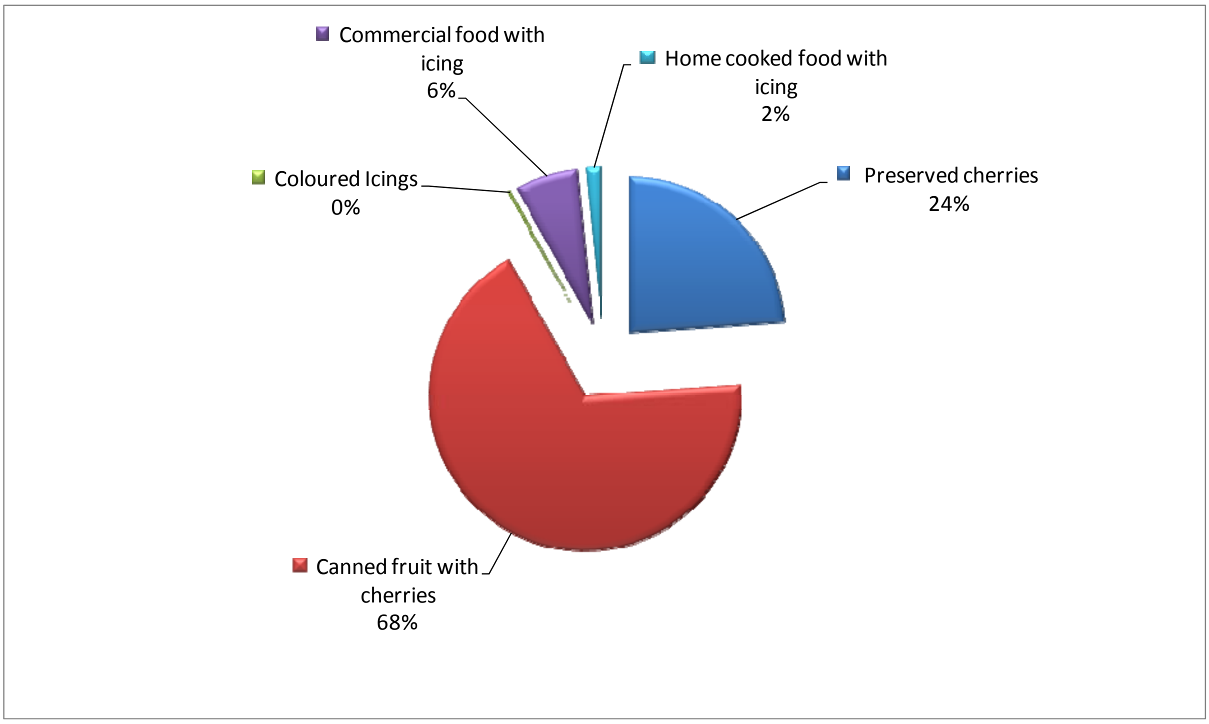


Figure 4: Major contributors to erythrosine dietary exposure for 2-6 year old Australian children (1995 NNS and 2007 NCNPAS)

(a) Scenario 1 existing plus proposed use level in icing



(b) Scenario 2 existing plus high use level in icing

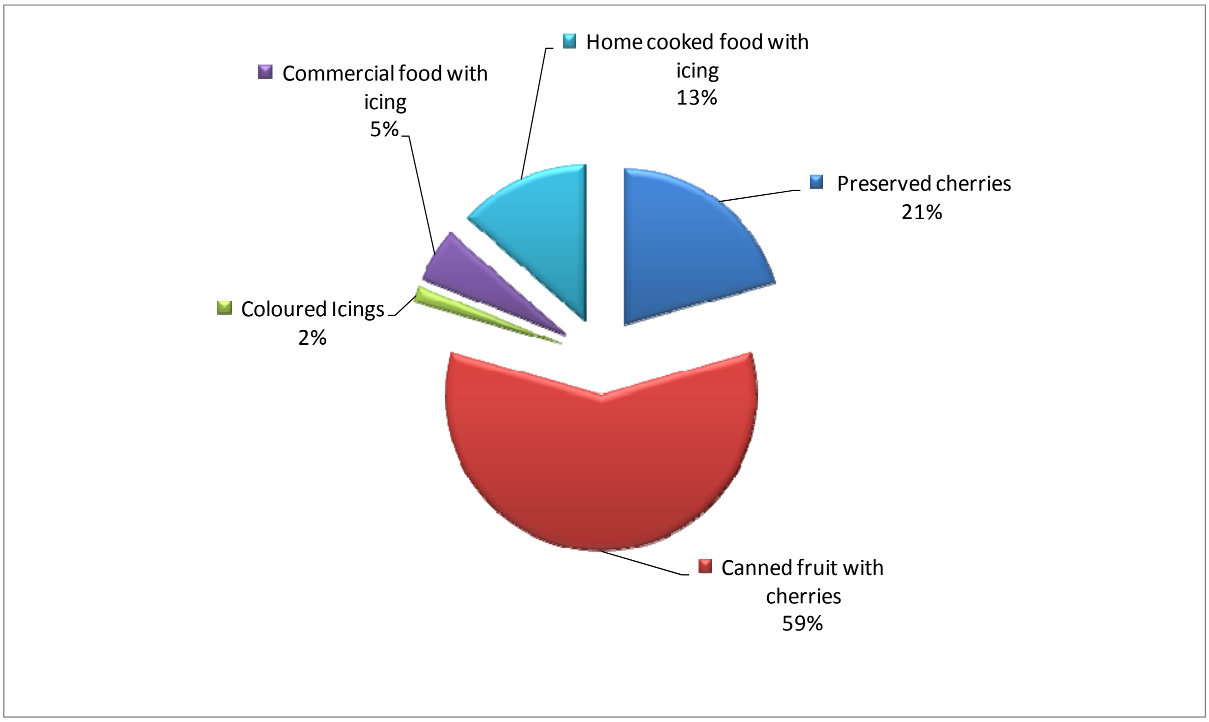


Figure 5: Major contributors to erythrosine dietary exposure for the New Zealand population (1997 NNS)

5.4 Comparison of the estimated dietary exposures with the reference health standard

In order to determine if the levels of dietary exposure to erythrosine are likely to be of a public health and safety concern, the estimated dietary exposures were compared to an Acceptable Daily Intake (ADI) for erythrosine of 0.1 mg/kg bw/day (see Figures 6 and 7 and Tables 7 and 8). For 2-6 year olds, the 2007 NCNPAS data form the best estimate of exposure for comparison because the data is more up to date, the sample size is larger and the calculations are based on two days of data.

In brief, all estimated exposures were below the ADI for the scenarios and population groups assessed.

Scenario 1 ‘existing plus proposed use level’ estimated mean dietary exposures for consumers of erythrosine were the lowest for Australians aged 2 years and above (3% of the ADI) and New Zealanders aged 15 years and above (4% of the ADI) and were the highest for Australian children aged 2-6 years at 5% ADI. The estimated 90th percentile dietary exposures for consumers were lowest at 9% of the ADI for Australians aged 2 years and above followed by New Zealanders aged 15 years and above (12%) and highest for Australian children 2 to 6 years old at 20% and 42 % of the ADI for the 2007 NCNPAS and 1995 NNS respectively (Table 7, Figures 6 and 7).

Scenario 2 ‘existing plus high use level’ estimated mean dietary exposures for consumers of foods containing erythrosine were very similar for all population groups at 5-6% of the ADI. Estimated 90th percentile dietary exposures for Scenario 2 were lowest for New Zealanders aged 15 years and above at 12% of the ADI and highest for Australian children aged 2 to 6 years at 21% and 28% of the ADI for the 2007 NCNPAS and 1995 NNS respectively.

As noted earlier, consumers of preserved cherries and foods containing preserved cherries have higher dietary exposure to erythrosine than consumers of iced products because of the far higher erythrosine level in preserved cherries than is proposed for icing. If it was assumed that consumers were only exposed to erythrosine through consumption of preserved cherries at the existing MPL of 200 mg/kg, mean dietary exposure was 19% of the ADI for Australians 2 years and above and 8% of the ADI for New Zealanders. For high consumers at the 90th percentile dietary exposure was 39% and 19% of the ADI respectively.

For any individual who is already a consumer of preserved cherries, consumption of iced foods coloured with erythrosine would increase erythrosine exposure only marginally, because the vast majority of exposure rests with the existing permissions to add erythrosine to preserved cherries. Therefore, extending the permission to use erythrosine to icing as proposed does not make an appreciable difference to the risk of exceeding the ADI for adults or children.

Table 7: Estimated mean and 90th percentile exposures to erythrosine under Scenario 1 as a percentage of the ADI

Country	Population	SCENARIO 1		
		Mean respondents	Mean consumers	90th percentile consumers
		% ADI	*% ADI*	*% ADI*
Australia	Whole population	<1	3	9
	2-6 years (1995 NNS)	1	12	42
	2-6 years (2007 NCNPAS)[a]	2	5	20
New Zealand	Whole population	<1	4	12

[a] weighted 2 day averages
Consumers include the people who have consumed a food that contains erythrosine. *Respondents* include all members of the survey population whether or not they consumed a food that contains erythrosine Acceptable Daily Intake (ADI) = 0.1 mg/kg bw/day`

Table 8: Estimated mean and 90th percentile exposures to erythrosine under Scenario 2 as a percentage of the ADI

Country	Population	SCENARIO 2		
		Mean respondents	Mean consumers	90th percentile consumers
		% ADI	*% ADI*	*% ADI*
Australia	Whole population	<1	5	13
	2-6 years (1995 NNS)	2	18	48
	2-6 years (2007 NCNPAS)[a]	2	6	21
New Zealand	Whole population	<1	5	12

[a] weighted 2 day averages
Consumers include the people who have consumed a food that contains erythrosine.
Respondents include all members of the survey population whether or not they consumed a food that contains erythrosine
Acceptable Daily Intake (ADI) = 0.1 mg/kg bw/day

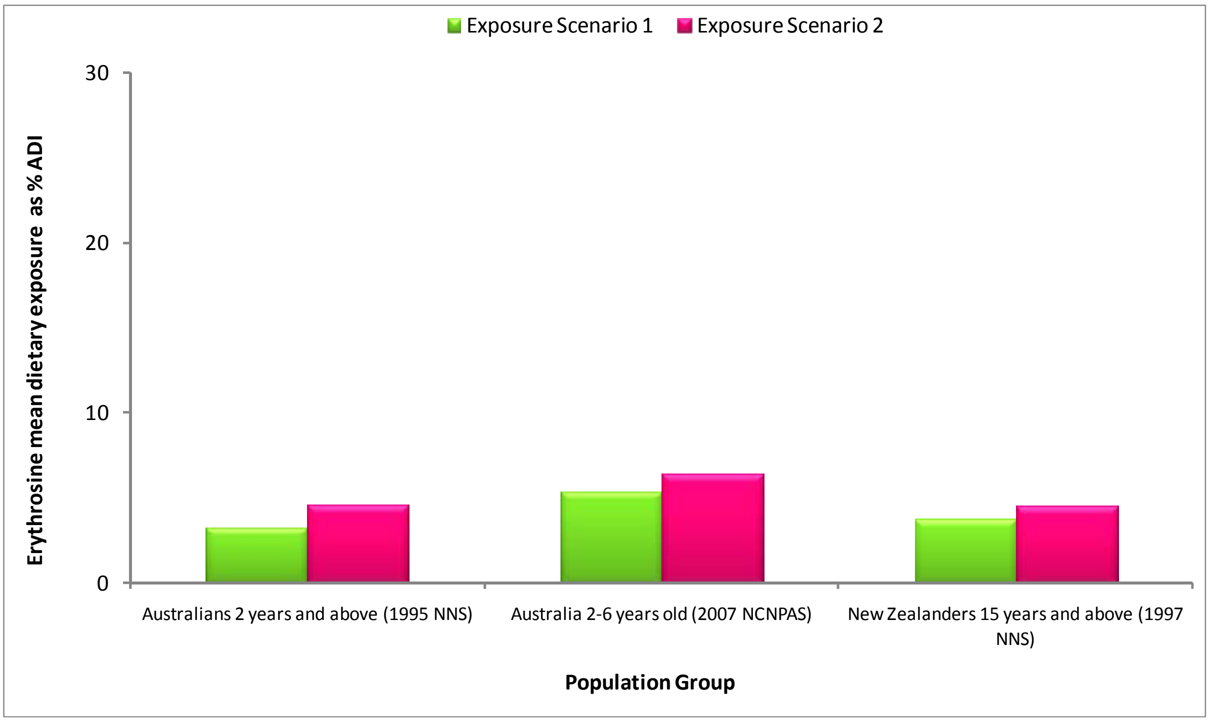


Figure 6: Estimated mean dietary exposures to erythrosine as a percentage of the ADI (consumers)

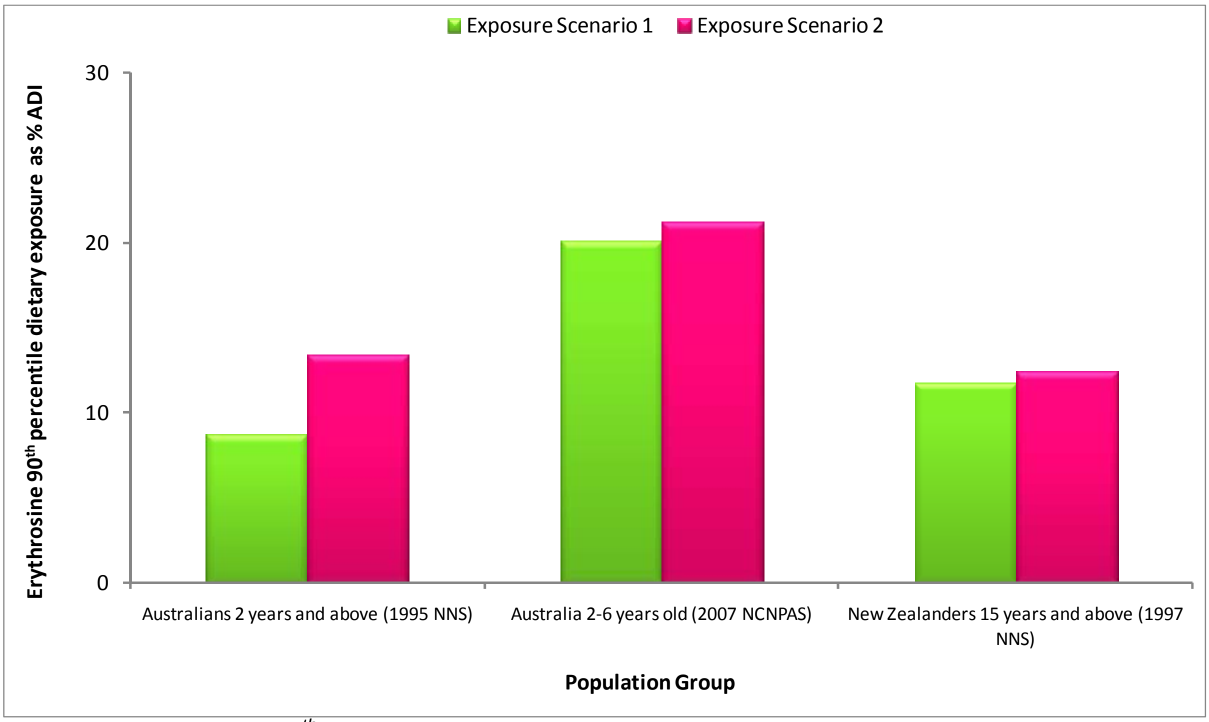


Figure 7: Estimated 90th percentile exposures to erythrosine as a percentage of the ADI (consumers)

6. Conclusions

- if the use of erythrosine is extended to foods with icing, consumers including children are highly unlikely to exceed the Acceptable Daily Intake (ADI) for erythrosine of 0.1 mg/kg bodyweight/day
- all estimated dietary exposures for the population groups assessed are below 50% of the ADI, even when highly protective assumptions are made
- consumption of iced foods coloured with erythrosine would increase erythrosine exposure only marginally, because the vast majority of exposure rests with the existing permissions
- home use of erythrosine is unlikely to lead to exposure of concern even if erythrosine is used at ten times the proposed maximum level in all iced home cooked foods.
- it is highly unlikely that foods other than icing to which erythrosine could be added in the home would be consumed in sufficient quantities on a daily basis to lead to levels of dietary exposure that pose a significant health risk, assuming a concentration of 2 mg of erythrosine/kg food.

7 References

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