

Bisphenol A (BPA)

Introduction

Bisphenol A (BPA) (4,4'-isopropylidenediphenol, chemical formula $C_{15}H_{16}O_2$) is an organic chemical used as a building block or monomer in the synthesis of polycarbonate plastics, which are widely used in many household items such as plastic bottles, tableware (plates, mugs, plastic utensils etc.), storage containers, plastic furniture, compact disks (CDs), etc. BPA is also a component of epoxy resins, used as protective coatings and linings for food and beverage cans and vats, in dental materials, as well as many other uses. Another widespread use of BPA is in thermal paper commonly used for till/cash register receipts.

Residues of BPA can migrate into food and beverages from packaging and be ingested by the consumer. BPA residues can be absorbed through the skin and by inhalation from other sources including thermal paper, cosmetics and dust.

Safety Evaluation

In relation to food safety, BPA is regulated as a food contact material. It was first evaluated for this use over 25 years ago by the EU Scientific Committee on Food (SCF) and since then the safety of BPA has been assessed by a number of international and national organisations, including the European Union in the context of Council Regulation (EEC) No 793/93 on the evaluation and control of existing substances, the World Health Organization (WHO), the US Food and Drug Administration (FDA), Health Canada, and the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). In January 2015, the European Food Safety Authority (EFSA), which is the European Union's risk assessment body, published a comprehensive re-evaluation of the safety of BPA having considered hundreds of scientific publications in peer-reviewed scientific journals as well as reports from studies submitted by industry.

The focus on the safety of BPA reflects concerns based on recent studies using novel testing approaches. BPA is known to have oestrogen-like properties, has been characterised as an endocrine-active substance or endocrine-disruptor, and has become one of the most studied substances.

After weighing up a significant body of new scientific information on its toxic effects, EFSA concluded that high doses of BPA are likely to adversely affect the kidney and liver. Uncertainties surrounding potential health effects of BPA on the mammary gland, reproductive, metabolic, neurobehavioural and immune systems have been quantified and factored in to the calculation of a safe level by EFSA.

A **temporary 'tolerable daily intake' (t-TDI) of 4 µg/kg bw/day** was set and EFSA concluded that BPA poses no health risk to consumers of any age group (including unborn children, infants and adolescents) at current exposure levels. In addition, the TDI is classified as temporary, pending the outcome of a long-term study in rats which is being conducted by the US National Toxicology Program that will help to reduce the uncertainties about BPA's toxic effects.

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Exposure to BPA

The general population can be exposed to BPA via food and drinking water and/or via non-dietary sources, i.e. consumer products and environmental sources.

As part of its comprehensive re-evaluation, in 2015, EFSA undertook an exposure assessment to BPA from dietary and non-dietary sources in the different age groups of the general population.

Data from the EFSA Comprehensive European Food Consumption Database¹ were used to assess dietary exposure to BPA in all age groups, excluding infants aged zero to six months, for whom model diets were used. The non-dietary sources considered for this assessment were thermal paper, indoor/outdoor air (including airborne dust), dust, toys and articles which may be put in the mouth, and cosmetics. Data on occurrence of BPA from non-dietary sources were selected from the scientific literature and migration and transfer of BPA from these non-food sources were estimated. The assumptions around these estimations add a considerable uncertainty to the exposure estimate for the non-dietary sources.

An average (A) and a high (H) exposure level were calculated for all sources of BPA, the latter being based on higher food intake (dietary sources) or increased frequency of use (non-food sources). With regard to dietary exposure, insufficient information on the type of packaging of food consumed was allowed for by calculating two different scenarios for each exposure level (A and H). For scenario one, only foods specifically codified as canned, in the dietary survey, were assigned the corresponding occurrence level for BPA, whereas for scenario two, a more conservative approach of any food having been codified as canned in at least one dietary survey, was always considered to be consumed as canned across all dietary surveys included in the Comprehensive Database. For the risk characterisation, the more conservative estimates of scenario two were used.

In order to assess the aggregated dietary and non-dietary exposure to BPA, the EFSA Expert Panel used physiology based pharmacokinetic (PBPK) modelling to express both sources in the same form (as unconjugated BPA), in order to sum up dietary and non-dietary sources. This aggregated exposure assessment included diet and house dust (the main oral-route sources) as well as thermal paper and cosmetics (the main dermal-route sources).

¹ <http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm>

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The estimates of external dietary and non-dietary exposure to BPA according to source and exposure route derived by EFSA are as follows:

Summary table on average (A) and high (H) exposure ($\mu\text{g}/\text{kg bw}/\text{day}$) from dietary (scenario 2) and non-dietary sources to BPA in the different age groups of the general population. Dermal doses are expressed as equivalent oral doses as obtained by PBPK modelling

AGE GROUP	EXPOSURE LEVEL	DIETARY	NON-DIETARY			SUM OF NON-DIETARY
		ORAL	ORAL	DERMAL	COSMETICS	
		FOOD & BEVERAGE	DUST & TOYS	THERMAL PAPER		
Infants 1-5 days (breastfed)	A	0.225	-	-	-	-
	H	0.435				
Infants 6 days - 3 months (breastfed)	A	0.165	0.009	-	-	0.009
	H	0.600	0.015			0.015
Infants 4-6 months (breastfed)	A	0.145	0.009	-	-	0.009
	H	0.528	0.015			0.015
Infants 0-6 months (formula fed)	A	0.030	0.009	-	-	0.009
	H	0.080	0.015			0.015
Infants 6-12 months	A	0.375	0.009	-	-	0.009
	H	0.857	0.015			0.015
Toddlers 1-3 years	A	0.375	0.007	-	-	0.007
	H	0.857	0.012			0.012
Children 3-10 years	A	0.290	0.003	0.053	0.008	0.064
	H	0.813	0.005	0.424	0.016	0.445
Adolescents 10-18 years	A	0.159	0.002	0.113	0.015	0.13
	H	0.381	0.003	1.036	0.029	1.068
Adults 18-45 years	A	0.126	0.0006	0.071	0.012	0.084
	H	0.388	0.001	0.650*	0.024*	0.675*
Other adults 45-65 years	A	0.126	0.0006	0.071	0.012	0.084
	H	0.341	0.001	0.650*	0.024*	0.675*
Elderly 65 years and over	A	0.116	0.0006	0.071	0.012	0.084
	H	0.375	0.001	0.650*	0.024*	0.675*

* It is assumed that the dermal exposures, expressed as equivalent oral doses for the age group men 18-45 years, also are representative for the age groups: women 18-45 years, other adults 45-65 years, and elderly 65 years and over, assuming that the toxicokinetics are not significantly different between these age groups.

Source: EFSA (2015)

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Based on these estimates, EFSA concluded that the dietary exposure to BPA for the highest exposed groups, which includes infants, toddlers and children, is below the t-TDI of 4 µg/kg bw/day, indicating that there is no health concern for BPA at the estimated levels of exposure.

EFSA further concluded that the central estimates for aggregated exposure to BPA via the dietary and non-dietary sources for the highest exposed groups, which includes children, adolescents and adults of all age groups, is also below the t-TDI of 4 µg/kg bw/day, indicating that the health concern for BPA is low at the estimated levels of exposure.

A relatively large amount of information on urinary BPA concentration was available for Europe and these data were used by EFSA to validate the exposure estimates derived from dietary and non-dietary sources. The latter were in good agreement with the estimates obtained from urinary bio-monitoring, suggesting that it is likely that no major exposure sources had been missed. It is however, important to highlight that assumptions resulting in likely overestimation of exposure could in theory, have hidden other possible sources of exposure, and that considerable uncertainties are associated with this comparative approach.

National assessment

BPA was analysed in the most recent Total Diet Study for Ireland (FSAI, in preparation), and intake estimates obtained for both adults and children are in good agreement with the estimates derived by EFSA (EFSA, 2015). Exposure estimates for both population groups are well below the t-TDI.

Estimated BPA Intake of the Irish Population from all Food Groups

AGE GROUP	DAILY INTAKE µg				DAILY INTAKE µg/kg bw				% of EFSA T-TDI (4 µg/kg bw/day)			
	Mean		P97.5		Mean		P97.5		Mean		P97.5	
	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
Adults	2.0	6.7	6.0	19.3	0.03	0.09	0.09	0.24	0.7	2.2	2.2	6.0
Children	0.8	2.4	3.1	5.7	0.02	0.08	0.10	0.17	0.6	1.9	2.6	4.3

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Legislation

BPA is permitted for use in food contact materials in the European Union (EU) under Regulation 10/2011/EU, relating to plastic materials and articles intending to come into contact with foodstuffs.

BPA is authorised to be used as a monomer for the production of plastic with a specific migration limit of 0.6 mg/kg food.

In January 2011, the European Commission adopted Directive 2011/8/EU, prohibiting the use of BPA for the manufacture of polycarbonate infant feeding bottles, on the basis of the precautionary principle.

- [Regulation EU 10/2011 on plastic materials and food contact materials](#)
- [Directive 2011/8/EU restricting the use of Bisphenol A in plastic infant feeding bottles](#)

For general legislative measures relating to food contact materials, see the FSAI's factsheet on food contact materials².

BPA is also permitted for food contact use in other countries such as the USA and Japan.

BPA is listed as entry 1 176 in Annex II (list of substances prohibited in cosmetic products) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Safeguard Measures

Article 18 of Regulation 1935/2004³ permits a Member State to temporarily suspend or restrict application of provisions within its territory, even though the provision complies with the relevant EU wide measures, when, as a result of new information or a reassessment of existing information, the Member State has detailed grounds for concluding that the use of a material or article endangers human health.

Several Member States have implemented such safeguard measures in relation to BPA: Bans on the use of BPA for food packaging intended for young children (zero to three years old) have been implemented by several EU Member States and one Member State has implemented a total ban on BPA in food packaging material. The European Commission has yet to address these issues in light of the recent EFSA opinion and decide whether to adapt specific EU legislation or to ask Member States to withdraw their suspension/restriction on the use of BPA.

² https://www.fsai.ie/publications_foodcontactmaterial/

³ Regulation 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

References/Further Reading

EFSA (2015) Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). *EFSA Journal* 2015;13(1):3978 doi:10.2903/j.efsa.2015.3978.

Available at: <http://www.efsa.europa.eu/en/efsajournal/pub/3978.htm>

FSAI (in preparation) Report on a Total Diet Study carried out by the Food Safety Authority of Ireland in the period 2012-2014

FSAI (2014) Toxicology factsheet series. Food Contact Materials

Available at: https://www.fsai.ie/publications_foodcontactmaterial/

European Parliament and Council (2004) Regulation 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food. OJ L 338, 13.11.2004, p. 4–17 OJ L 338, 13.11.2004, p. 4–17.

Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R1935&from=EN>

European Commission (2011) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1–89

Available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN>

Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles. OJ L 87, 2.4.2011, p. 1–2

Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0321&from=EN>

Websites:

- European Commission, DG Health and Consumers: Food Contact Materials;
Website: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm
- European Food Safety Authority: Topics: Food Contact Materials: Bisphenol A.
Website: <http://www.efsa.europa.eu/en/topics/topic/bisphenol.htm>
- Food Safety Authority of Ireland Materials And Articles Intended To Come Into Contact With Foodstuffs – Introduction.
Website: https://www.fsai.ie/legislation/food_legislation/materials_articles/introduction.html
- Food Safety Authority of Ireland. News Wednesday, 21 January 2015. No consumer health risk from Bisphenol A exposure.
Website: <https://www.fsai.ie/details.aspx?id=13615>