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

FSANZ ACTIVITIES IN RELATION TO BISPHENOL A

Executive Summary

- FSANZ is aware of public concern over the safety of Bisphenol A (BPA) that has leached from containers into food, particularly those foods that babies and small children consume.
- The toxicological database for BPA is comprehensive and has been evaluated by several international authorities (European Food Safety Authority (EFSA); United States Food and Drug Administration (US FDA) and Health Canada and a safe level (Tolerable Daily Intake (TDI[1])) of 0.05 mg per kg bodyweight per day established. FSANZ has carefully considered the toxicological data and concurs with the hazard assessment and TDI.
- The weight of scientific evidence indicates that exposure to BPA in food does not present a significant human health and safety issue at current exposure levels.
- A recent FSANZ survey of BPA levels in food and beverages in Australia affirms the conclusion that consumers are exposed to very low levels of BPA through food and beverage consumption. Only a limited number of products were found with detected levels of BPA and no detectable levels of BPA were found in infant formula. These results provide additional assurance that BPA concentrations in Australian food do not pose a health risk to consumers.
- FSANZ acknowledges that there are some unresolved uncertainties in the data on BPA, and notes that further studies are currently being conducted in the US to address these uncertainties. FSANZ will assess these new studies when they become available and provide advice to government on the level of risk.
- Notwithstanding the weight of scientific evidence indicating that BPA from the low levels found in food is safe, governments in some countries (Canada, Denmark, and France) have recently moved to ban the use of BPA in polycarbonate baby feeding bottles in response to consumer concerns about BPA
- In Australia, the Australian packaging industry has also responded to consumer concerns by voluntarily phasing out the use of BPA in polycarbonate baby feeding bottles.
- FSANZ has undertaken a number of activities to assess the safety of BPA in food and will continue to liaise with both national and international agencies on the safety and regulation of BPA, including participation in the upcoming joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Meeting on the safety of BPA, in Canada in November 2010.

[1] The TDI is an estimate of the amount of a substance in food that can be ingested daily over a lifetime without appreciable health risk. The TDI is based on animal studies and incorporates an uncertainty factor which allows calculation of a safe level of consumption for humans to be undertaken.

Introduction

BPA is an industrial chemical used as the starting material for the production of polycarbonate plastics and synthetic resins. BPA is found in items or containers that come into contact with foodstuffs such as drinking vessels, baby bottles, plastic tableware and the internal coating on cans for canned food. BPA plays an important role in preventing foods from coming into contact with metal and is also used to harden plastics. Small amounts of BPA can migrate from packaging into food and beverages.

FSANZ recognises that there are consumer concerns regarding the safety of BPA in foods particularly the safety of food consumed by infants. To respond to these issues, FSANZ has actively worked with national and international agencies to consider the safety of BPA. FSANZ has assessed the relevant scientific data relating to BPA and will continue to assess any new data which is published. FSANZ has also undertaken a survey of BPA levels in foods (**Annex 1**) to determine levels of exposure to BPA from packaging materials.

This paper is intended to provide an overview of FSANZ activities to address concerns over the use of BPA in packaging materials intended for food use. The paper covers various safety issues around BPA, recent FSANZ survey activities, national and international actions on BPA and consideration of alternatives to BPA.

BPA Hazard Assessment

A more comprehensive review of the safety information relating to BPA is provided in **Annex 2**.

The toxicological database for BPA is comprehensive and has been evaluated by several international authorities (European Food Safety Authority (EFSA); United States Food and Drug Administration (US FDA) and Health Canada and a safe level (TDI) of 0.05 mg per kg bodyweight per day established. FSANZ has carefully considered the toxicological data and concurs with the hazard assessment and TDI.

Much of the heavily publicised uncertainty regarding BPA comes from animal studies using novel approaches and unconventional endpoints, such as behaviour and brain development. Data from these types of studies report BPA effects on hormones, the reproductive system and neurobehaviour at levels below 0.05 mg per kg bodyweight per day. This has led to a focus on whether there are any potential health effects in humans, in particular newborns and infants under 18 months of age, at low levels of exposure.

It is important to note that there are uncertainties with respect to the overall interpretation of some of these studies and their potential implications for human health effects of BPA exposure. Additional oral dosing studies in laboratory animals (rat, monkey) are currently being conducted in the USA to answer key questions and clarify uncertainties in the data for BPA. FSANZ is liaising with the US FDA who is undertaking some of this new research, and will evaluate the outcomes of these studies when they become available (expected 2011-2012).

There have also been a number of recent epidemiological studies which have identified an association between the levels of total BPA (conjugated and unconjugated)[2] excreted in urine at a single time point and adverse chronic human health outcomes such as cancer, heart disease and diabetes. FSANZ has noted that the authors of these studies have stressed that they are preliminary findings and need to be confirmed in larger studies involving more participants.

[2] Conjugated refers to a biologically inactive derivative of a substance formed by its combination with other compounds within the body.

FSANZ Survey of BPA in foods

To better determine exposure to BPA from foods, FSANZ commissioned a detailed analytical survey on BPA levels in a range of foods in Australia (**Annex 1**). This survey looked at 70 food and beverage items packaged in plastic or canned. Foods were selected to represent foods and beverages likely to be purchased by the general consumer.

The survey found no detectable levels of BPA in infant formula, including infant formula made in BPA containing bottles. These results are consistent with the survey undertaken by the Australian Competition and Consumer Commission (ACCC) in January 2010, investigating the levels of BPA in infant formula, tap water, infant feeding bottles and sip cups in Australia. The results of the ACCC study also showed no detectable levels of BPA in any samples[3].

The survey results did identify very low levels of BPA present in a small number of samples, predominantly canned foods. The levels found were similar to those found in a recent survey by CHOICE although the CHOICE survey did find slightly higher levels in three of its samples[4]. Consumer exposure to BPA from food sources was estimated in this survey and compared with the TDI. This exposure assessment showed that extremely high quantities of foods need to be consumed to reach the TDI.

The survey of BPA levels in food and beverages supports previous conclusions by FSANZ that Australian consumers are exposed to very low levels of BPA through food consumption. This provides assurance that BPA concentrations do not pose a health risk to Australian consumers.

Further analysis of BPA in foods will be undertaken as part of the 24th Australian Total Diet Study. A detailed dietary exposure assessment and risk characterisation for BPA will be included in this report.

National activities

Government

In Australia, the regulation of chemicals in plastic articles for food use, including baby bottles, is a shared responsibility of several Australian Government regulatory agencies: FSANZ for the food sold in plastic containers; the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for the safety of the industrial chemicals used; and the ACCC for the safety of the plastic articles themselves. In New Zealand, chemicals in plastics are regulated by the Environmental Risk Management Authority (ERMA) and plastic consumer products by the New Zealand Ministry of Consumer Affairs. The New Zealand Food Safety Authority (NZFSA) also undertakes its own analytical surveys, safety assessments and risk management. FSANZ has been working with all these regulatory partners to consider concerns surrounding BPA, including safety.

Standard 1.4.3 – Articles and Materials in Contact with Food in the Australia New Zealand Food Standards Code (the Code) regulates food packaging materials in general terms, but does not specify individual packaging materials for food contact or how they should be produced or used. Standards Australia has developed an Australian Standard for Plastics Materials for Food Contact Use.

On 30 June 2010, the Australian Government announced the phase out by major Australian retailers of polycarbonate plastic baby bottles containing BPA. The voluntary phase out,

[3] http://www.productsafety.gov.au/content/index.phtml/itemId/971446#h2_44
[4] http://www.choice.com.au/Reviews-and-Tests/Food-and-Health/Food-and-drink/Safety/BPA-in-canned-foods/page/Introduction.aspx

effective from 1 July 2010, is consistent with approaches taken by governments in a number of other countries that have responded to consumer concerns about BPA[5].

Working with Industry

FSANZ is liaising with the food industry and food packaging suppliers on the issue of BPA in food packaging. The intent of these meetings is to share information on the safety of BPA, international developments in relation to its regulation and the development of alternatives to BPA.

International Activities

There have been a number of mandatory and voluntary actions taken by governments and industry at the international level in regard to BPA, particularly in Canada, USA and, more recently, Europe. These actions have focused attention on the safety and regulatory options for BPA in Australia and New Zealand.

In October 2008, the Canadian Government announced that it would prohibit the importation, sale and advertising of polycarbonate baby bottles. This decision was based on the application of the general principle of ALARA (as low as reasonably achievable) in order to facilitate continuing efforts on limiting BPA exposure from food packaging applications for newborns and infants. Notwithstanding the decision by the Canadian Government, its health agency (Health Canada) remains of the opinion that the health risk for BPA is very low at the levels of exposure it has found in polycarbonate plastic baby feeding bottles and in infant formula. Health Canada also recently reported on its research which has shown that very low levels of BPA are found in cans of liquid infant formula, but no BPA is present in powdered infant formula[6]. More recently, on 23 September 2010, Canada listed BPA as a toxic substance under the *Canadian Environmental Protection Act, 1999*. An assessment by Canada of the impact of human and environmental exposure to BPA has determined that BPA constitutes, or may constitute, a danger to human health and the environment as per criteria set out in the Act.

The decision by the Canadian Government to respond to consumer concerns has been mirrored by some other countries such as France and Denmark. Some states within the US have also passed legislation to restrict the use of BPA in infant feeding bottles and sip cups.

In the US, the US FDA announced in January 2010 that it would undertake further studies to consider the safety of BPA. Some previous studies have employed non-oral routes of exposure to BPA (e.g. intravenous); these have limited applicability to exposure to BPA via food or beverages. The new studies will employ oral routes of exposure. In the meantime, the US FDA is not removing products from the market or recommending that families change the use of infant formula or foods, as the benefit of a stable source of good nutrition outweighs any potential risk from BPA exposure.

In 2007, the European Food Safety Authority (EFSA) reviewed the available studies on BPA and concluded that it would maintain the Tolerable Daily Intake (TDI) for BPA at 0.05 mg per kilogram of body weight per day. An updated EFSA opinion on BPA was released on 30 September 2010 based on recent scientific literature. They concluded that no new study could be identified which would call for a revision of the current TDI and commented that this can be considered to be a conservative value based on all the information currently known on BPA toxicokinetics[7].

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[5] http://www.foodstandards.gov.au/scienceandeducation/newsroom/mediareleases/mediareleases2010/governmentannouncesb4822.cfm

[6] http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2008/2008_167-eng.php

[7] Toxicokinetics is the description of what rate a chemical will enter the body and what happens to it once it is in the body.

The FAO and WHO have organised an expert meeting to analyse the available safety and exposure data for BPA. This meeting will be held in November 2010[8], and FSANZ will be participating in this meeting and submitting data on the levels of BPA in Australian foods.

Alternatives to BPA

Currently, alternative materials such as stainless steel, glass, or BPA-free plastics are available. Replacing long standing, extensively studied chemicals with newer alternatives with a more limited safety database does not necessarily lead to safer products. As reliable can lining materials are a critical factor in ensuring the quality of heat processed liquid infant formula, safe replacement of such materials needs to consider both the integrity of the product while also being safe for food contact purposes.

FSANZ notes that the US FDA is facilitating the development of alternatives to BPA for the linings of infant formula cans. The US FDA has already noted increased interest on the part of infant formula manufacturers to explore alternatives to BPA-containing can linings, and has received notifications for alternative packaging. The US FDA is supporting efforts to develop and use alternatives by: working with manufacturers regarding the regulatory status and safety of alternative liners; giving technical assistance to those wishing to prepare applications for approval of alternatives; and expeditiously reviewing any such new applications for alternatives.

FSANZ will be discussing alternatives to BPA with the Packaging Council of Australia in November 2010 and also notes that the upcoming international expert panel organised jointly by the FAO and WHO in November 2010 will also consider alternatives to BPA.

Conclusion

FSANZ is not proposing any changes to our risk assessment opinion at this point in time, as the clear weight of scientific evidence, from an extensive range of studies and risk assessments undertaken over a considerable period of time, indicates that BPA does not present a significant human health risk for the whole population at current very low levels of exposure. Combined with the industry initiatives to phase out the use of BPA in polycarbonate baby bottles and various food containers, the low levels of exposure are likely to decrease even further.

FSANZ will continue to monitor and assess any new data generated relating to the safety of BPA and will also be undertaking further survey work in the future.

FSANZ acknowledges the voluntary steps being undertaken by industry to reduce human exposure to BPA. FSANZ will continue to liaise with industry in relation to the development, safety and regulatory aspects of alternative substances.

FSANZ will also continue to update the fact sheet for BPA when new data or information is received. The fact sheet is accessible on the FSANZ website www.foodstandards.gov.au.

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[8] http://www.who.int/foodsafety/chem/chemicals/bisphenol/en/index.html

ANNEX 1

FSANZ SURVEY OF BISPHENOL A IN AUSTRALIAN FOODS

SUMMARY

In response to increased consumer concerns over the potential presence of Bisphenol A (BPA) in food, Food Standards Australia New Zealand (FSANZ) commissioned an analytical survey to determine BPA levels in foods. The survey considered a range of foods and beverages available in the Australian market which are packaged in plastic or cans.

In this survey, a total of 70 foods and beverages were analysed for BPA. The results of this survey show that only a limited number of samples were identified with detected levels of BPA. Estimated dietary exposure to BPA shows that extremely large amounts of foods and beverages would need to be consumed to reach international safety thresholds established for BPA. This survey provides reassurance that levels and, therefore, dietary exposure to BPA for the Australian population is very low and safe for all age groups.

BACKGROUND

Over the past few years, FSANZ has become aware of increasing public health and safety concerns surrounding the presence of BPA in food and drink that has migrated from food packaging. BPA (2,2-(4,4'-dihydroxydiphenyl)propane, 4,4'-isopropylidenediphenol, or 2,2'-bis(4-hydroxyphenyl)propane) is an industrial chemical used in the production of polycarbonate plastics and synthetic resins. BPA is commonly used in the linings of food and beverage packaging used to protect the food from coming into contact with metal (Thomson & Grounds, 2005). Food packaging provides a vital function of ensuring that foods are not contaminated and also extends the shelf life of products. For example, epoxy resins used in the internal coating for food and beverage cans protects the food from direct contact with metal, avoids corrosion of the metal and leaching of metals into foods (Summerfield *et al.,* 2002; Bernardo *et al.,* 2005). In some circumstances, chemicals in food packaging can migrate into the food product, and vice versa, depending on the nature of the packaging and the food contained within (Coulier et al., 2010).

FSANZ regulates food packaging materials through *Standard 1.4.3 –Articles and Materials in Contact with Food.* Standard 1.4.3 deals with food contact materials in general terms, and does not give permissions for individual packaging materials for food contact use or specify how they should be produced and used. However, with respect to plastic packaging products, the standard refers to the Australian Standard for Plastic Materials for Food Contact Use, AS 2070-1999. This Standard provides a guide to industry about the production of plastic materials for food contact use. AS 2070, in turn, refers to regulations of the United States and European Union directives relevant to the manufacture and use of plastics. In addition, the various Australian State and Territory Food Acts make reference to food packaging issues.

Data on the levels of BPA in Australian foods are currently limited. Therefore, to enhance the evidence base and to update dietary exposure and risk assessments for the Australian population, FSANZ has undertaken this survey. This survey complements the recent Australian Competition and Consumer Commission (ACCC) survey of BPA in infant formula, water, infant bottles and sip cups (ACCC, 2010). It is intended that this survey, and the survey undertaken by ACCC, will be used as a source of information to inform international health risk evaluations of this chemical in food.

A Tolerable Daily Intake (TDI) level has been established internationally for BPA. A TDI is an estimate of the amount of a contaminant or natural toxicant, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable risk. The TDI established for BPA is based on animal studies and incorporates an uncertainty factor which allows calculation of a safe level of consumption for humans to be undertaken. The TDI established for BPA is 0.05 mg/kg body weight.

SURVEY OBJECTIVES

The objectives of this survey were:

- To determine the level of BPA in a range of foods sold in Australia.
- To assess whether there were any potential health and safety risks associated with BPA in foods where levels were detected.

METHODOLOGY

Sampling

Samples for this survey were purchased from a variety of local retail outlets in the ACT and NSW and through online grocery stores in May 2010. Samples selected for this survey were targeted based on packaging, with a specific focus on food and beverages packaged in plastic or cans. Samples selected are intended to represent foods and beverages likely to be purchased by the general consumer, and it was not always possible to identify if the packaging was polycarbonate or contained epoxy resins. Lacquer analysis of packaging linings was conducted on canned samples to identify if epoxy resins were used (Appendix 1).

A total of 183 individual samples were purchased for this survey (Table 1). All products sampled were nationally available in Australian supermarkets. For all foods, excluding infant food and infant formula, samples were composited from three individual primary purchases made up from three different brands. For most food types, leading brands were selected based on market leader information obtained from “Retail World’s Australian Grocery Guide 2008 – 18th edition” (Anon, 2008). Where the leading brands were not able to be specified or if specified brands were not available, a product from the brand occupying the most shelf space was selected. Where possible, an ‘own brand’ or ‘home brand’ option was also purchased as one of the primary purchases. For infant foods and infant formula (powder), the survey analysed individual brands. The survey also included one brand of ready-to-feed (RTF) liquid formula.

Where possible, the smallest packaging size for a product was purchased, as it was assumed to provide the greatest potential for the food to come into contact with packaging material (Table 1).

All samples were prepared to a ‘table ready’ state, where appropriate, as per label instructions e.g. pre-prepared frozen meals were heated in the microwave. For canned beverages, fruit salad and baked beans, the total content of the can was used and homogenised prior to analysis. For canned tuna, canned corn and olives in a glass jar, the liquid was drained, and the solid portion remaining was homogenised prior to analysis; the liquid portion was discarded.

Powdered infant formulas were prepared as per label instructions and analysed after preparation in both a BPA containing bottle and non-BPA containing bottle purchased specifically for the survey.

A full sample list is available in Appendix 2.

Table 1. Samples selected for BPA analysis

Package type	Package size range	Number of individual samples	Number of analyses conducted	Food Types
Beverages				
Canned	200 – 440 mL	6	2	Beer, soft drink
Plastic bottle, hard plastic lid	600 - 2400 mL	12	4	Cordial, milk, juice, water
Glass (metal and plastic screw cap)	750 mL 100 – 150 g	49	12	Wine, instant coffee
Tetra packed, aseptic (tetra brik or combibloc)	250 -1000 mL	9	3	Milk, juice, soy beverage
Foods				
Canned	85 - 825 g	21	7	Baked beans, corn, tomatoes, tuna, fruit, soup
Plastic bottle, hard plastic lid	375 – 1000 mL	6	2	Vegetable oil, tomato sauce
Glass bottle, metal lid	375 - 500 mL	3	1	Olive oil
Plastic jar, hard plastic lid	375 – 550 g	6	2	Blended spread, peanut butter
Glass jar, metal gasket lid	200 – 600 g	12	4	Olives, jam, pasta sauce, honey
Plastic, soft lid	100 – 500 g	9	3	Ham, yoghurt, pre-prepared meals
Foods bagged in plastic	150 – 1200 g	12	4	Sultanas, frozen vegetables, frozen fish, frozen potato chips
Plastic wrapped	100 – 1000 g	21	7	Frozen pizza, frozen meals, cheese (processed), soft cheese, bacon, beef mince, chicken breast
Infant Foods				
Canned	120 - 220g	2	2	Infant dessert - milk based
Glass jar, metal gasket lid	110 – 170 g	8	8	Infant cereal mix, infant dinner, infant dessert - milk based
Infant formula				
Canned	800 – 900 g	6	14	Powdered
Tetra Pack	200 mL	1	1	Liquid Ready-to-Eat (RTE)
Total		183	70	

Analysis

FSANZ engaged Asure Quality Ltd to analyse the samples using an International Accreditation New Zealand (IANZ) accredited method of gas chromatography-mass spectrometry (GC-MS) and quantified using isotopic dilution calibration with a recovery standard. The method for high moisture foods is based on the method by Goodman *et al.* (2002) and is accredited for baby food and adapted and validated for other food matrices in this survey. Using this method, the Limits of Quantification (LOQ) were 0.3, 0.6 and 3 µg/kg, according to the food matrix. The lacquer coatings used on the lids, base and sides of cans were identified using infra-red spectrometry.

SURVEY RESULTS

The results of this survey identified 31% of samples had detections of BPA above the LOQ, ranging from 1 µg/kg to 290 µg/kg. The highest detected limits were in infant dairy desserts (100 µg/kg and 290 µg/kg) and canned tuna (92 µg/kg). A summary of the results for this survey are presented in Table 2.

Table 2. Summary of BPA concentrations in food and beverages analysed

Product	Bisphenol A concentration (µg/kg)
Cordial, packaged in plastic	<0.3
Orange juice - long life, packaged in plastic bottle	<0.3
Blended vegetable oil, packaged in plastic bottle	<3
Liquid milk - full fat, packaged in plastic bottle	<0.6
Still water, packaged in plastic bottle	<0.3
White wine, glass bottle with screw top lid	1.0‡
Baked beans in tomato sauce, canned*	12
Beer, full strength, canned*	<0.3
Fruit salad in juice, canned*	4.7
Soft drink, various flavours, canned*	<0.3
Tuna in oil, canned*	92
Corn, canned*	25
Tomatoes, canned	15
Soup, canned	54‡
Orange juice, long life, tetra pack	<0.3
Liquid milk, full fat, long life, tetra pack	<0.6
Soy beverage, full fat, long life, tetra pack	<0.6
Black olives, regular, glass jar with metal gasket lid	<3
Strawberry jam, glass jar with metal gasket lid	<3
Savoury pasta sauce, glass jar with metal gasket lid	<3
Instant coffee, glass jar with plastic lid	<0.3
Peanut butter, plastic container with plastic lid	<3
Tomato sauce, plastic container with plastic lid	<3
Blended spread, plastic container with plastic lid	<3
Sliced ham, pre-packaged, plastic container	<3
Fruit yogurt, full fat, strawberry flavour, plastic container	<0.6
Dried sultanas, plastic bagged	<3
Frozen vegetables, plastic bagged	<3

Product	Bisphenol A concentration (µg/kg)
Frozen pre-prepared meals, plastic wrapped	<3
Frozen pizza, plastic wrapped	<3
Shelf-stable pre-prepared meal, plastic container	<3
Infant cereal mix	<3
Infant dessert, milk based, glass jar metal gasket lid	<0.6
Infant dessert, milk based, glass jar metal gasket lid	<0.6
Infant dessert, milk based, glass jar metal gasket lid	<0.6
Infant dinner, glass jar metal gasket lid	<3
Infant dinner, glass jar metal gasket lid	7.7
Infant dessert, milk based, canned	100
Infant dessert, milk based, canned	290
Infant formula, pre-prepared (tetra pack)	<0.6
Infant formula, prepared in glassware	<0.6
Infant formula, prepared in glassware	<0.6
Infant formula	<0.6
Infant formula	<0.6
Infant formula	<0.6
Infant formula	<0.6
Infant formula	<0.6
Infant formula	<0.6
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Infant formula	<0.6
Infant formula	<0.6
Infant formula	<0.6
Infant formula	<0.6
Infant formula	<0.6

* Indicates samples included cans identified as containing epoxy resin linings
‡ indicates a mean concentration value

EXPOSURE ASSESSMENT AND RISK CHARACTERISATION

In this survey, ten foods were found to contain levels of BPA above the LOQ, ranging from 1-290 µg/kg. The amount of food expressed in kilograms that would have to be consumed by infants, children and adults before they would reach the TDI is summarised in Tables 3, 4 and 5. Median and 90th percentile consumption of these foods for children and adults are also set out in Tables 4 and 5[9].

The results in Table 3 show that a 3 month old baby would have to consume at least 1 kg (8 x 120 g cans) of the milk-based infant dessert with the highest levels of BPA every day to reach the TDI. This would be an unlikely occurrence because the amounts of food that would need to be consumed are large. Daily consumption of the type of food in question, in such large quantities, does not follow a typical consumption pattern and the food is likely to have lower levels of BPA some of the time it is consumed. Furthermore, consuming 1 kg of custard is equivalent to 2250 kJ, 85-90% of the daily energy requirements of 3-6 month olds[10]. For 9-12 month old infants, consuming the 2 kg (equivalent to 4500 kJ) of custard needed to exceed the TDI is more than the total daily energy requirements for these age groups[2].

Canned tuna was the food (other than infant dairy dessert) for which the highest level of BPA was reported in this survey. Children would have to consume at least 10 kg (115 x 85 g cans) of canned tuna, every day to exceed the TDI (Table 4). Consuming such large amounts of tuna even on a single occasion is most improbable; especially as the 2007 National Children Nutrition and Physical Activity Survey reported that 2-6 year old high consumers of canned tuna consumed less than 100 g/day averaged over two days. For the other foods with lower levels of reported BPA, children would have to consume kilogram amounts of food that equal or exceed their average bodyweight on a daily basis before reaching the TDI.

Similarly, men and women would have to consume 45 and 37 kg of canned tuna every day respectively to reach the TDI and eat at least the equivalent of their average bodyweight, or more, of the other foods that had reportable levels of BPA, to reach the TDI (Table 5).

In summary, it is unlikely that the levels of BPA in food detected in this survey could lead to any of the population groups exceeding the TDI. This conclusion is consistent with the estimates of exposure to BPA reported in the literature across different countries; even the most conservative estimates of exposure were lower than the current health reference values (TDI) for BPA (Lakind and Naiman 2010, Health Canada 2008, EFSA 2006, Thomson and Grounds 2005).

[9] For details on how these figures were derived refer to Appendix 3.
[10] Daily energy requirements for boys of average weight: 2493 kJ for 3 months old, 2672, kJ for 6 month old, 2934 kJ for 9 month old and 3242kJ for 12 month old. Source: Human energy requirements. Report of a Joint FAO/WHO/UNU Expert Consultation, Rome, 17-24 October 2001. http://www.fao.org/docrep/007/y5686e/y5686e00.HTM

Table 3. Potential dietary exposure to BPA in infants (3-12 months)

Food	Can size g	BPA µg/kg	kg food to reach TDI for infant of different ages (months)[11]				Number of cans to reach TDI for infant of different ages (months)			
			3	*6*	*9*	*12*	*3*	*6*	*9*	*12*
Infant dinner, glass jar metal gasket lid	120	8	40	49	56	60	333	411	464	500
Infant dessert, milk based, canned	110	100	3	4	4	5	29	36	40	44
Infant dessert, milk based, canned	100	290	1	1	2	2	10	12	14	15

Table 4. Potential dietary exposure to BPA in children (2-6 years)

Food	BPA µg/kg	Amount of food typically consumed kg/day		kg food to reach TDI[12]
		Median	**High Consumer** *(90th centile)*	
Baked beans in tomato sauce, canned	12	0.07	0.11	79
Fruit salad in juice, canned	5	0.07	0.13	190
Tuna in oil, canned	92	0.02	0.09	10
Soup, canned	54	0.05	0.200	18
Tomatoes, canned	15	0.03	0.06	63
Corn, canned	25	0.01	0.04	38

[11] The following infant median body weights were used: 3 month: 6.4 kg, 6 month: 7.9 kg, 9 month: 8.9 kg, 12 months: 9.6 kg (Source: WHO, Weight for age, Boys: http://www.who.int/childgrowth/standards/WFA_boys_0_5_percentiles.pdf)
[12] The following children mean body weights were used: Children, 2-6 years, male & female: 19.0 kg (Source: 2007 Children's National Nutrition Survey)

Table 5. Potential dietary exposure to BPA in adults (18+ years)

Food	BPA µg/kg	Amount of food typically consumed kg/day		kg food to reach TDI [13]	
		Median	**High Consumer** *(90th centile)*	*men*	*women*
White wine, glass bottle with screw top lid	1	0.251	0.661	4180	3385
Baked beans in tomato sauce, canned	12	0.138	0.400	348	282
Fruit salad in juice, canned	5	0.133	0.272	836	677
Soup, canned	54	0.260	0.520	77	63
Tomatoes, canned	15	0.106	0.220	279	226
Tuna in oil, canned	92	0.061	0.154	45	37
Corn, canned	25	0.044	0.130	167	135

HEALTH SIGNIFICANCE OF SURVEY RESULTS

The results of the FSANZ survey and subsequent dietary exposure assessments confirm that Australian consumers are exposed to very low levels of BPA through food and beverage consumption. This assessment is consistent with other regulatory assessments from Canada, Europe and the USA. The results of this survey are also consistent with results from the ACCC survey of BPA for infant formula (ACCC, 2010).

FSANZ maintains that, although there are persistent public concerns over the safety of BPA, the clear weight of evidence, including international regulatory risk assessments, from an extensive range of studies and risk assessments, is that BPA does not pose a health riskn at the current low levels of exposure through the consumption of food. FSANZ is aware of the recent risk management approaches taken by other countries; however, FSANZ considers that based on the low level of risk, no regulatory actions are needed in relation to BPA levels in food at this stage in Australia or New Zealand.

FSANZ and other domestic and international regulators are continuing to monitor the safety of the use of BPA, including monitoring overseas developments and liaising with regulators in other countries. FSANZ will also be collecting further analytical data on the levels of BPA in foods through the 24th Australian Total Diet Study (ATDS) which is currently in the planning stage.

[13] The following mean body weights were used for adults: men, 83.6 kg and women, 67.7 kg. Source: Australian Bureau of Statistics, 2004/05, Overweight and Obesity in Adults http://www.ausstats.abs.gov.au/Ausstats/subscriber.nsf/0/A54D036CCD28533ACA2573DA001C9166/$File/47190_2004-05.pdf

FSANZ continues to update information on the FSANZ website (www.foodstandards.gov.au) including factsheets available at Bisphenol A (BPA) and food packaging (January 2010) - Food Standards Australia New Zealand and Bisphenol A (BPA) and food packaging (January 2010) - Food Standards Australia New Zealand. FSANZ will continue to provide up to date information on national and international developments in relation to BPA.

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Appendix 1: Results of can lacquer coating identification

PPN[14]	Product type	Packaging size	Lacquer present = Lid	Lacquer present = Bottom	Lacquer present = Sides
2	Baked Beans in tomato sauce	140g	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Not Applicable
3	Baked Beans in tomato sauce	230g	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Not Applicable
4	Beer – Full Strength	375ml	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
5	Beer – Full Strength	375ml	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
6	Beer – Full Strength	440ml	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
16	Fruit Salad	440g	- Bisphenol type epoxy ester resin - Evidence of a second layer/partial layer. Identity not known.	Not Applicable	Not Applicable
17	Fruit Salad	825g	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Not Applicable
18	Fruit Salad	410g	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Not Applicable
58	Soft Drink	200ml	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
59	Soft Drink	374ml	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
60	Soft Drink	375ml	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
68	Tuna in Oil	425g	Bisphenol type epoxy	Bisphenol type	Bisphenol type

[14] The Primary Purchase Number (PPN) refers to the individual sample on which lacquer analysis was undertaken.

PPN[14]	Product type	Packaging size	Lacquer present = Lid	Lacquer present = Bottom	Lacquer present = Sides
			ester resin	epoxy ester resin	epoxy ester resin
69	Tuna in Oil	425g	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
76	Vegetable (Corn)	420g	- Bisphenol type epoxy ester resin - Evidence of a second layer / partial layer. Identity not known. Possibly containing bisphenol type material.	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
77	Vegetable (Corn)	410g	- Bisphenol type epoxy ester resin - Evidence of a second layer / partial layer. Identity not known. Possibly containing bisphenol type material.	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin
78	Vegetable (Corn)	400g	- Bisphenol type epoxy ester resin - Evidence of a second layer / partial layer. Identity not known. Possibly containing bisphenol type material.	Bisphenol type epoxy ester resin	Bisphenol type epoxy ester resin

Appendix 2: BPA Sample list and preparation instructions

Product name of sample	Prepared to table ready state*	Preparation Instructions
Baked beans in tomato sauce, canned	Yes	Warm up in microwave for 2 min (include sauce)
Beer - full strength, canned	No	N/A
Instant coffee, packaged in glass jar with plastic lid	Yes	Make up as per instructions on packaging using boiled tap water, no milk to be added
Cordial, packaged in plastic	Yes	Make up as per instructions on packaging using tap water
Dried sultanas, packaged in plastic	No	N/A
Fruit salad, canned	No	Include a representative proportion of juice for analysis
Orange juice - long life, packaged in plastic bottle	No	N/A
Orange juice - long life, packaged in tetra pack	No	N/A
Honey, packaged in glass jar with metal screw cap lid	No	N/A
Liquid milk - full fat, long life, packaged in tetra pack	No	N/A
Liquid milk – full fat, packaged in plastic bottle	No	N/A
Blended vegetable oil, packaged in plastic bottle	No	N/A
Olive oil, packaged in glass bottle with metal lid	No	N/A
Black olives - regular, packaged in glass jar with metal lid	Yes	Drain liquid, only analyse solid portion
Peanut butter, packaged in plastic jar	No	N/A
Savoury pasta sauce, packaged in glass jar with metal lid	No	N/A
Tomato sauce, packaged in plastic bottle	No	N/A
Soft drink, canned	No	N/A

Product name of sample	Prepared to table ready state*	Preparation Instructions
Soy beverage - full fat, long life, packaged in tetra pack	No	N/A
Tuna in oil, canned	Yes	Drain liquid, only analyse solid portion
Preserved strawberry jam, packaged in glass jar with metal lid	No	N/A
Still water, packaged in plastic bottle	No	N/A
White wine, packaged in glass bottle with screw cap lid	No	N/A
White wine, packaged in glass bottle with cork	No	N/A
Red wine, packaged in glass bottle with screw cap lid	No	N/A
Red wine, packaged in glass bottle with cork	No	N/A
Corn, canned	Yes	Drain liquid, only analyse solid portion. Microwave for 2 minutes.
Tomatoes, canned	No	N/A
Soup, canned	No	N/A
Shelf-stable pre-prepared meal, packaged in plastic	Yes	Prepare as per instructions on packaging
Infant cereal mix, packaged in glass jar with metal screw cap lid	No	N/A
Infant dessert - milk based, packaged in glass jar with metal screw cap lid	No	N/A
Infant dessert - milk based, canned	No	N/A
Infant dinner, packaged in glass jar with metal screw cap lid	No	N/A
Bacon, pre-packaged in plastic	Yes	Remove rind and dry fry
Minced beef, pre-packaged in plastic	Yes	Dry fry until thoroughly browned, do not scrape pan
Soft cheese – full fat, packaged in plastic	No	N/A
Cheese – highly processed, individually packaged	No	N/A
Frozen fish portions, packaged in plastic	Yes	Bake as per instructions on packaging
Sliced ham – delicatessen style, pre-packaged	No	N/A

Product name of sample	Prepared to table ready state*	Preparation Instructions
Blended spread, packaged in plastic tub	No	N/A
Chicken breast, pre-packaged in plastic	Yes	Grill and discard fat in grill tray
Potato chips ”Oven Bake” – frozen	Yes	Bake in oven as per instructions on packaging
Fruit yogurt, strawberry flavour – full fat, packaged in plastic tub	No	N/A
Frozen vegetables "Steam Fresh”, pre-packaged	Yes	Prepare as per instructions on packaging
Frozen pre-prepared meals, packaged in plastic	Yes	Prepare as per instructions on packaging
Frozen pizza	Yes	Prepare as per instructions on packaging and cool
Infant formula, prepared in glassware	Yes	Make up using boiled and cooled tap water according to manufacturer’s directions.
Infant formula, prepared in BPA plastic bottle	Yes	Make up using boiled and cooled tap water according to manufacturer’s directions
Infant formula, prepared in non-BPA plastic bottle	Yes	Make up using boiled and cooled tap water according to manufacturer’s directions

* ‘No’ refers to food samples which did not require any preparation

Appendix 3: Data on consumption of certain foods containing BPA by Australian populations

Estimated consumption of specified foods was derived for Australian population groups aged:

- 2-6 years (excluding wine); and
- 18 years and above.

The food consumption data used were from the most recent available Australian dietary surveys, that is:

- The 2007 Australian National Children's Nutrition and Physical Activity Survey (also known as 'Kids Eat Kids Play') (2007 NCS), a survey of 4,487 children aged 2-16 years, for two non-consecutive 24-hour recalls
- 1995 Australian National Nutrition Survey (1995 NNS), a survey of 13,858 individuals aged 2 years and over, for one 24-hour recall.

Consumption data were derived using the FSANZ DIAMOND program and include the specified canned food where it was reported as consumed in the survey, for example, baked beans on toast, or canned fruit salad and ice-cream, but not where it was consumed as part of a recipe (for example, baked beans mixed with meat and vegetables and baked as a casserole).

For consumers of the specified foods, the median and the 90th percentile estimated consumption for each population group are set out in Table 1.

Table 1: Median and 90th percentile estimated food consumption (consumers only) for Australian population groups

				Food consumption (grams/day)		Food consumption (grams/kg bw/day)	
Age group	**Food**	**Number of consumers***	**Consumers as % of respondents#**	**median**	**P90**	**median**	**P90**
2007 NCS							
2-6 years	Canned tuna	92	6	24	93	1.3	3.7
2-6 years	Canned fruit salad	62	4	70	125	3.8	7.4
2-6 years	Canned baked beans	72	5	65	113	3.6	7.2
2-6 years	Canned sweet corn	60	4	11	44	0.6	2.3
2-6 years	Canned tomato	127	9	28	64	1.7	3.8
2-6 years	Canned soup	33	2	54	200	2.5	10.2
1995 NNS							
18 yrs & above	Canned tuna	212	2	61	154	0.9	2.1
18 yrs & above	Canned fruit salad	113	1	133	272	2.1	4.5
18 yrs & above	Canned baked beans	298	3	138	400	2.0	5.0
18 yrs & above	Canned sweet corn	227	2	44	130	0.7	1.8
18 yrs & above	Canned tomato	69	1	106	220	1.4	3.4
18 yrs & above	Canned soup	185	2	260	520	4	8.5
18 yrs & above	Wine (red and white)	1555	14	251	661	4.0	9.0

* Consumers includes only the respondents who have consumed the specified canned foods; in the case of the 2007 NCS this includes consumption on one or both days of the survey

Respondents includes all members of the survey population whether or not they consumed the specified foods. Total number of respondents: 2-6 years = 1463; 18 years and above = 10986.

Note: Consumption amounts for children (2007 NCS) are derived using the average of 2x24-hour recalls, whereas the consumption amount for adults (1995 NNS) is derived from a single day 24-hour recall. The effect of two days of consumption data for an infrequently consumed food is to reduce the median and high consumption estimates so that they are a better approximation of longer term consumption.

ANNEX 2

BPA Risk Assessments

Several risk assessments on BPA have been performed over the last 10 years by different regulatory bodies and expert groups in Europe, Canada, USA and Japan. The hazard assessments were mainly based on a comprehensive range of studies conducted in accordance with international testing guidelines and Good Laboratory Practices. In keeping with internationally approved test protocols the studies included oral administration, a large number of animals and a wide range of doses.

Based on these studies, the European Food Safety Authority (EFSA) established a Tolerable Daily Intake (TDI) for BPA of 0.05 mg per kilogram body weight per day (EFSA, 2006, 2008) which has recently been reconfirmed based on recent studies (EFSA, 2010). The TDI is an estimate of the amount of a substance in food that can be ingested daily over a lifetime without appreciable health risk. The TDI for BPA incorporates a safety factor to account for inter-individual differences in sensitivity and the extrapolation from animal data to humans. The extrapolation recognized the well described species differences in toxicokinetics, which showed a low level of free (unconjugated) BPA in humans compared with rats suggesting that the applied safety factor (100-fold) could be considered to be very conservative.

The US FDA has opted to use a 'margin of safety' (MOS) approach rather than a TDI for BPA (US FDA 2008). Nevertheless, the MOS approach yields a very similar outcome because an 'adequate' MOS needs to be in excess of 100. The MOS is based on the difference between a No Observed Adverse Effect Level (NOAEL) and the amount to which humans will be exposed. Using the same toxicological endpoint with a NOAEL of 5 mg/kg bw/day in a multigenerational rodent study as EFSA, the FDA calculated the MOS to be approximately 2,000 and 27,000 for infants and adults, respectively. The FDA concluded that an adequate MOS exists for BPA at current levels of exposure from food contact uses, for infants and adults (US FDA 2008).

There have been ongoing discussions on the reported low-dose effects of BPA, particularly about neurodevelopmental and behavioural effects in laboratory animals, and on the immaturity of metabolic pathways in the fetus and neonate, which are important issues for risk assessment. Some recent studies using novel approaches and different endpoints describe BPA effects in laboratory animals at very low doses corresponding to some estimated human exposures. Many of these new studies evaluated neonatal brain development or specialised behavioural effects that are not usual endpoints assessed in internationally standardized tests.

Several of these studies claiming low-dose effects of BPA in laboratory animals were considered to be relevant for human risk by panel members convened by the US National Institute of Health (the Chapel Hill meeting) on BPA (vom Saal et al., 2007), the US National Toxicology Program (USNTP) (Chapin et al., 2008; USNTP 2008), France (AFSSA 2010) and Denmark. However, many of the studies which have been proposed to support a lower TDI suffer from one or more deficiencies (US FDA 2008). First, a large number of the previous studies on BPA have employed non-oral routes of exposure (e.g. intravenous). The results of these studies have limited applicability to exposure to BPA via food or beverages. Second, some studies have resulted in low-dose findings which have not been reproducible or observed at higher doses. It is not apparent why results are discordant although the influence of endogenous estrogenic compounds in the diet, animal strain and/or genetic background are possible factors. Third, some studies include the use of only single dose administration, experimental designs lacking in reported details or otherwise flawed (i.e. no positive control, inappropriate vehicle, or the oral dose was only estimated).

There have also been a number of recent epidemiological studies which have identified an association between the levels of total BPA (conjugated and unconjugated) excreted in urine at a single time point and adverse chronic human health outcomes such as cancer, heart disease and diabetes (e.g. Lang et al 2008). FSANZ has reviewed these studies but remains of the opinion that there is no health risk for consumers, including infants. The authors of the Lang paper themselves concluded that 'Independent replication and follow-up studies are needed to confirm these findings and to provide evidence on whether the associations are causal'. EFSA has also evaluated this study and concluded there was insufficient evidence for a causal link between exposure to BPA and the health conditions mentioned in the study.

Based on the available data on BPA, Health Canada (2008), EFSA (2006, 2008, 2010), Food and Drug Administration of the United States of America (US FDA 2008) and the Japanese National Institute of Advanced Industrial Science and Technology (AIST 2007) remains of the opinion that there is negligible health risk for consumers, including infants.

However, in response to the uncertainties expressed by the USNTP and others, the US National Institute of Environmental Health Sciences (NIEHS) in 2009 committed 30 million dollars for research grants over two years. These grants are anticipated to supplement research undertaken by the U.S. Food and Drug Administration's National Center for Toxicological Research (NCTR). The NTCR research will be aimed at resolving questions regarding potential adverse effects of BPA on the juvenile brain, behaviour, and prostate gland. Additionally it will undertake studies to reduce the uncertainty around the potential implications for human health effects of BPA exposure. These uncertainties relate to issues such as the route of exposure employed, the lack of consistency among some of the measured endpoints or results between studies, the relevance of some animal models to human health, differences in the metabolism (and detoxification) and responses to BPA both at different ages and in different species. The results of two of these studies from NCTR have recently become available and they suggest that any toxicological effect observed in rats from early postnatal exposures could over-predict BPA effects in primates of the same age (Doerge 2010a, 2010b).

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