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

ETHYL CARBAMATE in AUSTRALIAN FOODS

Survey sampling and analysis conducted 2007

EXECUTIVE SUMMARY

Ethyl carbamate (EC), or urethane, is a chemical contaminant that occurs naturally in foods undergoing fermentation during processing or storage. Foods such as bread, soy sauce and yoghurt; as well as alcoholic beverages such as whisky, fruit brandies, beer and wine have been found to contain quantifiable levels of EC.

In 2007 FSANZ decided to undertake an analytical survey to quantify actual levels of EC in foods and alcoholic beverages in Australia. This was necessary to quantify levels of EC in the Australian food supply and to accurately estimate dietary exposure and assess potential risk to human health for Australians. This survey was undertaken as part of the surveillance program in 2007.

A total of 315 individual samples were purchased for analysis, targeting foods consumed in Australia which undergo fermentation in their production such as yoghurt, bread, soy sauce and a range of alcohols such as; wine, whisky, and fruit brandies. Other food and beverage samples such as; bread, milk and beer were also included in the sampling as they form a significant part of the Australian diet.

EC was not found in 75 of the 105 composite foods and beverages analysed, other than in 1 composite sample of soy sauce. Of the 30 composite samples of alcoholic beverages analysed EC was detected in 13. In general, EC levels were higher in alcohol in Danish and UK surveys in comparison to levels detected in US or Australia. In Australia, EC levels were highest in Sake, however this level was still lower than levels identified in the UK.

Given the absence of EC in the foods tested it was unnecessary to construct a complex dietary intake model. However, a simple dietary exposure model for 95th percentile consumers was constructed for males and females aged 18+ years. All alcoholic beverages having quantifiable levels of EC as well as soy sauce were used in the model. From this model, the estimated dietary exposure of high consumers (95th percentile) to EC in beverages and foods varied ranging from 4 – 378 ng/kg bw/day for men and 4 – 327 ng/kg bw/day for women.

In addition, a second consumption model was created using the Australian Alcohol Guidelines (NHMRC) as the basis. These national Guidelines recommend an upper daily alcohol intake for the population to avoid long term health risks from alcohol. MOEs based on the consumption set out in the Guidelines were also calculated and compared to the MOEs based on 95th percentile consumption for both male and females (18+ years). This comparison demonstrated that when individuals are consuming alcohol within the recommended Guidelines, the level of exposure to EC is lower than for the high (95th percentile) consumers.

This survey of Australian foods and beverages provides significant reassurance that EC is not present at quantifiable levels in all commonly available fermented foods surveyed, other than soy sauce. It is also only present in some alcoholic beverages. The risk to health and safety for Australians' from exposure to EC through consumption of food is considered to be negligible. The risk to health and safety for Australians' from exposure to EC through consumption of alcoholic beverages, other than Sake, is negligible, even for high (95th percentile) consumers. High (95th percentile) consumers of alcoholic beverages would enhance their Margin of Exposure to EC if their consumption was modified to comply with the Australian Government Guidelines.

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ABBREVIATIONS

AAG	Australian Alcohol Guidelines (NHMRC)
ADI	Acceptable Daily Intake
ATF	United States Bureau of Alcohol, Tobacco, Firearms and Explosives
BMDL	Bench Mark Dose lower confidence Limit
COT	Committee of Toxicity of Chemicals in Food, Consumer Products and the Environment
DIAMOND	Dietary Modelling of Nutritional Data (FSANZ computer software program), based on food consumption data from the 1995 NNS
EC	Ethyl Carbamate
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization
FDA	US Food and Drug Administration
FSANZ	Food Standard Australia New Zealand
IARC	International Agency For Research Cancer (WHO)
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	Limit of Detection
LOR	Limit of Reporting
LOQ	Limit of Quantification
MOE	Margin Of Exposure
NTP	US National Toxicology Program
µg/L	Micrograms per litre
ng	Nanogram (10^{-9} g)
ng/kg bw/day	Nanograms per kilogram of body weight per day
NHMRC	National Health and Medical Research Council
NSS	National Nutrition Survey
UK FSA	UK Food Standards Agency
WHO	World Health Organization

Note: Definitions for some of these abbreviations can be found in Appendix 1.

1. BACKGROUND

1.1 General

Ethyl carbamate (EC), or urethane, is a chemical contaminant that occurs naturally in foods undergoing fermentation during processing or storage. Foods such as bread, soy sauce and yoghurt; as well as alcoholic beverages such as whisky, fruit brandies, beer and wine have been found to contain quantifiable levels of EC (JECFA, 2005). EC (urethane) was also produced as a commercial chemical and it has a history of use in industry, medicine and veterinary applications. In the United States the use of EC in human medical treatments however, was banned in 1976 by the Food and Drug Administration (FDA) due to concerns about toxicity and lack of efficacy (Dunn et al., 1991).

The predominant source of EC exposure in humans today is through the consumption of foods and beverages containing EC. It has been shown that EC forms from the reaction of alcohol (ethanol) with urea during fermentation. Human exposure to EC through consumption of alcoholic beverages has been raised as an issue of concern for over twenty years, after Canadian Authorities found high levels of EC in certain wines and distilled spirits in November1985. Several international surveys of levels of EC in foods and beverages have been conducted over the last few decades culminating in the International Agency for Research on Cancer classifying EC as "possibly carcinogenic to humans" in 2004 (JECFA, 2005).

The 2005 JECFA evaluation of EC used a Benchmark dose lower confidence limit (BMDL) value of 300 μg/kg bw per day that was based on an increased incidence of alveolar and bronchiolar adenoma or carcinoma in mice. The estimated average daily intake of EC from foods (excluding alcoholic beverages) was 15 ng/kg bw per day giving a margin of exposure (MOE) of 20,000. When alcoholic beverages were also included, the estimated intake was 80 ng/kg bw per day. The calculated MOE for both food and alcohol is 3,800. The JECFA determined exposure levels from food only, to be of low concern however, when alcoholic beverages were included the Committee found dietary exposure to EC was of concern. JECFA concluded that efforts to reduce EC levels in alcoholic beverages should continue.

1.2 Overseas

In 1986, the US FDA and US Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) analysed approximately 1200 alcoholic beverages and found Bourbon to contain the highest level of EC in comparison to other spirits analysed. It was concluded that high EC content was the result of higher temperatures required for production. Variation in the EC levels in other alcoholic beverages was noted. For example, EC levels in; brandy ranged from 200 to 12,000 μg/L; dessert wines including cream sherries, varied from < 4 μg/L to several hundred μg/L; and table wines ranged from 0-25 μg/L (US FDA, 1988). These analyses suggested alcoholic beverages were a major source of human EC exposure and measures were implemented in many countries to reduce EC content of alcoholic beverages. Previously, urea, a metabolite for yeast, was added during manufacturing to assist with the fermentation process. This addition substantially increased the levels of EC in beverages due to a chemical reaction with ethanol. The use of urea in US wineries has now ceased and further changes implemented to the distillation process to reduce EC levels in the alcohol products, particularly Bourbon. Longitudinal studies proved that alterations to manufacturing and production procedures were successful in reducing levels of EC. A US study conducted over four years (1987-1991) showed a marked decrease in EC content in alcoholic beverages (Table 1) (US FDA, 1993). For example, fruit brandy contained EC levels of 1200 µg/L in 1987 and only 5 µg/L in 1991.

A similar study by the UK Food Standards Agency (UK FSA) in 2000 focussed primarily on the EC content in Scotch whisky over a period of ten years. This work also demonstrated a decrease in the mean EC content of Scotch whisky from 53µg/L to 30 µg/L over the period (Table 2) (UK FSA, 2000).

In 1985 Canada moved to limit the EC content of alcoholic beverages setting maximum limits of 30 µg/L for table wines and up to 400 µg/L for fruit brandies and liqueurs (Table 3). The higher allowable levels of EC in fortified wines, spirits, fruit brandies and liqueurs was due to the lower level of consumption in Canada (Health Canada, available at http://hc-sc.gc.ca/fn-an/securit/chem-chim/contaminants-guidelines-directives_e.html#guidelines)

The European Commission has not prescribed maximum limits for EC in food or beverages for the European Union however the European Food Safety Authority (EFSA) is currently collecting data on the presence of EC in foods and beverages (EFSA, 2006)

A timeline summarising the regulatory response to the issue of EC by Canada, the UK, the US and Australia is provided in Figure 1.

Table 1: Comparison of average EC levels in selected alcoholic beverages in 1987 and 1991 from the US.

Product	**Average Ethyl Carbamate level (µg/L)[‡]**		
	1987	**1991**	
		Domestic	*Imported*
Brandy (grape)	40	10	45
Brandy (fruit)	1200	5	255
Bourbon (retail)	150	70	55
Rum	20	2	5
Liqueur	100	10	25
Scotch	50	†	55
Sherry	130	10	40
Port	60	23	26
Grape wine	13	10	15
Sake	300	55	60

† Scotch is not manufactured domestically
‡ Table reference: http://vm.cfsan.fda.gov/~frf/fc0293ur.html

Table 2: Comparison of ethyl carbamate levels in Scotch Whiskies from 1990 to 1999 from the UK.

Sampling Year	No. of Samples	Ethyl Carbamate Concentration (μg/L)	
		Mean	*Range*
1990	6	53	21-72
1991	14	54	29-91
1992	13	45	21-74
1999	173	30	ND-239[†]

Table reference: http://www.food.gov.uk/science/surveillance/fsis2000/2whisky
[†] ND: not detected, <10 μg/L

Table 3: Maximum levels for ethyl carbamate outlined in the Canadian Standards.

Alcohol	Maximum Contaminant Concentration (μg/L)
Table wine	30
Fortified wine	100
Distilled spirit	150
Fruit brandies and liqueurs	400
Sake	200

Table reference: http://hc-sc.gc.ca/fn-an/securit/chem-chim/contaminants-guidelines-directives_e.html#guidelines

1.3 Australian and New Zealand

The Australia New Zealand Food Standards Code (the Code) does not prescribe an upper limit for ethyl carbamate. However, FSANZ has monitored the situation in relation to EC and taken a number of actions.

In 2005 FSANZ actively participated in the JECFA international evaluation of EC, preparing dietary exposure estimates for the Australian population and inputting the risk assessment. As there was no concentration data specific to the Australian food supply the dietary exposure estimates of EC prepared by FSANZ were based on the international concentration data accepted by JECFA. FSANZ modelled dietary exposure using the DIAMOND (Dietary Modelling of Nutritional Data) program combining individual Australian consumption records from the 1995 National Nutrition Survey (NSS) and assigning the international concentrations for each food. Individual exposure estimates for the population were calculated. The estimated mean dietary exposure for Australian consumers of EC was 1.4 μg/day (21 ng/kg bw per day). Data from a further five countries were also included in the JECFA evaluation with national mean estimates of exposure from food and beverages ranging from 1-4μg/person per day.

JECFA noted that the concentration data used by; Australia, New Zealand and South Korea in their estimates of mean intake was much lower than that used by; Denmark, Switzerland and USA. The higher concentration data tended to come from earlier studies in the 1990's (JECFA, 2005).

In the Australian model prepared for JECFA the theoretical main contributors to EC levels were calculated to be wine (36%), beer (20.6%), breads (15.5%), spirits including whisky (10.2%), cheese and cheese products (6.5%) and milk (5.45). A list of the foods contributing to the theoretical model is provided in Table 4. It is noteworthy that these findings were based on overseas concentration data and that the subsequent analytical survey of foods in Australia did not detect EC in many of these foods.

In 2006 Food Standards Australia New Zealand published the Final Assessment Report for Proposal P277 – Review of Processing Aids (other than enzymes), which proposed to remove the permission for the use of urea as a microbial nutrient or microbial nutrient adjunct in alcoholic beverages (FSANZ, 2006). As a result of the evaluation, the permission to use urea as a processing aid in the production of alcoholic beverages was removed from the Code and it is now only permitted to be used for food (FSANZ, 2006).

In 2007 FSANZ decided to undertake this analytical survey to quantify actual levels of EC in foods and alcoholic beverages in Australia. This was necessary to estimate dietary exposure and assess potential risk to human health for Australians. This survey was undertaken as part of the surveillance program in 2007.

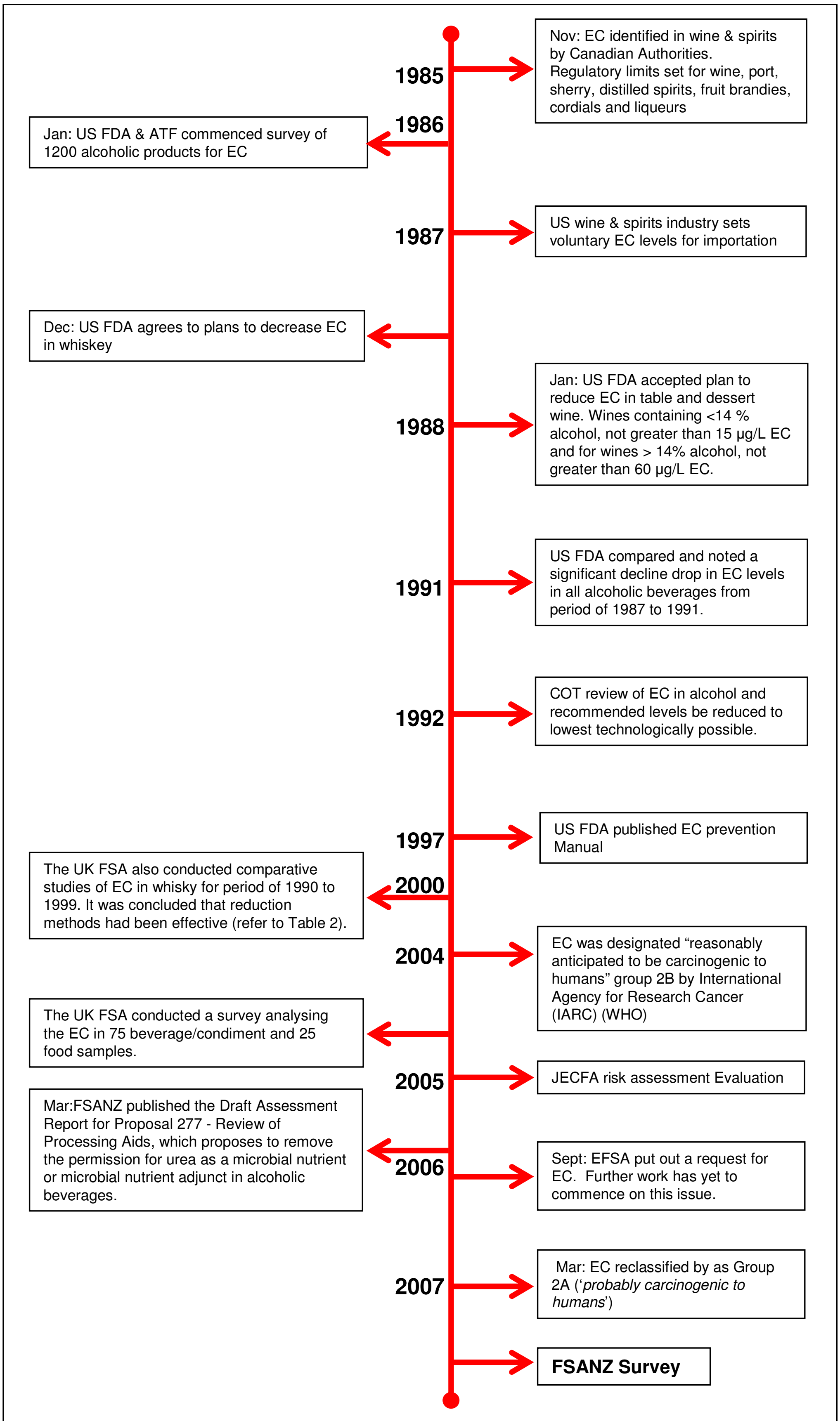
FSANZ also communicated the survey proposal to the New Zealand Food Safety Authority who also agreed to undertake a complementary survey activity in New Zealand.

Table 4: 2005 Theoretical contributions of each food group to total estimated exposure to ethyl carbamate for Australia.

ANZFCS classification code	Food Group Name	Contribution to Exposure (%)†
1.1	Liquid milk and milk based drinks	5.4
1.2	Fermented and rennetted milk products (yoghurts)	1.2
1.6	Cheese and cheese products	6.5
4.3.7.1	Soy sauce	0.6
7.1	Breads, plain and fancy	15.5
14.2.1	Beer	20.6
14.2.2	Wine	36.0
14.2.2.1	Fortified wine	4.1
14.2.5	Spirits and liqueurs (except whisky)	6.2
14.2.5.2	Whisky	3.6
14.2.5.3	Whisky canned, mixed drink	0.4

† prepared for JECFA based on overseas concentrations

Figure 1: Overview of international monitoring of EC in alcoholic beverages[†]



[†] Information taken from Health Canada (no date specified); US FDA, 1988; First Venture technologies Corp (no date specified); FSA UK, 2000; US FDA, 1993; US FDA, 1997; US National Toxicology Program (NTP, 2005); Hasnip et al., 2007; JECFA, 2005; FSANZ, 2006; EFSA; IARC 2007.

2. SURVEY OF EC IN AUSTRALIAN FOOD

Planning and consultation for the survey was undertaken in early 2007. A suitably contracted laboratory was engage after a competitive selection process Sampling took place in May 2007 and analysis was completed in June 2007.

2.1 Survey sampling

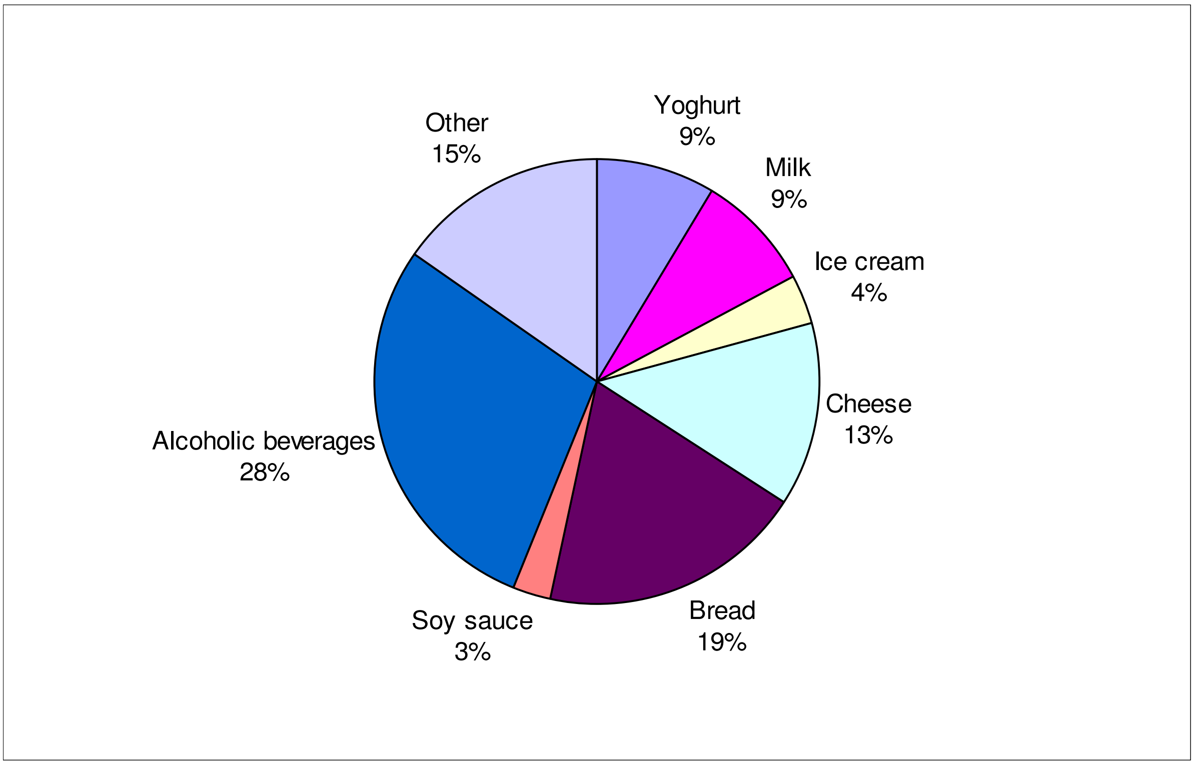
Survey sampling was targeted at foods which undergo fermentation in their production and that previous overseas studies have found to contain EC. Foods such as yoghurt, bread, soy sauce and a range of alcohols such as; wine, whisky, and fruit brandies were sampled because of their potential to contain higher concentrations of EC. Other food and beverage samples such as; bread, milk and beer were also included in the sampling as they form a significant part of the Australian diet. To ensure the survey was able to best represent dietary exposure to EC leading brands in each food category were purchased from typical retail outlets. Samples were not necessarily produced in Australia, rather they represented what was most typically available and consumed in Australia. Alcoholic beverages constituted about 28% of the samples analysed and products such as Scotch and Bourbon are imported by definition. Beverage samples included wine, fortified wine, beer, spirits and liquors. Premixed drinks containing spirits were also included in the analysis as they are a significant part of the market.

A total of 315 individual (primary) samples were purchased for analysis. Three primary samples from the same category eg cheese, white wine were combined to form 105 composite samples for analysis.

Most samples were purchased from a variety of stores in Melbourne, Victoria. These products were regarded as being readily available nationally. Some foods that have significant consumption and might be expected to have only regional distribution were also sampled. A total of 36 primary samples of; bread, cheese, milk, low fat milk, yoghurt and ice cream were also collected in Brisbane, Queensland and Perth, Western Australia. All the foods sampled were already in their table ready form (ie did not require cooking) at the time of purchase. Figure 2 shows the proportion of the various types of foods and beverages included in the sampling.

A list of the 105 composite samples analysed for EC is provided at Appendix 2.

Figure 2: Proportion of sample types analysed for Ethyl Carbamate§



§ Regional foods; cheese, bread, ice cream, milk and yoghurt samples taken from Victoria, Queensland and Western Australia.

2.2: Survey analysis

At total of 315 primary samples were combined to form 105 composite samples. Each composite sample comprised three primary samples from the same food category. Equal quantities of each of the three primary samples were combined to produce a homogenous sample. Analysis for ethyl carbamate was conducted by purge and trap Gas Chromatography-Mass Selective Detection procedure.

The samples were analysed on a fresh weight basis and concentrations reported in milligrams per litre (mg/L; liquid sample) or milligrams per kilogram (mg/kg; solid sample) but have been converted to micrograms per litre (µg/L) or micrograms per kilogram (µg/kg) for the purpose of this report. The Limits of Reporting are provided in Table 5.

Table 5: LOR for liquid and solid matrices

Test	Limit of Reporting (LOR)
EC in liquid matrix	5 µg/L
EC in solid matrix	5 µg/kg

The laboratory contracted to do the analysis is an accredited facility by The National Association of Testing Authorities (NATA). Quality Assurance procedures were part of the test routine. One blank sample was analysed every 10 test samples. One duplicate sample was also run with every 10 test samples. A standard ethyl carbamate source was also available and 1 matrix spiked every 10 samples. A 6-point calibration curve was also conducted to ensure accurate measurements were produced from the instrument.

3. FOOD SURVEY ANALYTICAL RESULTS

3.1: EC concentrations in foods and beverages

Of the total 105 composite samples that were analysed, 91 (87%) reported non-detects. The remaining 14 (13%) samples had quantified values or "detections" of EC at low levels.

EC was not found in any of the 75 composite foods and beverages analysed, other than in 1 out of the 3 samples of soy sauce (13 µg/L). Of the 30 composite samples of alcoholic beverages analysed EC was detected in 13 (5.1 - 86 µg/L).

A summary of the detections of EC found in the samples analysed is shown in Table 6. A summary of the results for all the foods and beverages tested is provided in Appendix 2.

Table 6: A summary of ethyl carbamate levels in Australian food and beverage samples for samples with quantified values

Food/beverage sample†	µg/L‡
Liquors, Sake	86
Fortified Wine, Sherry	23
Fortified Wine, Port	18
Liquors, Liqueur	15
Soy Sauce, Light	13
Spirits, Brandy	13
Spirits, Rum	11
Liquors, Stone Fruit Spirits	11
Spirits, Gin	9.3
Liquors, Stone Fruit Spirits	7.3
Spirits, Tequila	6.4
Fortified Wine, Green Ginger Wine	5.9
Spirits, Bourbon	5.3
Wine, White	5.1

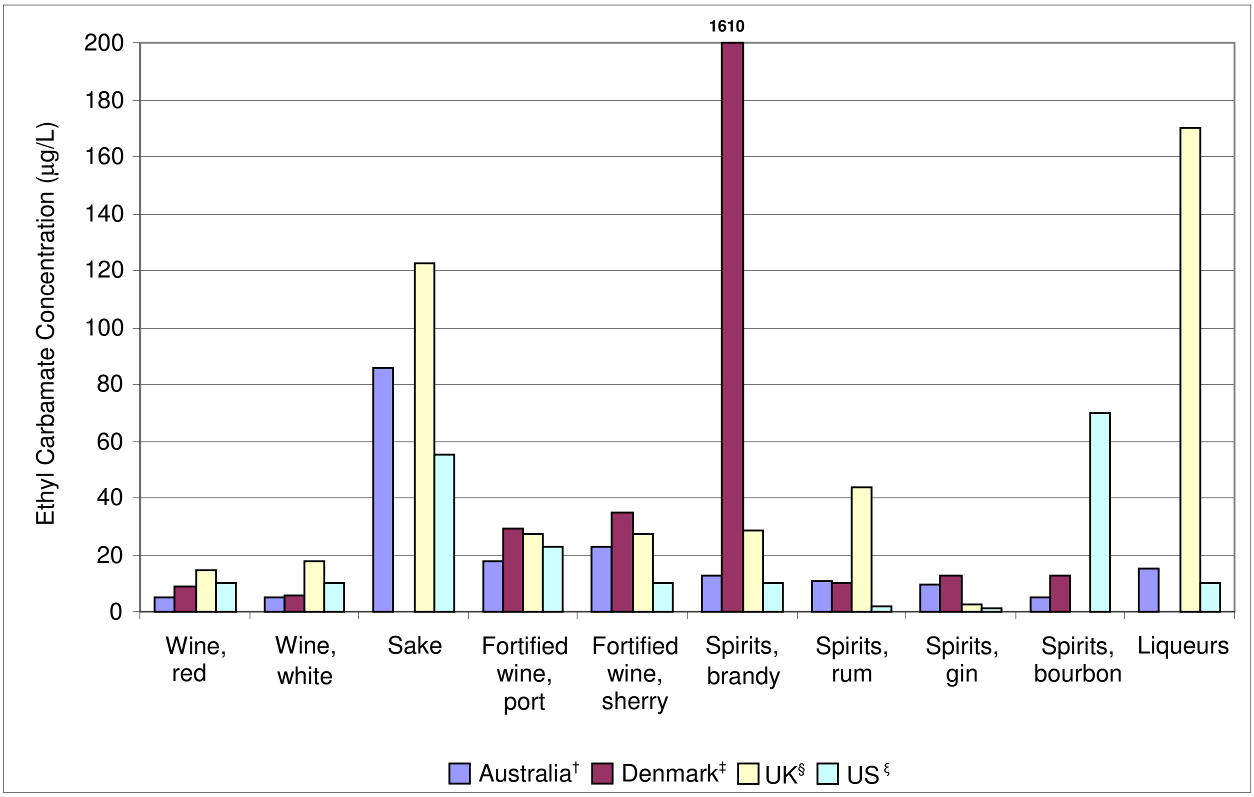
† Summary only presents positive food samples
‡ LOR = <5 µg/L

3.2: Comparison of EC concentrations in food and beverages from other countries

Comparison of EC levels in alcoholic beverages from a variety of countries is shown in Figure 3. The comparison does not compare all foods and beverages analysed in this study, but provide a general indication of trends between different countries. In general, EC levels were higher in samples from Denmark and the UK in comparison to levels detected in US or Australia. In Australia, EC levels were highest in Sake (86 µg/L), however this level was still lower than levels identified in the UK (122.5 µg/L). The highest levels of EC in the UK were identified in liqueurs (170 µg/L). In contrast, the highest levels of EC in the US and Denmark were identified in Bourbon (70 µg/L) and Brandy (1610 µg/L), respectively. The variation in EC levels between different countries for similar beverages may reflect differences in manufacturing, processing and purification of alcohol.

Comparison of the EC levels in food samples from a variety of countries is shown in Table 6. EC levels in Australian food were low in most foods tested other than in soy sauce in comparison to other countries. However, EC levels were highest in both traditional and non-traditional soy sauces from Korea.

Figure 3: Comparison of EC concentrations in alcoholic beverages from other countries



† Australian data presented is from this study. Value for red wine was at the LOR of <5 µg/L
‡ Vahl, 1993; mean values presented; value presented for gin and bourbon values are values for 'other spirits'. Value for brandy is 1610 µg/L. Value for Sake and liqueurs not available.
§ Hasnip et al., 2007; values presented are an average of the range, value for gin taken from Dennis et al., 1989
ξ US FDA, 1993.
Value for gin taken from Battaglia et al., 1990. Wine, does not distinguish between white and red wine.

Table 7: Comparison of EC concentrations (μg/kg) food samples from other countries

Food sample	Australia†	UK§	Korea‡	Denmark§
Yoghurt	<5	0-1	-	0.2
Milk	<5	-	-	0.2
Ice cream	<5	-	-	-
Cheese	<5	0.6 - 5.1	-	-
Bread	<5	0 - 5	-	2.6
Soy Sauce	13	10	14.6 (r) 17.1 (t)	-
Sauerkraut	<5	29	-	-

† Data presented from this study. LOR = <5 μg/kg
§ UK values for sauerkraut in white wine and soy sauce taken from Hasnip et al.,2007. Other mean concentration values are taken from Dennis et al.,1989
‡ Korea mean concentration values taken from Kim et al., 2000; mean values presented; r = regular, t = traditional
§ Denmark mean concentration values from Vahl, 1993. Value for wheat bread; milk value is for all acidified milks

4. DIETARY EXPOSURE AND RISK CHARACTERISATION

4.1: Estimated dietary exposure to EC from food and risk characterisation

As the analysis found no EC present in any food samples, other than light soy sauce, the dietary exposure to EC from food is therefore negligible. Prior to the current survey it was theorised that; yoghurt, bread, cheese, milk and beer would contribute to Australian's dietary exposure to EC. The previous dietary modelling prepared by FSANZ for JECFA in 2005 estimated a mean intake of 1.4 μg/day based on overseas concentrations and would therefore have led to an overestimate of dietary exposure to EC in Australia. (JECFA, 2005).

Given the absence of EC in the foods tested it was considered unnecessary to construct a complex dietary intake model. It was considered more appropriate to calculate the dietary exposure for the highest consumers (95th percentile) of the beverages where EC was found and to then determine whether the MOE were acceptable.

Light soy sauce was the only food sample found to contain quantifiable EC levels. Two other composite samples of soy sauce did not contain EC. Consumption figures for 95th percentile of consumers were found to be 30 and 20 ml for male and females, respectively. Estimated exposure of high consumers (95th percentile) to EC from soy sauce was found to be 4.45 ng/kg bw/day for males and 4.09 ng/kg bw/day for females. The MOE for EC in soy sauce was found to be high for both men and women (67,340 and 73,330, respectively), suggesting negligible risk from EC in soy sauce (Table 8 &9).

JECFA had previously concluded in 2005 that dietary exposure to EC from food was not of concern, so the lower concentrations and resultant MOE found in this survey provide even greater reassurance that the risk is negligible.

4.2: Estimated dietary exposure to EC from alcohol consumption and risk characterisation

This study determined that dietary exposure to EC was primarily through consumption of alcoholic beverages. A small number of alcoholic beverages contained low concentrations of EC and the dietary exposure for the high consumers (95^{th} percentile) of these beverages was calculated in order to determine whether the MOE were acceptable.

The estimated dietary exposure of high consumers (95^{th} percentile) to EC was variable ranging from 18 – 378 ng/kg bw/day for men and 13 – 327 ng/kg bw/day for women. Estimated dietary exposure of high consumers was greatest for both men and women consuming Sake (378 and 327 ng/kg bw/day, respectively). These exposure estimates may be overstated as it was assumed that Sake consumption in Australia was equivalent to consumption of other fortified wines. Estimated dietary exposure to EC for high consumers (95^{th} percentile) drinking Port were 87 and 102 ng/kg bw/day for men and women, respectively. In contrast, the lowest estimated dietary exposure of EC to high consumers (95^{th} percentile) was found in men and women consuming Bourbon (18.7 and 16.3 ng/kg bw/day). Dietary exposure estimates of EC in white wine and Brandy were similar in men (59 & 55 ng/kg bw/day) but not in women (56 & 22 ng/kg bw/day). A comprehensive summary of the dietary exposure estimates for high consumers (95^{th} percentile) for all alcoholic beverages that tested positive to EC is outlined in Table 8 & 9.

A simple dietary exposure model was constructed for males and females aged 18+ years based on the legal age of alcohol possession and consumption prescribed in Australian legislation (Liquor Act 1975 Sect. 152/154). Alcohol consumption data was based on the 1995 National Nutrition Survey (NNS) which surveyed 13 858 Australians aged 2 years and above using a 24-hour food recall methodology. The 95^{th} percentile consumers of all the alcoholic beverages having quantifiable amounts of EC were used in the model. Where no specific consumption information was available for alcoholic beverages containing EC, consumption volumes for comparable beverages with similar alcohol contents were used. This was the case for both Sake and Green Ginger wine, which used consumption data for all fortified wines. From the consumption volume (L/day), an estimated dietary intake/exposure to EC was determined and subsequent MOE values were calculated for 18+ year old male and female groups (Table 7&8). The MOE were based on the BMDL of 300 μg/kg bw per day as outlined above.

As well as modelling the 95^{th} percentile consumers from the NNS, a second consumption model was created using the Australian Alcohol Guidelines (AAG; NHMRC, 2001) as the basis. These national Guidelines recommend an upper daily alcohol intake for the population to avoid long term health risks from alcohol. Generally, the Guidelines recommend men have a maximum average of four standard drinks per day and women a maximum average of two standard drinks per day. Where the Guidelines did not specify standard drink volumes for beverages found to contain EC, the consumption volume was calculated using the alcohol content declared on the label. In the case of Sake the consumption data for fortified wines was used. This has probably led to an overestimate of consumption for Sake which is not a widely consumed alcoholic beverage in Australia. MOEs based on the consumption set out in the Guidelines were then also calculated and these are compared to the MOEs based on NSS 95^{th} percentile consumption for both male and females (18+ years) in Figure 4 & 5. This comparison demonstrates that when individuals are consuming alcohol within the recommended Guidelines, the level of exposure to EC is lower than for the high (95th percentile) consumers.

Generally the MOE for EC from alcohol was higher for females than males. This directly reflects the lower volumes of alcohol consumed by females. The MOE values ranged from 3,430 (Port) to 16,010 (Bourbon) for males and 2,910 (Port) to 21,510 (Gin) for females.

The estimated MOE determined from 95th percentile consumption of Sake in both male and female populations was low (790 and 920, respectively), suggesting a higher level of exposure to EC, however this a likely overestimate as the consumption of fortified wine was used as a basis, due to a lack of specific consumption data for Sake. Nonetheless, it is noteworthy that Sake was found to contain the highest concentrations of EC (86 µg/L).

Table 8: Consumer and theoretical MOE to ethyl carbamate in males aged 18+ years

		ETHYL CARBAMATE (URETHANE) SURVEY RESULTS[ℓ]					
		Males (18+ years)					
Sample[†]	Concentration (µg/L)[‡]	Consumption 95th percentile NNS consumers Males 18+ yrs L/day[β]	95th percentile dietary exposure µg/day	95th Percentile consumer dietary exposure ng//kg/bw/day[≠]	Margin of Exposure (MOE)[Σ]	Australian Alcohol Guidelines (NH&MRC) L/day	MOE at upper limit of AAG[Σ]
Liquors, Sake[∞]	86	0.361	31.046	378.61	790	0.336	850
Fortified Wine, Sherry	23	0.277	6.371	77.70	3,860	0.272	3,930
Fortified Wine, Port	18	0.399	7.182	87.59	3,430	0.288	4,750
Liquors, Liqueur	15	0.367	5.505	67.13	4,470	0.268	6,120
Soy Sauce, Light[§]	13	0.028	0.365	4.45	67,340	NA	NA
Spirits, Brandy	13	0.352	4.576	55.80	5,380	0.140	13,520
Spirits, Rum	11	0.326	3.586	43.73	6,860	0.136	16,440
Spirits, Gin[ζ]	9.3	0.180	1.674	20.41	14,700	0.136	19,450
Liquors, Stone Fruit Spirits[¥]	9.15	0.290	2.654	32.36	9,270	0.128	21,000
Spirits, Tequila[δ]	6.4	0.290	1.856	22.63	13,250	0.128	30,030
Fortified Wine, Green Ginger Wine[η]	5.9	0.361	2.130	25.97	11,550	0.328	12,710
Spirits, Bourbon[ξ]	5.3	0.290	1.537	18.74	16,010	0.120	38,680
Wine, White[Ψ]	5.1	0.959	4.891	59.65	5,030	0.400	12,060

ℓ Tabulated results are a summary of the positive samples obtained from the survey

† All composites of leading brands

‡ LOR = <5 µg/L

β Assumes that 1 gram of alcoholic beverage is equal to 1 millilitre

≠ Assumes an average body weight of 82 kg

∞ Insufficient consumers of rice wine, therefore used consumption for all fortified wines

§ Consumption figures for all soy sauces. Includes where soy sauces have been used as a part of a mixed food e.g. stir-fry

ζ Insufficient consumers to derive a robust 95th percentile consumption figure, therefore used 95th percentile figure for males + females

¥ Average of two values ie (11+7.3)/2 =9.15; Stone fruit spirits not identified in NNS, therefore used consumption for all spirits

δ Tequila not consumed, therefore used consumption for all spirits. However, mixed drinks containing tequila were consumed.

η Insufficient consumers of green wine, therefore used consumption for all fortified wines

ξ Includes all whisky types

Ψ Excludes sparkling

Σ Values are rounded to the nearest 10.

Table 9: Consumer and theoretical MOE to ethyl carbamate in females aged 18+ years

		ETHYL CARBAMATE (URETHANE) SURVEY RESULTS[ℓ]					
		Females (18+ years)					
Sample[†]	Concentration (µg/L)[‡]	Consumption 95th percentile NNS consumers Females 18+ yrs L/day[β]	95th percentile dietary exposure µg/day	95th Percentile consumer dietary exposure ng//kg/bw/day[≠]	Margin of Exposure (MOE)[Σ]	Australian Alcohol Guidelines (NH&MRC) L/day	MOE at upper limit of AAG[Σ]
Liquors, Sake[∞]	86	0.259	22.274	327.56	920	0.168	1,410
Fortified Wine, Sherry	23	0.207	4.761	70.01	4,290	0.136	6,520
Fortified Wine, Port	18	0.389	7.002	102.97	2,910	0.144	7,870
Liquors, Liqueur	15	0.277	4.155	61.10	4,910	0.134	10,150
Soy Sauce, Light[§]	13	0.021	0.278	4.09	73,330	NA	NA
Spirits, Brandy	13	0.118	1.534	22.56	13,300	0.070	22,420
Spirits, Rum	11	0.226	2.486	36.56	8,210	0.068	27,270
Spirits, Gin[ζ]	9.3	0.102	0.949	13.95	21,510	0.068	32,260
Liquors, Stone Fruit Spirits[¥]	9.15	0.179	1.638	24.09	12,460	0.064	34,840
Spirits, Tequila[δ]	6.4	0.179	1.146	16.85	17,810	0.064	49,810
Fortified Wine, Green Ginger Wine[η]	5.9	0.259	1.528	22.47	13,350	0.164	21,080
Spirits, Bourbon[ξ]	5.3	0.209	1.108	16.29	18,420	0.060	64,150
Wine, White[Ψ]	5.1	0.749	3.820	56.18	5,340	0.200	20,000

[ℓ] Tabulated results are a summary of the positive samples obtained from the survey

[†] All composites of leading brands

[‡] LOR = 5µg/L

[β] Assumes that 1 gram of alcoholic beverage is equal to 1 millilitre

[≠] Assumes an average body weight of 68 kg

[∞] Insufficient consumers of rice wine, therefore used consumption for all fortified wines

[§] Consumption figures for all soy sauces. Includes where soy sauces have been used as a part of a mixed food e.g. stir-fry

[¥] Average of two values ie (11+7.3)/2 =9.15; Stone fruit spirits not identified in NNS, therefore used consumption for all spirits

[δ] Tequila not consumed, therefore used consumption for all spirits. However, mixed drinks containing tequila were consumed.

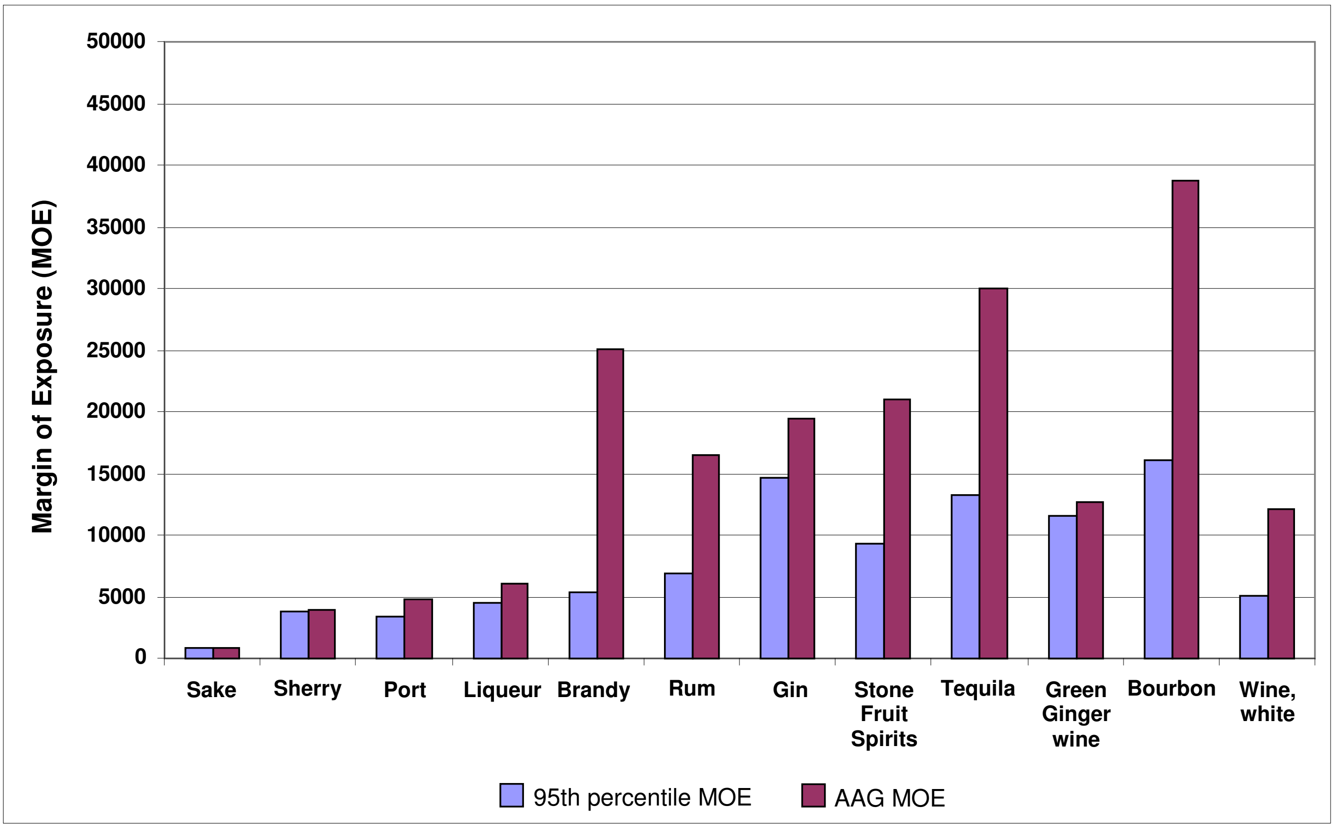
[η] Insufficient consumers of green wine, therefore used consumption for all fortified wines

[ξ] Includes all whisky types

[Ψ] Excludes sparkling

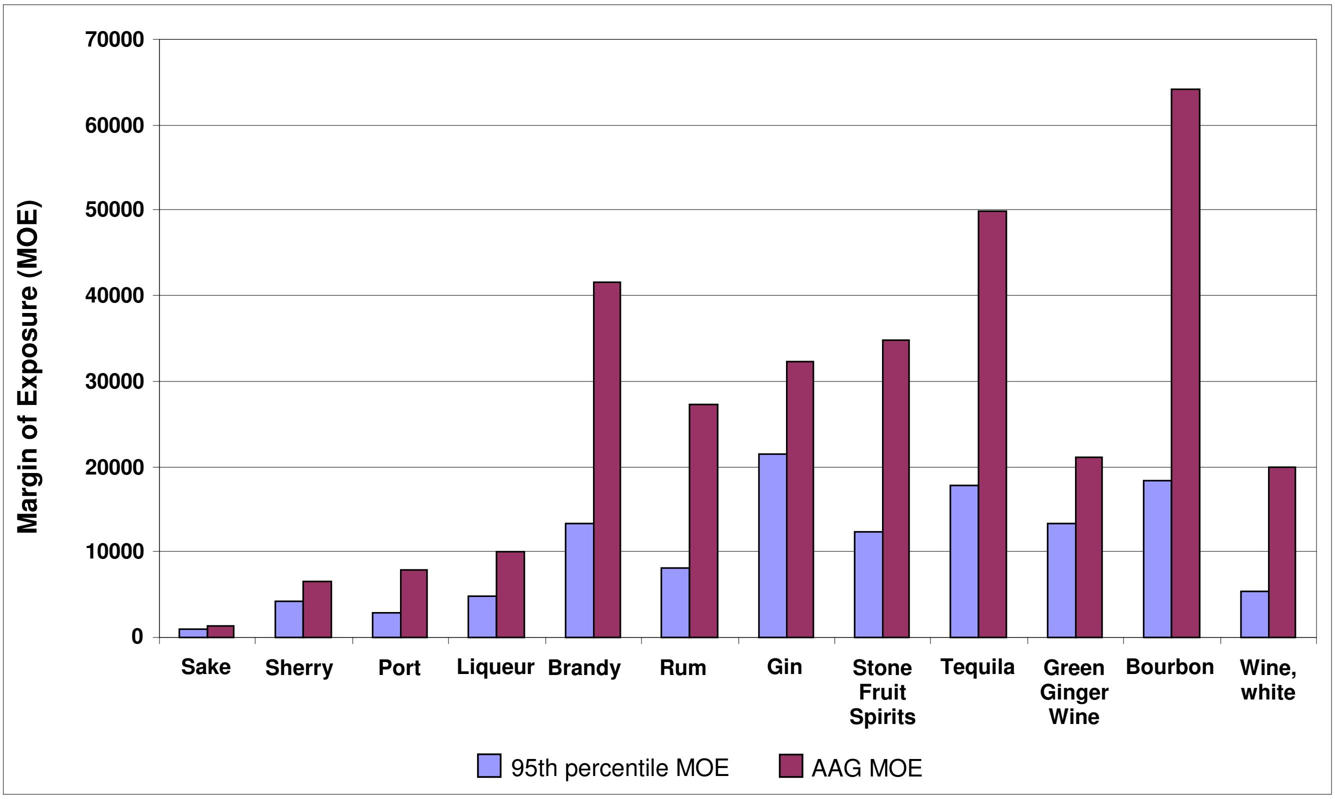
[Σ] Values are rounded to the nearest 10.

Figure 4: Comparison of 95th percentile consumption MOE and calculated MOE based on Australian Alcohol consumption guidelines (NH&MRC, 2001) for men (18+ yrs)†



† MOEs were calculated based on either 95th percentile consumption data (NNS) or derived from the Australian Alcohol Guidelines (NH&MRC, 2001) (described in Section 4.1 &4.2).

Figure 5: Comparison of 95th percentile consumption MOE and calculated MOE based on Australian Alcohol consumption guidelines (NH&MRC, 2001) for women (18+ yrs)†



† MOEs were calculated based on either 95th percentile consumption data (NNS) or derived from the Australian Alcohol Guidelines (NH&MRC, 2001) (described in Section 4.1 & 4.2).

5. CONCLUSIONS

This survey of Australian foods and beverages produced through fermentation provides significant reassurance that Ethyl carbamate is:

- only present in some alcoholic beverages and in some light soy sauce at very low levels; and
- not present at quantifiable levels in all commonly available fermented foods surveyed.

Concentrations of Ethyl carbamate in typical foods and beverages supplied in Australia are low compared to levels found in previous overseas surveys.

The risk to health and safety for Australians' from exposure to EC through consumption of food is negligible.

The risk to health and safety for Australians' from exposure to EC through consumption of alcoholic beverages, other than Sake, is negligible, even for high (95th percentile) consumers.

High (95th percentile) consumers of alcoholic beverages would enhance their Margin of Exposure to EC if their consumption was modified to comply with the Australian Government Guidelines.

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APPENDIX 1: DEFINITIONS AND GLOSSARY OF TERMS

Bench Mark Dose lower confidence Limit (BMDL)
The BMDL is the lower confidence limit of the bench mark dose for a 10% level of response, called the benchmark response.

Limit of Detection (LOD)
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). For the purposes of this study, analytical results reported as being less than the LOD were assumed to be zero.

Limit of Quantification (LOQ)
The LOQ 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.

Limit of Reporting (LOR)
The LOR is the lowest concentration level that the laboratory reports analytical results. For the purposes of this report, the LOD was chosen as the basis for the LOR (i.e. the LOR is equivalent to the LOD).

Mapping
The process that assigns the levels of substances detected in survey foods to the appropriate food consumption data to estimate dietary exposure to the substance. Given that a survey cannot analyse all foods in the food supply, a single survey food may be assumed to represent a whole group of foods with appropriate adjustment factors for concentration.

Margin of Exposure (MOE)
The ratio of the BMDL to the estimated exposure dose.

APPENDIX 2

Table A 1: Ethyl carbamate concentration in food samples analysed

Food Category	Foods	Comments	Ethyl Carbamate Conc. (µg/L)‡	Composite No.†
ALCOHOL	Beer	includes off the shelf products, leading brands	nd	4
	Wine, Red,	includes off the shelf products, leading brands	nd	3
	Wine, White,	includes off the shelf products, leading brands	nd	2
	Wine, White	includes off the shelf products, leading brands	**5.1**	1
	Sparkling Wine	includes off the shelf products, leading brands	nd	2
	Fortified Wine, Alcoholic Cider	includes off the shelf products, leading brands	nd	1
	Fortified Wine, Port	includes off the shelf products, leading brands	**18**	1
	Fortified Wine, Sherry	includes off the shelf products, leading brands	**23**	1
	Fortified Wine, Vermouth	includes off the shelf products, leading brands	nd	1
	Fortified Wine, Green Ginger Wine	includes off the shelf products, leading brands	**5.9**	1
	Fortified Wine, Other	includes off the shelf products, leading brands	nd	1
	Spirits, Scotch	includes off the shelf products, leading brands	nd	1
	Spirits, Bourbon	includes off the shelf products, leading brands	**5.3**	1
	Spirits, Brandy	includes off the shelf products, leading brands	**13**	1
	Spirits, Gin	includes off the shelf products, leading brands	**9.3**	1
	Spirits, Vodka	includes off the shelf products, leading brands	nd	1
	Spirits, Tequila	includes off the shelf products, leading brands	**6.4**	1
	Spirits, Rum	includes off the shelf products, leading brands	**11**	1
	Liquors, Stone Fruit Spirits	includes off the shelf products, leading brands	nd	1
	Liquors, Stone Fruit Spirits	includes off the shelf products, leading brands	**11**	1
	Liquors, Stone Fruit Spirits	includes off the shelf products,leading brands	**7.3**	1
	Liquors, Liqueur	includes off the shelf products, leading brands	**15**	1
	Liquors, Sake	includes off the shelf products, leading brands	**86**	1
BREAD	Bread§	includes regular, medium loaf, white, wholemeal, grain sliced commercial, speciality loaf commercial, sourdough style, white, wholemeal and grain bread rolls, white french sticks & dinner rolls	nd	20
CHEESE	Cheese§	includes cheddar tasty, vintage & colby block &sliced, speciality, fetta & mozzarella	nd	14
ICE CREAM	Ice Cream§	includes full & reduced fat, vanilla & popular flavours	nd	4
MILK	Milk§	includes unflavoured, full, low & skim milk plus soy milk both fresh & UHT	nd	9
OTHER	Fruit/Christmas Cake/Pudding	Includes golden, light & dark fruit cakes	nd	1
	Fruit Juice	Shelf Stable: tropical, orange, orange & mango	nd	1
	Olives	Includes black, stuffed & pitted olives	nd	1
	Oyster/Fish Sauce	Includes oyster sauce & fish sauce	nd	1
	Pickled Vegetables	Includes cucumber, gerkins, onions, vegetables	nd	2
	Prunes	Includes dried & pitted	nd	1
	Sauerkraut	Fresh & canned	nd	1
	Soybean Paste		nd	1
	Tea Bags	includes tea bags & loose leafs	nd	2
	Tempeh,	Includes organic, tasty & pressed	nd	1
	Tofu	Includes organic tofu	nd	1
	Vegemite	includes Promite/Marmite/Mighty Might	nd	2
	Vinegar	All varieties-red wine, balsamic & apple cider	nd	1
SOY SAUCE	Soy Sauce	includes dark, full & low salt	nd	2
	Soy Sauce	light	**13**	1
YOGHURT	Drinking Yoghurt		nd	1
	Yoghurt§	includes full/reduced fat, natural & flavoured	nd	8

† Composite samples consisting of three leading brand primary samples were analysed.

‡ nd: <5 µg/kg for solids and mg/L for liquids.

§ Regional foods; samples taken from Victoria, Queensland and Western Australia.