

Supporting document 2

Dietary Exposure Assessment Report – Application A1015

Ethyl Lauroyl Arginate as a Food Additive

EXECUTIVE SUMMARY

A dietary exposure assessment was undertaken by FSANZ for ethyl lauroyl arginate. Food consumption data from the 1995 Australian and 1997 New Zealand National Nutrition Surveys were used for the exposure assessments. The population groups assessed were the Australian population (2 years and above), New Zealanders 15 years and above and Australian children 2 to 6 years only.

The Applicant provided FSANZ with information on proposed levels of use for ethyl lauroyl arginate for specific food groups and the expected foods within each food group that may contain it. Based on this information, dietary exposure was estimated assuming that ethyl lauroyl arginate is present in foods at the maximum permitted level suggested by the Applicant. This scenario is highly protective of consumers.

Estimated dietary exposures were compared with the reference health standard, an Acceptable Daily Intake (ADI) of 0-5 mg/kg bw.

The dietary exposure assessment shows that if the requested permissions for ethyl lauroyl arginate are approved, consumers of foods containing ethyl lauroyl arginate including children are unlikely to exceed the ADI. All estimated dietary exposures for the population groups assessed were below the ADI, even when it was assumed that ethyl lauroyl arginate was in all foods for which permission is sought, at the maximum permitted level.

Based on the food groups proposed by the Applicant, the major contributor to ethyl lauroyl arginate dietary exposure for Australians aged 2 years and above and for New Zealanders aged 15 years and above was comminuted meat products and whole pieces of processed meat. For Australian children aged 2 to 6 years, the major contributor was cordials.

Introduction

FSANZ received an Application from Competitive Advantage on behalf of Laboratorios Miret, S.A. (LAMIRSA) on 18 August 2008 seeking to amend Standard 1.3.1 – Food Additives. The Applicant is seeking to add ethyl lauroyl arginate to a food additive preparation that would be added to products such as beverages, cheeses, vegetables (including legumes), cooked rice, noodles and pasta, meats and meat products and mixed food items (e.g. savoury toppings and fillings, desserts, and dips). This dietary exposure assessment for ethyl lauroyl arginate for the Australian and New Zealand populations assumed use of ethyl lauroyl arginate was permitted as proposed.

Information provided by the Applicant for the dietary exposure assessment

The Applicant provided dietary exposure information considered at the 38th session of the Codex Committee on Food Additives and Contaminants and the 69th Session of the Joint FAO/WHO Expert Committee on Food Additives. As an essential part of the Application the Applicant provided information on the foods and the concentrations of ethyl lauroyl arginate that were proposed to be included in the Code (Table 1).

Dietary modelling

The dietary exposure assessment used dietary modelling techniques that combine food consumption data with food chemical concentration data to estimate the exposure to the food chemical from the diet:

$$\text{Dietary exposure} = \text{food chemical concentration} \times \text{food consumption}$$

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 ethyl lauroyl arginate in foods.

Food consumption 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.

Conducting dietary modelling based on 1995 or 1997 NNS food consumption data provides the best available 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 which make up the majority of most people's diet is unlikely to have changed markedly. 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 on the market were not available in 1995 in Australia or 1997 in New Zealand.

Dietary survey data from both New Zealand's 2002 National Children's Nutrition Survey and Australia's 2007 Children's Nutrition and Physical Activity Survey were not available in the correct format to allow dietary exposure assessments to be undertaken at the time dietary modelling for Application 1015 was conducted.

Additional food consumption data or other relevant data

At the time of completing this report, work still remains to incorporate the additional datasets into DIAMOND before food additive modelling can be conducted. However, food consumption data is available to be used.

The consumption data for the major contributors to ethyl lauroyl arginate exposure for Australian children aged 2 to 6 years from the 1995 and 2007 nutrition surveys may indicate a potential for estimated dietary exposures to be lower based on more recent consumption data (see Section 9.1.4 for detail).

Population groups assessed

The dietary exposure assessment was conducted for both Australian and New Zealand populations. The assessment for Australians was conducted for the population aged 2 years and above, as well as for children aged 2 to 6 years. The assessment for New Zealanders was conducted for the population group 15 years and above. 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 because children generally have higher exposures on a body weight basis as they consume more food per kilogram of body weight compared to adults. They also consume many of the foods and drinks proposed to contain ethyl lauroyl arginate, such as cordials, soft drinks and fruit and vegetable juice products. 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.

Ethyl lauroyl arginate concentration levels

The levels of ethyl lauroyl arginate in foods that were used in the dietary exposure assessment were derived from data submitted by the Applicant. The foods and levels of use used in the dietary modelling are listed in Table 3.1.

Concentrations of ethyl lauroyl arginate were 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 *8.3 Comminuted meat products* with an entry for 'sausage', 'frankfurts' and 'saveloys'.

The foods proposed by the Applicant to contain ethyl lauroyl arginate were matched to the most appropriate processed food codes in Schedule 1 for modelling purposes.

Scenarios for dietary modelling

Only one scenario was modelled for the purpose of this Application. This scenario assumes that ethyl lauroyl arginate is present in foods at the Maximum Permitted Level (MPL) currently suggested by the Applicant.

How were the estimated dietary exposures calculated?

Each individual's exposure to ethyl lauroyl arginate was calculated using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of ethyl lauroyl arginate by the amount of food that an individual consumed

from that group in order to estimate the exposure to ethyl lauroyl arginate from each food. Once this has been completed for all of the foods specified to contain ethyl lauroyl arginate, the total amount of ethyl lauroyl arginate consumed from all foods is summed for each individual. Population statistics (mean and 90th percentile exposures) 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 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 ethyl lauroyl arginate and multiplying this by 100.

Table 3.1: Concentrations of ethyl lauroyl arginate used in the dietary modelling

	Food types *	Concentration (mg/kg)**	Notes
0.1	Preparations of food additives	225	
1.6	Cheese – Soft /cream/processed	450	
1.6	Cheese – Mozzarella	225	
1.6	Cheese – Hard/semi hard	100	Estimated 500 mg/kg for an average block of cheese based on surface area, then estimated 20% of cheese consumed is rind
4.1.3	Peeled and/or cut fruits & vegetables	225	Excludes potatoes products
4.3.8	Re-hydrated legumes	225	
6.3	Cereal – Cooked rice	225	
6.4	Flour products – Cooked pasta/noodles	225	
8.2	Whole pieces of processed meat	225	Ham, corned beef, pickled pork etc...
8.3	Comminuted meat products	350	Including poultry
9.3	Fish products	450	
14.1.2	Fruit & vegetable juices and fruit & vegetable-based drinks	55	Includes apple juice and apple-based drinks***

	Food types *	Concentration (mg/kg)**	Notes
14.1.3	Water-based flavoured drinks/high energy drinks/soft drinks	55	Excludes regular cola products
20.2	Cheese-based savoury topping and fillings	450	E.g. pizza toppings
20.2	Vegetable-based savoury topping and fillings	225	E.g. sauces
20.2	Dairy & fat-based desserts and dips	450	

* The code number and food types are as listed in the Code, Standard 1.3.1, Schedule 1.

** The concentration used for the dietary modelling is for the whole compound of ethyl lauroyl arginate only. This is different to what will be drafted into the Code, as the concentration is for the active component of ethyl lauroyl arginate, which is approximately 85-90% of the whole compound. Please refer to the Hazard Report (Supporting Document 1) for information on how the ADI was set and the reason for using the active component concentration in the Code.

*** Apple juice and apple-based drinks were excluded from the dietary exposure assessment for the Assessment Report. Refer to section 9.1.3 in the Approval Report for the reason for inclusion.

Assumptions in the dietary exposure assessment

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

Assumptions made in the dietary exposure assessment include:

- all the foods within the group contain ethyl lauroyl arginate at the levels specified in Table 3.1. Unless otherwise specified, the maximum proposed concentration of ethyl lauroyl arginate in each food category has been used;
- consumption of foods as recorded in the NNS represent current food consumption patterns;
- consumers do not alter their food consumption habits besides substituting non-ethyl lauroyl arginate containing products with ethyl lauroyl arginate containing products;
- consumers do not increase their consumption of foods/food groups upon foods/food groups containing ethyl lauroyl arginate becoming available;
- the calculation is based mainly on food use. However, FSANZ is aware that there may be other sources. For example, should ethyl lauroyl arginate be added to cosmetics such as lipsticks;
- where a food was not included in the exposure assessment, it was assumed to contain a zero concentration of ethyl lauroyl arginate;
- where a food has a specified ethyl lauroyl arginate concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient; and
- there are no reductions in ethyl lauroyl arginate concentrations from food preparation or due to cooking.

These assumptions are likely to lead to a highly protective estimate for ethyl lauroyl arginate dietary exposure.

Limitations of the dietary modelling

A limitation of estimating dietary exposure is that only 24-hour dietary survey data are 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 based on a longer period of time. This may specifically affect some of the food groups in this assessment, such as re-hydrated legumes.

FSANZ does not apply statistical population weights to each individual in the 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 because population weights were not used.

Results

Estimated dietary exposures to ethyl lauroyl arginate

The number of Australians and New Zealanders that reported consuming foods that may contain ethyl lauroyl arginate are listed in Table 3.2. In summary, approximately 86-96% of Australians and New Zealanders ate foods that might contain ethyl lauroyl arginate if the permissions sought in the Application were added to the Code.

The estimated dietary exposures of ethyl lauroyl arginate for Australia and New Zealand are shown in Table 3.3 and in Figure 1. Overall, Australian children 2 to 6 years had a higher exposure to ethyl lauroyl arginate on a bodyweight basis than the whole population.

The estimated mean respondent dietary exposures of ethyl lauroyl arginate ranged from 28.1 to 36.2 mg/day or 0.4 to 2.0 mg/kg bw/day. The 90th percentile dietary exposures for consumers for Australia and New Zealand were between 73.1 and 82.8 mg/day (1.0 and 4.0 mg/kg bw/day) respectively (Table 3.3).

Estimated mean and 90th percentile dietary exposures to ethyl lauroyl arginate for the Australian population (2 years and above) were higher than those for New Zealanders 15 years and above. This may be due to different food consumption patterns (food types and/or amounts) between the two countries and/or differences in survey methodology.

Table 3.2: Population groups, number of consumers that reported consuming foods that may contain ethyl lauroyl arginate and consumers as a percentage of respondents to the surveys

Country	Population group	Number of respondents	Number of consumers*	Consumers as a % of respondents
Australia	2 years and above	13858	12524	90.4%
	2 to 6 years	989	950	96.1%
New Zealand	15 years and above	4636	4010	86.5%

Table 3.3: Estimated mean and 90th percentile dietary exposures to ethyl lauroyl arginate

Country	Population	Mean all respondents mg/day (mg/kg bw/day)	Mean consumers mg/day (mg/kg bw/day)	90 th percentile consumers mg/day (mg/kg bw/day)
Australia	2 years and above	34.6 (0.6)	38.3 (0.7)	82.8 (1.6)
	2 to 6 years	36.2 (2.0)	37.7 (2.1)	73.1 (4.0)
New Zealand	15 years and above	28.1 (0.4)	32.4 (0.4)	75.6 (1.0)

Consumers include the people who have consumed a food that contains ethyl lauroyl arginate.
 Respondents include all members of the survey population whether or not they consumed a food that contains ethyl lauroyl arginate

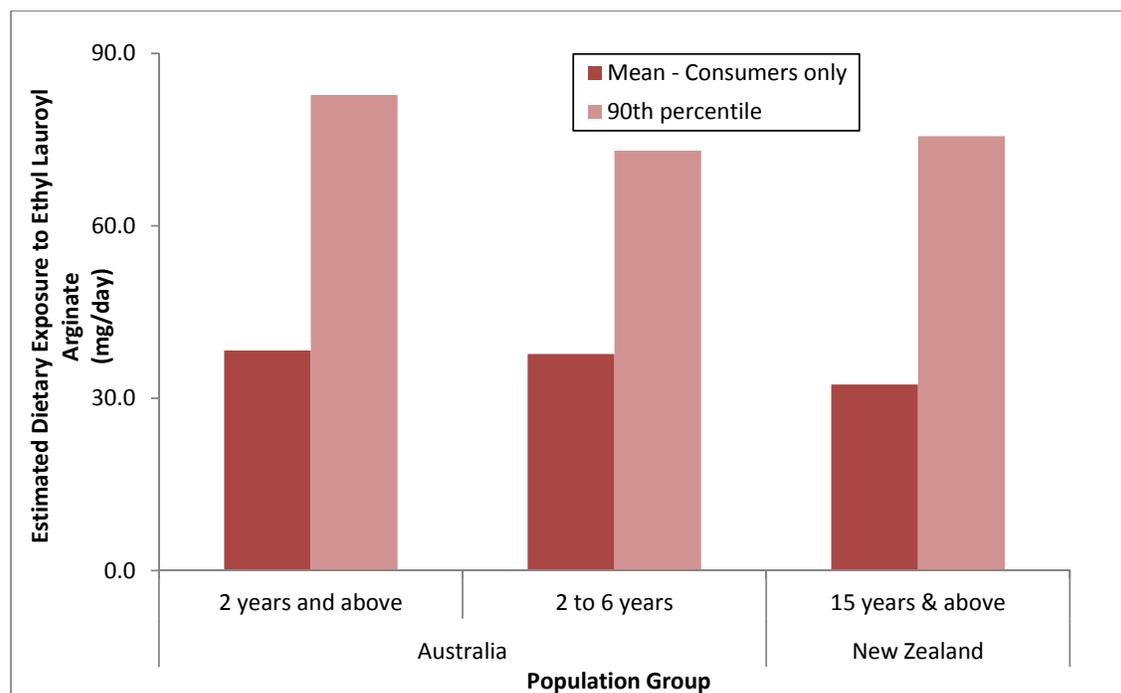


Figure 1: Estimated mean dietary exposures (mg/day) and 90th percentile dietary exposures (mg/day) for consumers of ethyl lauroyl arginate for the Australian and New Zealand population groups

Major contributing foods to total estimated dietary exposures

The major contributors (>5%) to total ethyl lauroyl arginate dietary exposures for the three population groups assessed are shown in Figures 2–4. The main contributor for the Australians aged 2 years and above and New Zealanders aged 15 and above was comminuted meat products and whole pieces of processed meat (ranging between 29% and 43%). For Australians aged between 2 and 6, cordial was the major contributor (28%).

Other contributors to ethyl lauroyl arginate exposure in all population groups assessed were beverages (e.g. fruit and vegetable juices, fruit and vegetable-based drinks and soft drinks; between 8% and 26%) and cheeses (between 9% and 10%).

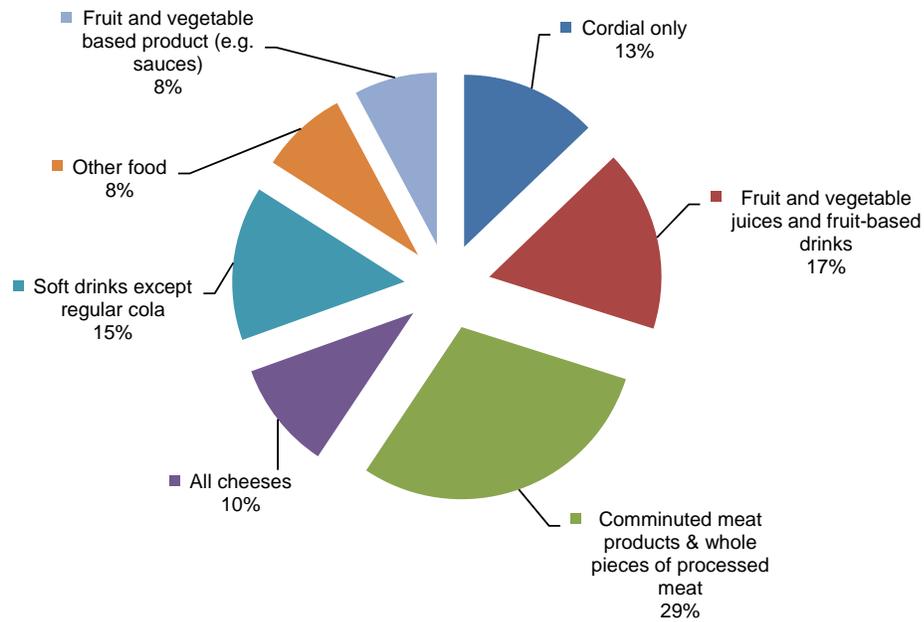


Figure 2: Major contributors to ethyl lauroyl arginate dietary exposures for Australians aged 2 years and above

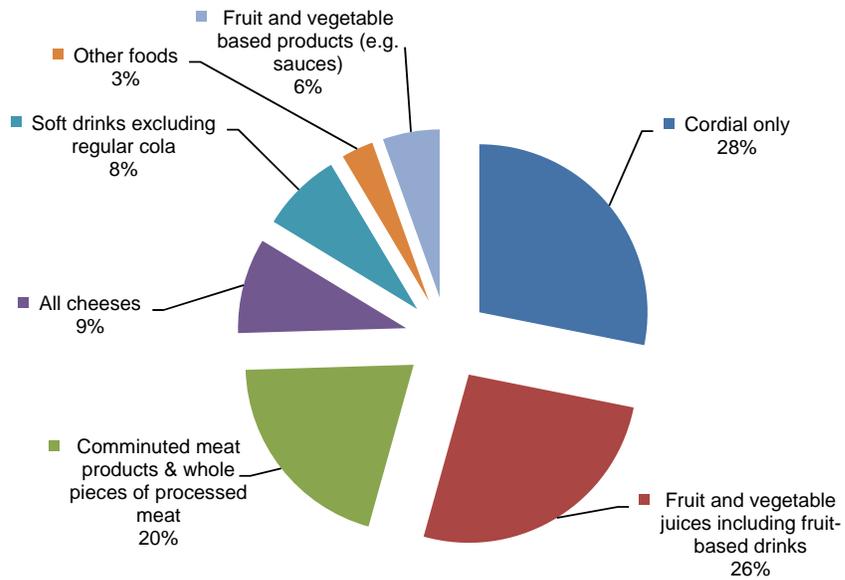


Figure 3: Major contributors to ethyl lauroyl arginate dietary exposures for Australians aged 2 to 6 years

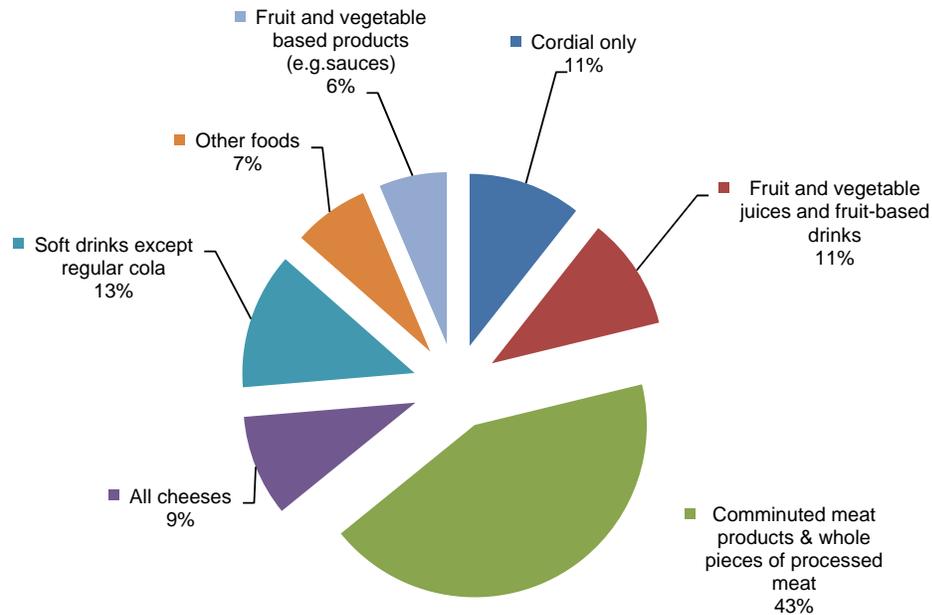


Figure 4: Major contributors to ethyl lauroyl arginate dietary exposures for New Zealanders aged 15 years and above

Comparison of the estimated dietary exposures with the reference health standard

In order to determine if the levels of dietary exposure to ethyl lauroyl arginate are likely to be of a public health and safety concern, the estimated dietary exposures were compared to an Acceptable Daily Intake (ADI) of 0 – 5 mg/kg bw (Figure 5 and Table 3.4).

In summary, all estimated mean and 90th percentile exposures were below the ADI for the population groups assessed.

The estimated mean dietary exposures for consumers of ethyl lauroyl arginate were the lowest for New Zealanders aged 15 years and above (9% of the ADI) and Australians aged 2 years and above (14% of the ADI) and were the highest for Australian children aged 2 to 6 years at 41% ADI. The estimated 90th percentile dietary exposures for consumers were lowest at 21% of the ADI for New Zealanders aged 15 years and above followed by Australians aged 2 years and above at 32% of the ADI and highest for Australian children 2 to 6 years old at 80% of the ADI.

Table 3.4: Estimated mean and 90th percentile exposures to ethyl lauroyl arginate as a % of the ADI

Country	Population	Mean all respondents	Mean consumers	90 th percentile consumers
		% ADI	% ADI	% ADI
Australia	2 years & above	13	14	32
	2 to 6 years	39	41	80
New Zealand	15 years and above	8	9	21

Consumers include the people who have consumed a food that contains ethyl lauroyl arginate.

Respondents include all members of the survey population whether or not they consumed a food that contains ethyl lauroyl arginate.

Acceptable Daily Intake (ADI) = 0 – 5 mg/kg bw.

Conclusion

The dietary exposure assessment shows that if the requested permissions for ethyl lauroyl arginate are included in the Code, consumers including children are unlikely to exceed the ADI of 0 – 5 mg/kg bw. All estimated dietary exposures for the population groups assessed were below the ADI, even when it was assumed that ethyl lauroyl arginate was in 100% of all permitted foods at the maximum permitted level.

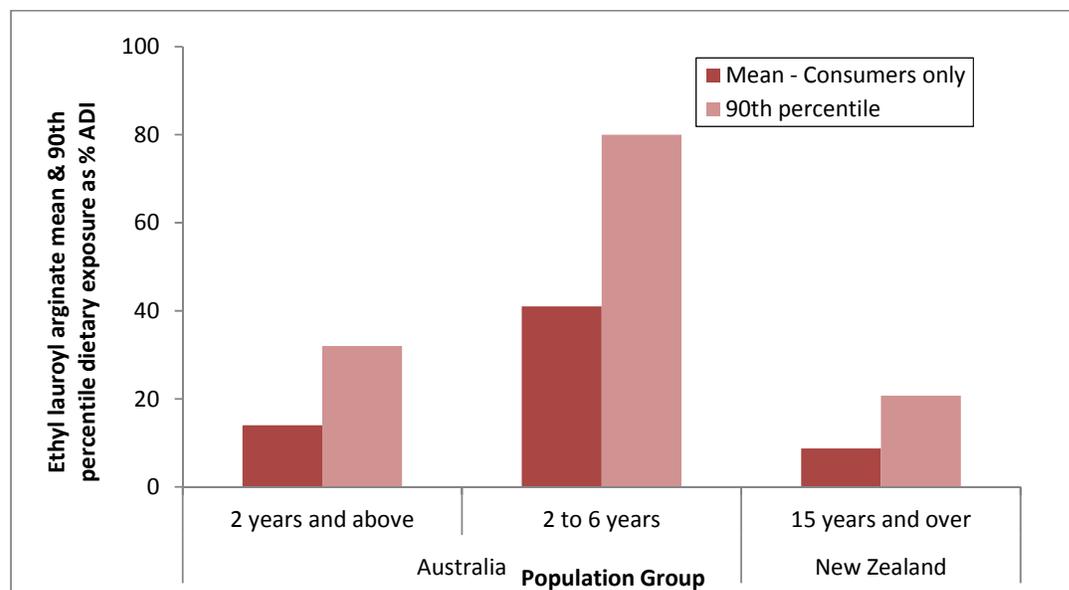


Figure 5: Estimated mean & 90th percentile dietary exposures to ethyl lauroyl arginate as a percentage of the ADI

REFERENCES

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